24 November 2025
EMA/PRAC/354765/2025
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 24-27 November 2025

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

24 November 2025, 13:00 – 19:30, room 1C

25 November 2025, 08:30 – 19:30, room 1C

26 November 2025, 08:30 – 19:30, room 1C

27 November 2025, 08:30 – 16:00, room 1C

Organisational, regulatory and methodological matters (ORGAM)

10 December 2025, 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).

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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 24-27 November 2025. See December month 2025 PRAC minutes (to be published post January 2026 PRAC meeting).

1.2. Agenda of the meeting on 24-27 November 2025

Action: For adoption

1.3. Minutes of the previous meeting on 27-30 October 2025

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 procedures

None

3.2. Ongoing procedures

3.2.1. Levamisole hydrochloride (NAP) – EMA/REF/0000293746

Applicants: various

PRAC Rapporteur: Roxana Dondera, PRAC Co-rapporteur: Barbara Kovacic Bytyqi

Scope: Review of the benefit-risk balance following notification by Romania of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

Action: For adoption

3.3. Procedures for finalisation

None

3.4. Re-examination procedures[1]

None

3.5. Others

None

4. Signals assessment and prioritisation[2]

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

4.1.1. Axicabtagene ciloleucel – YESCARTA (CAP)

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Signal of increased risk of brain oedema in primary mediastinal large B-cell lymphoma (PMBCL) patients

Action: For adoption of PRAC recommendation

EPITT 20224 – New signal

Lead Member State(s): DK

[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

4.1.2. Ponatinib – ICLUSIG (CAP)

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Signal of congenital megacolon, maternal exposure during pregnancy

Action: For adoption of PRAC recommendation

EPITT 20231 – New signal

Lead Member State(s): SE

4.1.3. Venlafaxine (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of cardiotoxicity

Action: For adoption of PRAC recommendation

EPITT 20230 – New signal

Lead Member State(s): SE

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 May 2025

4.2.2. Valproate (NAP) and related substances[3]

Applicant(s): various

PRAC Rapporteur: Liana Martirosyan

Scope: Signal of neurodevelopmental disorders with paternal exposure

Action: For adoption

EPITT 20191 – Follow-up to July 2025

[3] Valproic acid, sodium valproate, valproate semisodium, valpromide,

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. Acoziborole - (Art 58[4] MAA) - EMEA/H/W/006686

Scope (pre D-120 phase, accelerated assessment): Treatment of first and second-stage human African trypanosomiases (HAT) due to Trypanosoma brucei gambiense

Action: For adoption

5.1.2. Aficamten - (CAP MAA) - EMEA/H/C/006228

Scope (pre D-210 phase): Treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) in adult patients

Action: For adoption

5.1.3. Copper (^{64}Cu) oxodotreotide - (CAP MAA) - EMEA/H/C/006608, Orphan

Applicant: Cis Bio International

Scope (pre D-180 phase): Positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine neoplasms (NENs).

Action: For adoption

5.1.4. Furosemide - (CAP MAA) - EMEA/H/C/006617, PUMA[5]

Scope (pre D-180 phase): Treatment of all conditions requiring diuresis due to mechanical obstruction or venous insufficiency.

Action: For adoption

5.1.5. Influenza and COVID-19 vaccine - (CAP MAA) - EMEA/H/C/006472

Scope (pre D-180 phase): Immunisation for the prevention of diseases associated with seasonal influenza viruses and SARS-CoV-2

Action: For adoption

[4] 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)
[5] Paediatric use marketing authorisation(s)

5.1.6. Insulin aspart - (CAP MAA) - EMEA/H/C/006187

Scope (pre D-180 phase): Treatment of diabetes mellitus

Action: For adoption

5.1.7. Insulin lispro - (CAP MAA) - EMEA/H/C/006158

Scope (pre D-180 phase): Treatment of diabetes mellitus

Action: For adoption

5.1.8. Levodopa / Carbidopa - (CAP MAA) - EMEA/H/C/006429

Scope (pre D-180 phase): Treatment of motor fluctuations in patients with Parkinson's disease

Action: For adoption

5.1.9. Mavorixafor - (CAP MAA) - EMEA/H/C/006496, Orphan

Applicant: X4 Pharmaceuticals (Austria) GmbH

Scope (pre D-180 phase): Treatment of WHIM syndrome

Action: For adoption

5.1.10. Nadofaragene firadenovec - (CAP MAA) - EMEA/H/C/005856

ATMPScope (pre D-180 phase): Treatment of adult patients with high-grade (HG), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC).

Action: For adoption

5.1.11. Paltusotine - (CAP MAA) - EMEA/H/C/006636, Orphan

Applicant: Crinetics Pharmaceuticals Europe GmbH

Scope (pre D-180 phase): Maintenance treatment in adult patients with acromegaly

Action: For adoption

5.1.12. Pertuzumab - (CAP MAA) - EMEA/H/C/006583

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

Action: For adoption

5.1.13. Remibrutinib - (CAP MAA) - EMEA/H/C/006313

Scope (pre D-180 phase): Treatment of chronic spontaneous urticaria in patients with

inadequate response to H1 antihistamine

Action: For adoption

5.1.14. Tocilizumab - (CAP MAA) - EMEA/H/C/006416

Scope (pre D-180 phase): Treatment of rheumatoid arthritis and other immunological conditions

Action: For adoption

5.1.15. Tovorafenib - (CAP MAA) - EMEA/H/C/006140, Orphan

Applicant: Ipsen Pharma

Scope (pre D-180 phase): Treatment of paediatric low-grade glioma (LGG)

Action: For adoption

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

5.2.1. Adalimumab – HEFIYA (CAP); HYRIMOZ (CAP) – EMA/VR/0000295410

Applicants: Sandoz GmbH

PRAC Rapporteur: Karin Bolin

Scope: C.I.11.z - to update the Risk Management Plan (RMP) for Hyrimoz and Hefiya (duplicate of Hyrimoz) to align it with the originator's (Humira) RMP.

Action: For adoption

5.2.2. Darbepoetin alfa – ARANESP (CAP) – EMA/VR/0000267359

Applicants: Amgen Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of an updated RMP version 10.0 in order to remove the safety concern and risk minimisation measures regarding the 'Incorrect Use of the Pre-filled Pen Device Associated with Adverse Reactions, Including Underdose and Drug Dose Omission'. The Annex II is updated accordingly.

Action: For adoption

5.2.3. Denosumab – XGEVA (CAP) – EMA/VR/0000272344

Applicants: Amgen Europe B.V.

PRAC Rapporteur: Mari Thorn

Scope: Submission of an updated RMP version 37.0 in order to modify and update the list of safety concerns based on previously completed post-authorization safety studies, including registry study 20101102 and the long-term safety follow-up study 20140114.

Action: For adoption

5.2.4. Emtricitabine / Rilpivirine / Tenofovir disoproxil – EVIPLERA (CAP) – EMA/VR/0000287296

Applicants: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of two variations:

C.I.11.b: Submission of an updated RMP version 16.1 in order to propose the removal of 'Missing information' (Safety in pregnancy) and the removal of a Category 3 Additional Pharmacovigilance Activity (Antiretroviral Pregnancy Registry [APR]).

C.I.11.b: Submission of an updated RMP version 16.1 in order to propose the removal of Specific Adverse Reaction Follow-up Questionnaires related to bone and renal risks.

Action: For adoption

5.2.5. Epcoritamab – TEPKINLY (CAP) – EMA/VR/0000296114

Applicants: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Submission of an updated RMP version 3.0 in order to amend the important identified risk of serious infections to now encompass progressive multifocal leukoencephalopathy (PML).

Action: For adoption

5.2.6. Erenumab – AIMOVIG (CAP) – EMA/VR/0000267640

Applicants: Novartis Europharm Limited

PRAC Rapporteur: Terhi Lehtinen

Scope: Submission of the final study report for the non-interventional (NIS) study CAMG334A2023; this is a non-interventional study to examine patient characteristics and drug utilization patterns in migraine patients treated with prophylactic drugs in Nordic countries, listed as a category 3 PASS in the RMP. The RMP version 5.0 has also been submitted.

Action: For adoption

5.2.7. Fingolimod – FINGOLIMOD MYLAN (CAP); NAP – EMA/VR/0000280709

Applicants: Mylan Pharmaceuticals Limited, various

PRAC Rapporteur: Tiphaine Vaillant

Scope: C.I.11.z - to implement changes to the Risk Management Plans for Fingolimod Mylan and Mulfiyna, following relevant updates to the Risk Management Plan of the innovator product Gilenya (Novartis Europharm Limited, EMEA/H/C/002202).

Action: For adoption

5.2.8. Latanoprost / Netarsudil – ROCLANDA (CAP); netarsudil – RHOKIINSA (CAP) – EMA/VR/0000290523

Applicants: Santen Oy

PRAC Rapporteur: Maria del Pilar Rayon

Scope: C.I.11.z (Type IB) – To update the RMP by removing the PASS study from the RMP, as agreed during the MEA 001.6 (EMA/PAM/0000272898) procedure.

Action: For adoption

5.2.9. Mepolizumab – NUCALA (CAP) – EMA/VR/0000291438

Applicants: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of an updated RMP version 15 following procedure EMA/CHMP/PRAC/525630/2024.

Action: For adoption

5.2.10. Ocrelizumab – OCREVUS (CAP) – EMA/VR/0000296075

Applicants: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of an updated RMP version 14.0 in order to amend the study description (primary and secondary endpoints) of Category 3 Post-Authorisation Safety Study WA40404 (O'HAND) to align with the latest study protocol version 6.0. In addition, the MAH proposes to postpone the milestone date for the final CSR of this study.

Action: For adoption

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

5.3.1. Aflibercept – EYLEA (CAP) – EMA/VR/0000264981

Applicants: Bayer AG

PRAC Rapporteur: Zoubida Amimour

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

C.I.6: Extension of indication to include the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch, central and hemiretinal retinal vein

occlusion, RVO) for EYLEA, based on results from study 22153 (QUASAR); this is a randomized, double-masked, active-controlled Phase 3 study of the efficacy and safety of aflibercept 8 mg in macular edema secondary to retinal vein occlusion. 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 accordingly. The RMP version 36.1 has also been submitted.

C.I.4: Update of section 4.2 of the SmPC in order to change posology recommendations of the approved indications neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME) based on the results from study 22153 (QUASAR) and post-hoc analysis of the pivotal studies 20968 (PULSAR), 21091 (PHOTON) and Phase II study 21086 (CANDELA).

Action: For adoption

5.3.2. Amivantamab – RYBREVANT (CAP) – EMA/X/0000268898

Applicants: Janssen Cilag International

PRAC Rapporteur: Dirk Mentzer

Scope: Extension application to add a new strength of 2400 mg and 3520 mg (solution for injection) grouped with the following variations:

C.I.4: Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 6.6 in order to include the Q3W dosing regimen based on data from relevant cohorts from the Phase 2 bridging study PALOMA-2 (NSC2002) and supported by data from the Phase 1 PALOMA study (NSC1003). The Package Leaflet and Labelling are updated accordingly. The RMP version 7.1 has also been submitted.

C.I.4: Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 6.6 in order to introduce a new Q4W dosing regimen based on data from the PALOMA-2 study (NSC2002) and supported by data from the Phase 1 PALOMA study (NSC1003). The Package Leaflet and Labelling are updated accordingly. The RMP version 7.1 has also been submitted.

Action: For adoption

5.3.3. Apalutamide – ERLEADA (CAP) – EMA/VR/0000296280

Applicants: Janssen Cilag International

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of sections 4.2, and 5.2 of the SmPC in order to introduce a dose recommendation for apalutamide in patients with severe hepatic impairment based on the results from Study 56021927PCR1026 listed as a category 3 study in the RMP; this is an open-label, single-dose, multi-center, non-randomized Phase 1 PK study of apalutamide in participants who either had severe hepatic impairment (Child-Pugh Class C) or healthy participants with Normal hepatic function ; the Package Leaflet is updated accordingly. The RMP version 8.2 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI.

Action: For adoption

5.3.4. Asciminib – SCEMBLIX (CAP) – EMA/X/0000256688

Applicants: Novartis Europharm Limited

PRAC Rapporteur: Eva Jirsová

Scope: Extension application to introduce a new strength (100 mg film-coated tablets) grouped with a type II variation (C.I.6.a) to add a new indication (treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) harbouring the T315I mutation), based on final results from study CABL001X2101 and study CABL001A2004. Study CABL001X2101 is a Phase I, multicenter, open-label, dose escalation FIH study to define the MTD/RDEs, to characterize safety and tolerability, and to assess the PK profile and preliminary evidence of efficacy of asciminib given as single agent or in combination with either nilotinib or imatinib or dasatinib in patients with Ph+ CML or Ph+ ALL. Study CABL001A2004 assessed the real-world effectiveness of asciminib and treatment patterns in patients with Chronic Myeloid Leukemia with T315I mutation. As a consequence, sections 1, 2, 3, 4, 5, 6 and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.5. Avelumab – BAVENCIO (CAP) – EMA/VR/0000261861

Applicants: Merck Europe B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add "Gastritis" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on postmarketing data and literature. The Package Leaflet is updated accordingly. The RMP version 9.1 has also been submitted.

Action: For adoption

5.3.6. Axicabtagene ciloleucel – YESCARTA (CAP) – EMA/VR/0000301490

Applicants: Kite Pharma EU B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the final report from study KTE-C19-105 (ZUMA-5) to fulfil additional pharmacovigilance activities (Category 3) requirements listed in RMP. This is a phase 2 multicenter study of axicabtagene ciloleucel in subjects with relapsed/refractory indolent non-Hodgkin lymphoma. The RMP version 11.3 has also been submitted.

Action: For adoption

5.3.7. Baricitinib – OLUMIANT (CAP) – EMA/X/0000257923

Applicants: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to introduce a new pharmaceutical form (oral suspension) associated with a new strength (2 mg/ml).

Action: For adoption

5.3.8. Blinatumomab – BLINCYTO (CAP) – EMA/VR/0000286935

Applicants: Amgen Europe B.V.

PRAC Rapporteur: Veronika Macurova

Scope: Update of sections 4.4, 4.8 of the SmPC in order to add a new warning on Haemophagocytic lymphohistiocytosis (HLH)/Immune effector-cell-associated haemophagocytic lymphohistiocytosis-like syndrome (IEC-HS) following the evolving understanding of cytokine release syndrome and HLH/IEC-HS; the Package Leaflet is updated accordingly. The RMP version 20.0 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI.

Action: For adoption

5.3.9. Budesonide – JORVEZA (CAP) – EMA/X/0000257468

Applicants: Dr. Falk Pharma GmbH

PRAC Rapporteur: Zane Neikena

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (0.2 mg/ml oral suspension). The new presentation is indicated for paediatric patients 2 to 17 years of age.

Action: For adoption

5.3.10. Cangrelor – KENGREXAL (CAP) – EMA/VR/0000295860

Applicants: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Amelia Cupelli

Scope: Update of sections 4.2 and 4.5 of the SmPC with regards to the transitioning scheme to the oral therapy with P2Y12 inhibitors based on the 2023 European Society of Cardiology guidelines for the management of Acute Coronary Syndrome, and based on new evidence from post-marketing clinical studies (PK/PD, real-world safety and efficacy). The Package Leaflet is updated accordingly. The RMP version 6.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

5.3.11. Capivasertib – TRUQAP (CAP) – EMA/VR/0000293735

Applicants: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Extension of indication to include include Truqap in combination with abiraterone for the treatment of metastatic castration-sensitive prostate cancer characterized by PTEN deficient tumours based on non-clinical and clinical dataset, including interim results from the pivotal study D361BC00001 (CAPItello-281); this is a Phase III double-blind, randomised, placebo-controlled study assessing the efficacy and safety of capivasertib + abiraterone versus placebo + abiraterone as treatment for patients with de novo metastatic hormone-sensitive prostate cancer (mHSPC) characterised by PTEN deficiency; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.12. COVID-19 mRNA vaccine – KOSTAIVE (CAP) – EMA/VR/0000284897

Applicants: Seqirus Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Update of sections 4.5, 4.8 and 5.1 of the SmPC in order to add information based on final results from study ARCT-2303-01 listed as a category 3 study in the RMP; this is a Phase 3 observer-blind, randomized controlled study to evaluate the immunogenicity, reactogenicity, and safety of Kostaive administered concomitantly with quadrivalent influenza vaccines in adults. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH is taking the opportunity to implement editorial changes to the PI.

Action: For adoption

5.3.13. Dabrafenib – TAFINLAR (CAP); Trametinib – MEKINIST (CAP) – EMA/VR/0000278305

Applicants: Novartis Europharm Limited

PRAC Rapporteur: David Olsen

Scope: Extension of indication to include treatment of differentiated thyroid cancer (DTC) for TAFINLAR and MEKINIST based on primary analysis from pivotal study CDRB436J12301. This is a randomized, double-blind, placebo-controlled Phase 3 study to evaluate the efficacy and safety of dabrafenib plus trametinib in previously treated patients with locally advanced or metastatic, radio-active iodine refractory BRAF V600E mutation-positive differentiated thyroid cancer. 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 14.0 and Version 22.0 of the RMPs for Tafinlar and Mekinist, respectively, have also been submitted.

Action: For adoption

5.3.14. Formoterol / Glycopyrronium bromide / Budesonide – TRIXEO AEROSPHERE (CAP) – EMA/X/0000287664

Applicants: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Extension application to introduce a new strength (5 µg / 14.4 µg / 160 µg Pressurised inhalation, suspension) associated with a new indication for the "maintenance treatment of asthma in patients 12 years of age and older who are not adequately controlled by a combination of a medium or high dose inhaled corticosteroid and a long-acting beta2-agonist". The RMP (version 3.1) is updated in accordance.

Action: For adoption

5.3.15. Formoterol / Glycopyrronium bromide / Budesonide – RILTRAVA AEROSPHERE (CAP) – EMA/X/0000287672

Applicants: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Extension application to introduce a new strength (5 µg / 14.4 µg / 160 µg Pressurised inhalation, suspension) associated with a new indication for the "maintenance treatment of asthma in patients 12 years of age and older who are not adequately controlled by a combination of a medium or high dose inhaled corticosteroid and a long-acting beta2-agonist". The RMP (version 3.1) is updated in accordance.

Action: For adoption

5.3.16. Fosnetupitant / Netupitant / Palonosetron – AKYNZEO (CAP) – EMA/X/0000258060

Applicants: Helsinn Birex Pharmaceuticals Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new pharmaceutical form (300 mg / 0.5 ml oral suspension).

Action: For adoption

5.3.17. Gadopiclenol – ELUCIREM (CAP); VUEWAY (CAP) – EMA/VR/0000249008

Applicants: Bracco Imaging S.p.A., Guerbet

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include treatment of new population (0 to 2 years of age patients) for ELUCIREM / VUEWAY, based on final results from study GDX-44-015; this is a phase II clinical study concerning gadopiclenol pharmacokinetics, safety and efficacy in pediatric patients < 2 years of age undergoing contrast-enhanced MRI; extension of indication is also supported with the non-clinical data. 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 0.4 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to remove Annex IV from the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

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

Applicants: 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

5.3.19. Golimumab - SIMPONI (CAP) - EMEA/H/C/000992/II/0121

Applicant: Janssen Cilag International

PRAC Rapporteur: Karin Bolin

Scope: Extension of indication to include treatment of paediatric ulcerative colitis for SIMPONI, based on results from study CNTO148UCO3003; this is a Phase 3 Randomized, Open-label Study to Assess the Efficacy, Safety, and Pharmacokinetics of Golimumab Treatment, a Human anti-TNFα Monoclonal Antibody, Administered Subcutaneously in Paediatric Participants with Moderately to Severely Active Ulcerative Colitis; As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. Version 28.1 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, the PI is updated in accordance with the latest EMA excipients guideline and aligned with the latest QRD template version 10.4.

Action: For adoption

5.3.20. Inclisiran – LEQVIO (CAP) – EMA/VR/0000293324

Applicants: Novartis Europharm Limited

PRAC Rapporteur: Kimmo Jaakkola

Scope: Grouping of two Type II C.I.6 variations to support the extension of the LEQVIO indication to paediatric patients aged 12 to less than 18 years with heterozygous and homozygous familial hypercholesterolaemia, as follows:

C.I.6: Extension of indication to include the treatment of paediatric patients aged 12 to less than 18 years with heterozygous familial hypercholesterolaemia (HeFH) for LEQVIO based on the final results from study CKJX839C12301 (ORION-16). ORION-16 is a two part (double-blind inclisiran versus placebo [Year 1] followed by open-label inclisiran [Year 2]) randomized multicenter study to evaluate safety, tolerability, and efficacy of inclisiran in paediatric patients (12 to less than 18 years) with heterozygous familial hypercholesterolemia and elevated LDL-cholesterol.

C.I.6: Extension of indication to include the treatment of paediatric patients aged 12 to less than 18 years with homozygous familial hypercholesterolaemia (HoFH) for LEQVIO based on the final results from study CKJX839C12302 (ORION-13). ORION-13 is a two part (double-blind inclisiran versus placebo [Year 1] followed by open-label inclisiran [Year 2]) randomized multicenter study to evaluate safety, tolerability, and efficacy of inclisiran in paediatric

patients (12 to less than 18 years) with homozygous familial hypercholesterolemia and elevated LDL-cholesterol.

As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted.

Action: For adoption

5.3.21. Inebilizumab – UPLIZNA (CAP) – EMA/VR/0000257358

Applicants: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: A grouped application consisting of:

C.I.6 (Extension of indication): Extension of indication to include add-on to standard therapy for the treatment of adult patients with generalised myasthenia gravis (gMG) for Uplizna, based on primary analysis results from Study MINT (VIB0551.P3.S1); this is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adults subjects with myasthenia gravis. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1, 5.2, and 7 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 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, the PI is brought in line with the latest QRD template version 10.4.

A.6: Update of the ATC code of inebilizumab to L04AG10 in line with the 2024 ATC INDEX.

Action: For adoption

5.3.22. Influenza vaccine (live, nasal) – FLUENZ (CAP) – EMA/VR/0000302352

Applicants: AstraZeneca AB

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.2 and 4.4 of the SmPC in order to introduce self-administration instructions based on postmarketing data and literature. The Package Leaflet and Labelling updated accordingly. The RMP version 13.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

5.3.23. Leuprorelin – CAMCEVI (CAP) – EMA/X/0000258054

Applicants: Accord Healthcare S.L.U.

PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to add a new strength of 21 mg for Leuproelin prolonged-release suspension for injection pre-filled syringe, for subcutaneous (SC) administration.

Action: For adoption

5.3.24. Lomitapide – LOJUXTA (CAP) – EMA/X/0000258068

Applicants: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Bianca Mulder

Scope: Extension application to add a new strength of 2 mg hard capsules.

This application is grouped with

- type II variation (C.I.6.a): an Extension of Indication to include treatment of paediatric patients aged 5 years and older with homozygous familial hypercholesterolaemia (HoFH) for LOJUXTA, based on final results from the pivotal paediatric study APH-19; this is a phase 3, single-arm, open-label, international, multi-centre study to evaluate the efficacy and safety of lomitapide in paediatric patients with homozygous familial hypercholesterolaemia (HOFH) on stable lipid-lowering therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Annex II and Package Leaflet are updated accordingly. The RMP version 7.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.

- 3 x type IB variations (C.I.7.b): to delete the 30 mg, 40 mg and 60 mg strengths from the Lojuxta marketing authorisation (EU/1/13/851/004 - 006).

Action: For adoption

5.3.25. Nivolumab – OPDIVO (CAP) – EMA/VR/0000288087

Applicants: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Update of sections 4.1 and 4.2 of the SmPC following procedure EMEA/H/C/003985/X/0144. In addition, the MAH took the opportunity to update sections 4.4, 4.8, and 5.1 of the SmPC to align it with the new indications and to implement editorial changes to the PI. The Package Leaflet is updated in accordance. The RMP version 46.0 has also been submitted.

Action: For adoption

5.3.26. Nivolumab – OPDIVO (CAP) – EMA/VR/0000278256

Applicants: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of the final report for the final Overall Survival analysis from the post authorisation efficacy study (PAES) CA209577 listed as an obligation in the Annex II of the Product Information. This is a randomized, multicenter, double-blind phase 3 study of adjuvant nivolumab in subjects with resected oesophageal cancer or gastroesophageal cancer who have received chemoradiotherapy followed by surgery. The Annex II and the RMP (version 45.0) are updated accordingly.

Action: For adoption

5.3.27. Omaveloxolone – SKYCLARYS (CAP) – EMA/VR/0000296476

Applicants: Biogen Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Update of section 5.3 of the SmPC in order to update preclinical information based on results from study RTA-P-21070: this is a 104-week once daily oral gavage toxicity and toxicokinetic study with RTA 408 in rats. The RMP version 2.0 has also been submitted.

Action: For adoption

5.3.28. Pembrolizumab – KEYTRUDA (CAP) – EMA/VR/0000293815

Applicants: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include in combination with paclitaxel, with or without bevacizumab, the treatment of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1 and who have received one or two prior systemic treatment regimens for KEYTRUDA, based on interim results from study PB96V01MK3475 (KEYNOTE-B96); this is a Phase 3, randomized, double-blind study of pembrolizumab in combination with paclitaxel with or without bevacizumab for the treatment of platinum-resistant recurrent ovarian cancer. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 50.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.3.29. Pneumococcal polysaccharide conjugate vaccine (21-valent) – CAPVAXIVE (CAP) – EMA/VR/0000294070

Applicants: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Extension of indication to include treatment of children and adolescents 2 to less than 18 years of age for CAPVAXIVE, based on final results from study V116-013 (P013V116); this is a phase 3, randomized, double-blind study to evaluate the safety, tolerability, and immunogenicity of V116 in children and adolescents with increased risk of pneumococcal disease; As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.

Action: For adoption

5.3.30. Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E – AREXVY (CAP) – EMA/VR/0000276225

Applicants: GlaxoSmithKline Biologicals

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 18 years of age and older for AREXVY, based on results from study 222253 (RSV OA=ADJ-025); this is a Phase 3b, open-label study to evaluate the non-inferiority of the immune response and to evaluate the safety of the RSVPreF3 OA investigational vaccine in adults 18-49 years of age at increased risk of respiratory syncytial virus disease, compared to older adults ≥60 years of age. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 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

5.3.31. Somapacitan – SOGROYA (CAP) – EMA/VR/0000264734

Applicants: Novo Nordisk A/S

PRAC Rapporteur: Martin Huber

Scope: Grouped extension of indication application to include treatment of children born small for gestational age (SGA), Noonan syndrome (NS) and idiopathic short stature (ISS) for SOGROYA, based on interim results from the pivotal, confirmatory phase 3 study NN8640-4467 supported by the phase 3 study NN8640-4469 and the phase 2 study NN8640-4245. Study 4467 is a study comparing the effect and safety of once weekly dosing of somapacitan with daily Norditropin as well as evaluating long-term safety of somapacitan in a basket study design in children with short stature either born small for gestational age or with Turner syndrome, Noonan syndrome, or idiopathic short stature. Study 4469 is a study evaluating the safety and efficacy of once-weekly dosing of somapacitan in a basket study design in paediatric participants with short stature either born small for gestational age or with turner syndrome, Noonan syndrome or idiopathic short stature. Study 4245 is a dose-finding trial evaluating the effect and safety of once-weekly treatment of somapacitan compared to daily Norditropin in children with short stature born small for gestational age with no catch-up growth by 2 years of age or older. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.32. Tafamidis – VYNDAQEL (CAP) – EMA/X/0000287968

Applicants: Pfizer Europe MA EEIG

PRAC Rapporteur: Zoubida Amimour

Scope: Extension application to introduce a new pharmaceutical form (61 mg film-coated tablet). The RMP (version 10.1) is updated in accordance.

Action: For adoption

5.3.33. Tirzepatide – MOUNJARO (CAP) – EMA/VR/0000281937

Applicants: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise for MOUNJARO, based on final results from study I8F-MC-GPGV (SURPASS-PEDS); this is a study to evaluate efficacy, safety, and pharmacokinetics/pharmacodynamics of tirzepatide compared to placebo in paediatric and adolescent participants with type 2 diabetes mellitus inadequately controlled with metformin, or basal insulin, or both. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has also been submitted.

Action: For adoption

5.3.34. Tofersen – QALSODY (CAP) – EMA/VR/0000296462

Applicants: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Update of sections 4.8, 5.1, and 5.2 of the SmPC to numerically update the summary of safety profile and description of selected adverse reactions, as well as, to update clinical efficacy and pharmacokinetic information based on final integrated analysis from Study 233AS101 and Study 233AS102. Submission of the final results of Study 233AS102 is listed as a specific obligation in the Annex II and a category 2 study in the RMP. Study 233AAS102 was an open label extension study to assess the long-term safety, tolerability, pharmacokinetics, and effect on disease progression of tofersen administered to previously treated adults with amyotrophic lateral sclerosis caused by superoxide dismutase 1 mutation. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to update the Annex II.

Action: For adoption

5.3.35. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/VR/0000293327

Applicants: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumours who have received prior treatment and who have no satisfactory alternative treatment options for Enhertu, based on pooled pop-PK analysis and interim results from study D967VC00001 (DESTINY-PanTumor02); this is a Phase II, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of Trastuzumab Deruxtecan (T-DXd, DS-8201a) for the Treatment of Selected HER2-expressing Tumors; 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 9.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI.

Action: For adoption

5.3.36. Ustekinumab – OTULFI (CAP) – EMA/VR/0000296289

Applicants: Fresenius Kabi Deutschland GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Quality

Action: For adoption

5.3.37. Vamorolone – AGAMREE (CAP) – EMA/VR/0000293535

Applicants: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of 2 to <4 year olds for AGAMREE, based on final results from study VBP15-006; this is a phase II open-label, multiple dose study to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and exploratory efficacy of vamorolone in boys ages 2 to <4 years and 7 to <18 years with Duchenne Muscular Dystrophy (DMD) and an updated paediatric extrapolation report referencing 4 to <7-year-old subjects with DMD from Study VBP15-004, compared to the 2 to <4-year-old population from Study VBP15-006. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to make some editorial corrections to SmPC.

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. Abaloparatide – ELADYNOS (CAP) – EMA/PSUR/0000288287

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00011029/202504)

Action: For adoption

6.1.2. Alogliptin – VIPIDIA (CAP); alogliptin / metformin VIPDOMET (CAP); alogliptin / pioglitazone INCRESYNC (CAP) – EMA/PSUR/0000288265

Applicant: Takeda Pharma A/S

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010061/202504)

Action: For adoption

6.1.3. Andexanet alfa – ONDEXXYA (CAP) – EMA/PSUR/0000288243

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010764/202504)

Action: For adoption

6.1.4. Asciminib – SCEMBLIX (CAP) – EMA/PSUR/0000288288

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00011008/202504)

Action: For adoption

6.1.5. Aztreonam / Avibactam – EMBLAVEO (CAP) – EMA/PSUR/0000288268

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure (PSUSA/00011055/202504)

Action: For adoption

6.1.6. Capivasertib – TRUQAP (CAP) – EMA/PSUR/0000288286

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011061/202505)

Action: For adoption

6.1.7. Capmatinib – TABRECTA (CAP) – EMA/PSUR/0000288242

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00011022/202505)

Action: For adoption

6.1.8. Chikungunya vaccine (live) – IXCHIQ (CAP) – EMA/PSUR/0000288260

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011058/202505)

Action: For adoption

6.1.9. Conestat alfa – RUCONEST (CAP) – EMA/PSUR/0000288246

Applicant: Pharming Group N.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000873/202504)

Action: For adoption

6.1.10. Delamanid – DELTYBA (CAP) – EMA/PSUR/0000288248

Applicant: Otsuka Novel Products GmbH

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00010213/202504)

Action: For adoption

6.1.11. Diphtheria / tetanus / pertussis antigens (pertussis toxoid, filamentous haemagglutinin) (acellular, component) / hepatitis b (rDNA) / poliomyelitis (inactivated) / *Haemophilus* type B conjugate vaccines (adsorbed) – HEXACIMA (CAP); HEXYON (CAP) – EMA/PSUR/0000288217

Applicant: Sanofi Winthrop Industrie

PRAC Lead: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010091/202504)

Action: For adoption

6.1.12. Dostarlimab – JEMPERLI (CAP) – EMA/PSUR/0000288247

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010931/202504)

Action: For adoption

6.1.13. Durvalumab – IMFINZI (CAP) – EMA/PSUR/0000288249

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010723/202504)

Action: For adoption

6.1.14. Efbemalenograstim alfa – RYZNEUTA (CAP) – EMA/PSUR/0000288213

Applicant: Evive Biotechnology Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000286/202505)

Action: For adoption

6.1.15. Ertapenem – INVANZ (CAP) – EMA/PSUR/0000288215

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00001256/202503)

Action: For adoption

6.1.16. Estrogens conjugated / Bazedoxifene – DUAVIVE (CAP) – EMA/PSUR/0000288280

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010321/202504)

Action: For adoption

6.1.17. Exagamglogene autotemcel – CASGEVY (CAP) – EMA/PSUR/0000288219

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000244/202505)

Action: For adoption

6.1.18. Febuxostat – ADENURIC (CAP) – EMA/PSUR/0000288258

Applicant: Menarini International Operations Luxembourg S.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00001353/202504)

Action: For adoption

6.1.19. Fezolinetant – VEOZA (CAP) – EMA/PSUR/0000288230

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000231/202505)

Action: For adoption

6.1.20. Florbetapir (^{18}F) – AMYVID (CAP) – EMA/PSUR/0000288236

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010032/202504)

Action: For adoption

6.1.21. Insulin glargine - ABASAGLAR (CAP); LANTUS (CAP); SEMGLEE (CAP); TOUJEO (CAP) – EMA/PSUR/0000288220

Applicants: Biosimilar Collaborations Ireland Limited, Eli Lilly Nederland B.V., Sanofi-Aventis Deutschland GmbH

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001751/202504)

Action: For adoption

6.1.22. Ivosidenib – TIBSOVO (CAP) – EMA/PSUR/0000288259

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011048/202505)

Action: For adoption

6.1.23. Linzagolix choline – YSELTY (CAP) – EMA/PSUR/0000288245

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010998/202505)

Action: For adoption

6.1.24. Loncastuximab tesirine – ZYNLONTA (CAP) – EMA/PSUR/0000288255

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00011027/202504)

Action: For adoption

6.1.25. Mannitol – BRONCHITOL (CAP) – EMA/PSUR/0000288227

Applicant: Pharmaxis Europe Limited

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00009226/202504)

Action: For adoption

6.1.26. Mavacamten – CAMZYOS (CAP) – EMA/PSUR/0000288218

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00000074/202504)

Action: For adoption

6.1.27. Mirvetuximab soravtansine – ELAHERE (CAP) – EMA/PSUR/0000288269

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00011097/202505)

Action: For adoption

6.1.28. Niraparib / Abiraterone acetate – AKEEGA (CAP) – EMA/PSUR/0000288266

Applicant: Janssen Cilag International

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011051/202504)

Action: For adoption

6.1.29. Nirsevimab – BEYFORTUS (CAP) – EMA/PSUR/0000288237

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00011026/202504)

Action: For adoption

6.1.30. Parathyroid hormone – NATPAR (CAP) – EMA/PSUR/0000288231

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00010591/202504)

Action: For adoption

6.1.31. Potassium citrate / Potassium hydrogen carbonate – SIBNAYAL (CAP) – EMA/PSUR/0000288250

Applicant: Advicenne

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010932/202504)

Action: For adoption

6.1.32. rADAMTS13 – ADZYNMA (CAP) – EMA/PSUR/0000288290

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00011077/202505)

Action: For adoption

6.1.33. Ramucirumab – CYRAMZA (CAP) – EMA/PSUR/0000288229

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010323/202504)

Action: For adoption

6.1.34. RdESAT-6 / rCFP-10 – SIILTIBCY (CAP) – EMA/PSUR/0000288289

Applicant: Serum Life Science Europe GmbH

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011104/202505)

Action: For adoption

6.1.35. Recombinant vesicular stomatitis virus (strain indiana) with A deletion of the envelope glycoprotein, replaced with the Zaire Eebolavirus (strain kikwit-1995) surface glycoprotein – ERVEBO (CAP) – EMA/PSUR/0000288234

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010834/202505)

Action: For adoption

6.1.36. Remdesivir – VEKLURY (CAP) – EMA/PSUR/0000288244

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00010840/202505)

Action: For adoption

6.1.37. Repotrectinib – AUGTYRO (CAP) – EMA/PSUR/0000288264

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00011102/202505)

Action: For adoption

6.1.38. Ripretinib – QINLOCK (CAP) – EMA/PSUR/0000288238

Applicant: Deciphera Pharmaceuticals (Netherlands) B.V.

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00010962/202505)

Action: For adoption

6.1.39. Sacituzumab govitecan – TRODELVY (CAP) – EMA/PSUR/0000288232

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010959/202504)

Action: For adoption

6.1.40. Selpercatinib – RETSEVMO (CAP) – EMA/PSUR/0000288253

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010917/202505)

Action: For adoption

6.1.41. Siltuximab – SYLVANT (CAP) – EMA/PSUR/0000288233

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010254/202504)

Action: For adoption

6.1.42. Tirzepatide – MOUNJARO (CAP) – EMA/PSUR/0000288292

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011019/202505)

Action: For adoption

6.1.43. Tocilizumab - AVTOZMA (CAP); ROACTEMRA (CAP); TOFIDENCE (CAP); TYENNE (CAP) – EMA/PSUR/0000288251

Applicants: Celltrion Healthcare Hungary Kft., Fresenius Kabi Deutschland GmbH, Roche Registration GmbH, STADA Arzneimittel AG

PRAC Lead: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00002980/202504)

Action: For adoption

6.1.44. Tofersen – QALSODY (CAP) – EMA/PSUR/0000288271

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00011064/202504)

Action: For adoption

6.1.45. Tremelimumab – IMJUDO (CAP) – EMA/PSUR/0000288263

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011038/202504)

Action: For adoption

6.1.46. Vamorolone – AGAMREE (CAP) – EMA/PSUR/0000288222

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00000223/202504)

Action: For adoption

6.1.47. Volanesorsen – WAYLIVRA (CAP) – EMA/PSUR/0000288252

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010762/202505)

Action: For adoption

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

6.2.1. Cetrorelix - CETROTIDE (CAP); NAP – EMA/PSUR/0000288224

Applicants: Merck Europe B.V., various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000633/202504)

Action: For adoption

6.2.2. Fesoterodine – TOVIAZ (CAP); NAP – EMA/PSUR/0000288254

Applicants: Pfizer Europe MA EEIG, various

PRAC Lead: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00001387/202504)

Action: For adoption

6.2.3. Olanzapine - ZALASTA (CAP); ZYPADHERA (CAP); ZYPREXA (CAP); ZYPREXA VELOTAB (CAP); NAP – EMA/PSUR/0000288282

Applicants: Cheplapharm Registration GmbH, KRKA tovarna zdravil d.d. Novo mesto, various

PRAC Lead: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010540/202503)

Action: For adoption

6.2.4. Tacrolimus (topical formulations) - PROTOPIC (CAP); NAP – EMA/PSUR/0000288228

Applicants: LEO PHARMA A/S, various

PRAC Lead: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00002840/202503)

Action: For adoption

6.2.5. Telmisartan – KINZALMONO (CAP); MICARDIS (CAP); PRITOR (CAP); NAP; Telmisartan / Hydrochlorothiazide - KINZALKOMB (SRD[6]); PRITORPLUS (SRD[7]) – EMA/PSUR/0000288281

Applicants: Bayer AG, Boehringer Ingelheim International GmbH, various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00002882/202503)

Action: For adoption

6.2.6. Telmisartan / Amlodipine - TWYNSTA (CAP); NAP – EMA/PSUR/0000288216

Applicants: Boehringer Ingelheim International GmbH, various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000180/202503)

Action: For adoption

6.2.7. Zonisamide - ZONEGRAN (CAP); NAP – EMA/PSUR/0000288293

Applicants: Amdipharm Limited, various

PRAC Lead: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00003152/202503)

Action: For adoption

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

6.3.1. Captopril (NAP) – EMA/PSUR/0000288214

Applicants: various

PRAC Lead: Anna Mareková

Scope: Evaluation of a PSUSA procedure (PSUSA/00000535/202504)

Action: For adoption

[6] European Commission decision for the withdrawal of the marketing authorisation, at the holder's request: 26.09.2025

[7] European Commission decision for the withdrawal of the marketing authorisation, at the holder's request: 1.10.2025

6.3.2. Carvedilol / ivabradine (NAP) – EMA/PSUR/0000288241

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010883/202504)

Action: For adoption

6.3.3. Cefditoren (NAP) – EMA/PSUR/0000288221

Applicants: various

PRAC Lead: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00000592/202503)

Action: For adoption

6.3.4. Cytarabine (NAP) – EMA/PSUR/0000288257

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00000911/202503)

Action: For adoption

6.3.5. Ethinylestradiol / levonorgestrel (NAP) – EMA/PSUR/0000288262

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001309/202504)

Action: For adoption

6.3.6. Isotretinoin (oral formulations) (NAP) – EMA/PSUR/0000288240

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00010488/202505)

Action: For adoption

6.3.7. Ivermectin (systemic use) (NAP) – EMA/PSUR/0000288278

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00010377/202504)

Action: For adoption

6.3.8. Linezolid (NAP) – EMA/PSUR/0000288225

Applicants: various

PRAC Lead: Anna Mareková

Scope: Evaluation of a PSUSA procedure (PSUSA/00001888/202504)

Action: For adoption

6.3.9. Nefopam (NAP) – EMA/PSUR/0000288226

Applicants: various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00002131/202503)

Action: For adoption

6.3.10. Ofloxacin (systemic use) (NAP) – EMA/PSUR/0000288261

Applicants: various

PRAC Lead: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00002203/202504)

Action: For adoption

6.3.11. Piritramide (NAP) – EMA/PSUR/0000288223

Applicants: various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00002437/202503)

Action: For adoption

6.3.12. Reboxetine (NAP) – EMA/PSUR/0000288277

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00002615/202504)

Action: For adoption

6.3.13. Simvastatin (NAP) – EMA/PSUR/0000288235

Applicants: various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00002709/202504)

Action: For adoption

6.3.14. Sulprostone (NAP) – EMA/PSUR/0000288256

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00002828/202504)

Action: For adoption

6.3.15. Triamcinolone (intraocular formulations) (NAP) – EMA/PSUR/0000288267

Applicants: various

PRAC Lead: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010292/202503)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Dolutegravir – TIVICAY (CAP) – EMA/PAM/0000268716

Applicants: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Responses to request for supplementary information on PAM/LEG submission for Tivicay, Dovato, Triumeq regarding diabetes and hypertension evaluation.

Action: For adoption

6.4.2. Dolutegravir / Abacavir / Lamivudine – TRIUMEQ (CAP) – EMA/PAM/0000268721

Applicants: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Responses to request for supplementary information on PAM/LEG submission for Tivicay, Dovato, Triumeq regarding diabetes and hypertension evaluation.

Action: For adoption

6.4.3. Dolutegravir / Lamivudine – DOVATO (CAP) – EMA/PAM/0000268725

Applicants: ViiV Healthcare B.V.

PRAC Rapporteur: David Olsen

Scope: Responses to request for supplementary information on PAM/LEG submission for Tivicay, Dovato, Triumeq regarding diabetes and hypertension evaluation.

Action: For adoption

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Semaglutide – OZEMPIC (CAP); RYBELSUS (CAP) – EMA/VR/0000292593

Applicants: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Update of section 4.8 of the SmPC in order to add Dysaesthesia to the list of adverse drug reactions (ADRs) for Ozempic and Rybelsus following PRAC request for cumulative review of "Altered skin sensation" for semaglutide PSUR (EMEA/H/C/PSUSA/00010671/202405); the Package Leaflet is updated accordingly.

Action: For adoption

6.5.2. Vortioxetine – BRINTELLIX (CAP) – EMA/VR/0000296460

Applicants: H. Lundbeck A/S

PRAC Rapporteur: Jo Robays

Scope: Update of section 4.6 of the SmPC in order to update information regarding lactation, following the PRAC Assessment Report for PSUSA/00010052/20240. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

Action: For adoption

6.6. Expedited summary safety reviews[8]

None

[8] 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

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[9]

7.1.1. Lecanemab – LEQEMBI (CAP) – EMA/PASS/0000267311

Applicant: Eisai GmbH

PRAC Rapporteur: Eva Jirsová

Scope: PASS protocol [107n]: Study BAN2401-G000-505; A prospective observational registry study to evaluate the use and safety of LEQEMBI in routine clinical practice (EEA)

Action: For adoption

7.1.2. Obecabtagene autoleucel – AUCATZYL (CAP) – EMA/PASS/0000300590

Applicants: Autolus GmbH

PRAC Rapporteur: Karin Erneholm

Scope: PASS protocol [107n]: Prospective, international, non-interventional study to assess the short- and long-term safety and effectiveness of adult patients with relapsed or refractory B cell acute lymphoblastic leukemia receiving Aucatzyl treatment.

Action: For adoption

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[10]

7.2.1. Garadacimab – ANDEMBRY (CAP) – EMA/PAM/0000267718

Applicants: CSL Behring GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Feasibility and protocol assessment of the Non-Interventional Post Authorisation Safety Study CSL312_5006 to assess the long-term safety in adults and adolescents.

Action: For adoption

7.2.2. Inavolisib – ITOVEBI (CAP) – EMA/PAM/0000301716

Applicants: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: PASS Protocol GO46271: Evaluating safety in insulin-requiring diabetic receiving inavolisib plus endrocrine therapy-based regiments in the real world.

[9] In accordance with Article 107n of Directive 2001/83/EC
[10] 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

Action: For adoption

7.2.3. Nemolizumab – NEMLUVIO (CAP) – EMA/PAM/0000269409

Applicants: Galderma International

PRAC Rapporteur: Liana Martirosyan

Scope: First study protocol for a non-imposed non-interventional PASS to evaluate fetal and infant outcomes following maternal exposure to nemolizumab for treatment of moderate to severe Atopic dermatitis or Prurigo nodularis during pregnancy.

Action: For adoption

7.3. Results of PASS imposed in the marketing authorisation(s)[11]

7.3.1. Deferasirox – EXJADE (CAP) – EMA/VR/0000280855

Applicants: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of section D of Annex II of the PI based on the submission of the final report from study CICL670E2422, listed as an imposed PASS in the Annex II. This is an observational study that evaluated the safety of deferasirox in the treatment of pediatric patients with non-transfusion-dependent iron overload. The RMP version 23.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

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

7.4. Results of PASS non-imposed in the marketing authorisation(s)[12]

7.4.1. Conestat alfa – RUCONEST (CAP) – EMA/VR/0000263304

Applicants: Pharming Group N.V.

[11] In accordance with Article 107p-q of Directive 2001/83/EC
[12] 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

PRAC Rapporteur: Jan Neuhauser

Scope: Submission of the final report from Ruconest EU registry listed as a category 3 study in the RMP. This is a non-imposed non-interventional PASS (phase IV) of C1 inhibitor Treatment Registry to assess the Safety and Immunological Profile of Ruconest in the treatment of HAE Attacks.

Action: For adoption

7.4.2. Elosulfase alfa – VIMIZIM (CAP) – EMA/VR/0000268096

Applicants: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Update of sections 4.6, 4.8 and 5.1 of the SmPC based on final results from Morquio A Registry Study (MARS, Study 110-504) listed as a category 1 study in the RMP; this is an observational registry study to evaluate long-term safety and effectiveness of elosulfase alfa. The RMP version 7.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II and to update the PI in accordance with the latest EMA excipients guideline.

Action: For adoption

7.4.3. Fenfluramine – FINTEPLA (CAP) – EMA/VR/0000296039

Applicants: UCB Pharma

PRAC Rapporteur: Martin Huber

Scope: Submission of the final report for study EP0220 listed as a category 3 study in the RMP. This is a non-interventional study to assess the effectiveness of risk minimization measures in approved indications for fenfluramine hydrochloride. The RMP version 5.1 has been updated accordingly.

Action: For adoption

7.4.4. Tofacitinib – XELJANZ (CAP) – EMA/VR/0000296333

Applicants: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final report from RWE study A3921427 listed as a category 3 study (PASS) in the RMP. This is an observational study of effectiveness and safety of recombinant zoster vaccine (Shingrix) in moderately to severely active ulcerative colitis or rheumatoid arthritis patients treated with tofacitinib (Xeljanz) in real-world clinical care settings.

Action: For adoption

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

7.5.1. Adalimumab – HUMIRA (CAP) – EMA/PAM/0000293837

Applicants: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Karin Bolin

Scope: Eighth Annual Interim Report of Study No. P11-292 Registry: Paediatric Crohn's disease registry: A long-Term Non-Interventional Registry to Assess Safety and Effectiveness of Humira (Adalimumab) in Paediatric Patients with Moderately to Severely Active Crohn's Disease (CD).

Action: For adoption

7.5.2. Botulinum toxin type A – NUCEIVA (CAP) – EMA/PAM/0000301773

Applicants: Evolus Pharma B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Non-Interventional Post-Authorisation Safety Study of NUCEIVA for the Treatment of Moderate-to-Severe Glabellar Lines (Study EV-010) - Annual update

Action: For adoption

7.5.3. Brexucabtagene autoleucel – TECARTUS (CAP) – EMA/PAM/0000267756

Applicants: Kite Pharma EU B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Second Annual Interim Safety Report for the Category 1 (ANX) Non-interventional Post Authorisation Efficacy and Safety Study (PAES/PASS) for Tecartus (Study KT-EU-472-6036) for the MCL indication

Action: For adoption

7.5.4. Cannabidiol – EPIDYOLEX (CAP) – EMA/PAM/0000301780

Applicants: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: A Prospective, Observational Cohort Study to Assess Long-Term Safety in Patients Prescribed Epidyolex with a Focus on Drug-induced Liver Injury (Study GWEP21042) - Annual update

Action: For adoption

7.5.5. Ciltacabtagene autoleucel – CARVYKTI (CAP) – EMA/PAM/0000301551

Applicants: Janssen Cilag International, ATMP

PRAC Rapporteur: Jo Robays

Scope: Third Interim Report for Study 68284528MMY4004 - An Observational Post-authorization Safety Study to Evaluate the Safety of Multiple Myeloma Patients Treated with Ciltacabtagene Autoleucel (CARVYKTI)

Action: For adoption

7.5.6. Ciltacabtagene autoleucel – CARVYKTI (CAP) – EMA/PAM/0000304040

Applicants: Janssen Cilag International, ATMP

PRAC Rapporteur: Jo Robays

Scope: First Interim Report for Study 68284528MMY4009 – A Post-authorization Safety Study to Evaluate the Safety of Multiple Myeloma Patients Treated with Ciltacabtagene Autoleucel (CARVYKTI)

Action: For adoption

7.5.7. Dinutuximab beta – QARZIBA (CAP) – EMA/PAM/0000303342

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: An interim report for the non-interventional post-authorisation safety study (PASS)

titled: A Patient Registry of Patients with High-Risk Neuroblastoma Being Treated with the Monoclonal Antibody Dinutuximab Beta" (EUSA DB 0001)

Action: For adoption

7.5.8. Ganaxolone – ZTALMY (CAP) – EMA/PAM/0000301696

Applicants: Immedica Pharma AB

PRAC Rapporteur: Adam Przybylkowski

Scope: Study LLF001 (Candid observational study) - Interim report at milestone = after 100 participants completed the 1st year visit.

Action: For adoption

7.5.9. Infliximab – REMSIMA (CAP) – EMA/PAM/0000301635

Applicants: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Following EMA/PAM/0000245463, MAH presents the 3-year interim report for Study CT-P13 4.8. An observational, prospective cohort study to evaluate safety of Remsima SC patients with Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis and Psoriasis

Action: For adoption

7.5.10. Mavacamten – CAMZYOS (CAP) – EMA/PAM/0000293843

Applicants: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Interim study results for the Cat 3 PASS Study CV027012 (DISCOVER-HCM): Deliver Insights on Safety in Hypertrophic Cardiomyopathy and Observe Endpoints in Real-world. This is an observational, multicenter registry of prospectively enrolled adult patients with symptomatic (New York Heart Association [NYHA] functional class II-IV) obstructive hypertrophic cardiomyopathy (oHCM) in the United States (US) and Puerto Rico and left ventricular ejection fraction (LVEF) ≥ 55% at enrollment. The registry aims to recruit an estimated 65 sites in the US and Puerto Rico to enroll at least 550 patients with oHCM including at least 350 patients initiating treatment with mavacamten at enrollment, once it is available. Enrollment is estimated to require two years.

Action: For adoption

7.5.11. Naltrexone hydrochloride / Bupropion hydrochloride – MYSIMBA (CAP) – EMA/PAM/0000292603

Applicants: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Study NB-451: Interim report of Drug Utilisation and Safety Study (Study NB-451) for Mysimba/ Contrave in Europe and the United States.

Action: For adoption

7.5.12. Ropeginterferon alfa-2b – BESREMI (CAP) – EMA/PAM/0000295680

Applicants: Aop Orphan Pharmaceuticals GmbH

PRAC Rapporteur: Carla Torre

Scope: Submission of an interim study report of EUPAS29462: a Prospective, multicentre, non-interventional, observational, post-authorisation safety study of Ropeginterferon alfa-2b in polycythaemia vera patients.

Action: For adoption

7.5.13. Tofacitinib – XELJANZ (CAP) – EMA/PAM/0000294280

Applicants: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Xeljanz Submission of A3921321 study interim report (RMP category 3 study; MEA) "A Post-Authorisation Safety Study of the Utilisation and Prescribing Patterns of Xeljanz (tofacitinib) in the European Union Using Secondary Data Sources"

Action: For adoption

7.6. New Scientific Advice

7.7. Ongoing Scientific Advice

None

7.8. Final Scientific Advice (Reports and Scientific Advice letters)

None

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Asfotase alfa – STRENSIQ (CAP) – EMA/S/0000293951

Applicants: Alexion Europe

PRAC Rapporteur: Eamon O Murchu

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.2. Cerliponase alfa – BRINEURA (CAP) – EMA/S/0000290075

Applicants: Biomarin International Limited

PRAC Rapporteur: Mari Thorn

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. Eladocagene exuparvovec – UPSTAZA (CAP) – EMA/S/0000293355

Applicants: PTC Therapeutics International Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.4. Mecasermin – INCRELEX (CAP) – EMA/S/0000293938

Applicants: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Terhi Lehtinen

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.5. Vestronidase alfa – MEPSEVII (CAP) – EMA/S/0000289610

Applicants: Ultragenyx Germany GmbH

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

8.2.1. Delamanid – DELTYBA (CAP) – EMA/R/0000293774

Applicants: Otsuka Novel Products GmbH

PRAC Rapporteur: Jo Robays

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.2. Exagamglogene autotemcel – CASGEVY (CAP) – EMA/R/0000290395

Applicants: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.3. Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) – INCELLIPAN (CAP) – EMA/R/0000302072

Applicants: Seqirus Netherlands B.V.

PRAC Rapporteur: Karin Bolin

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.4. Parathyroid hormone – NATPAR (CAP) – EMA/R/0000301520

Applicants: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Rhea Fitzgerald

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.5. Pemigatinib – PEMAZYRE (CAP) – EMA/R/0000302406

Applicants: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Adalimumab – YUFLYMA (CAP) – EMA/R/0000295845

Applicants: Celltrion Healthcare Hungary Kft. Kft.

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.2. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence – STRIMVELIS (CAP) – EMA/R/0000290462

Applicants: Fondazione Telethon Ets

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.3. Berotralstat – ORLADEYO (CAP) – EMA/R/0000282356

Applicants: Biocryst Ireland Limited

PRAC Rapporteur: Julia Pallos

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.4. Evinacumab – EVKEEZA (CAP) – EMA/R/0000293523

Applicants: Ultragenyx Germany GmbH

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Ponesimod – PONVORY (CAP) – EMA/R/0000292277

Applicants: Laboratoires Juvise Pharmaceuticals

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. Satralizumab – ENSPRYNG (CAP) – EMA/R/0000293585

Applicants: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.7. Thiotepa – THIOTEPA RIEMSER (CAP) – EMA/R/0000282361

Applicants: Esteve Pharmaceuticals GmbH

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.8. Tirbanibulin – KLISYRI (CAP) – EMA/R/0000293300

Applicants: Almirall S.A.

PRAC Rapporteur: Anna Mareková

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 CHMP or the EMA

10.1. Safety related variations of the marketing authorisation

None

10.2. Timing and message content in relation to Member States' safety announcements

None

10.3. Other requests

None

10.4. Scientific Advice

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

11. Other safety issues for discussion requested by the Member States

11.1. Safety related variations of the marketing authorisation

11.1.1. Ciprofloxacin (intravenous and oral use) (NAP); Moxifloxacin (intravenous and oral use) (NAP) - FR/H/xxxx/WS/485

Applicant(s): Bayer HealthCare S.A.S. (Iziflox, Ciflox)

PRAC Lead: Zoubida Amimour

Scope: PRAC consultation on a worksharing variation procedure (FR/H/xxxx/WS/485) to update the product information in order to add information on acute myocardial ischemia with or without myocardial infarction as part of a hypersensitivity reaction (Kounis syndrome), at request of France.

Action: For adoption

11.1.2. Ketoprofen (NAP) - FR/H/xxxx/WS/558

Applicant(s): Sanofi Winthrop Industrie (Profemigr, Toprec, Profenid, Bi-Profenid)

PRAC Lead: Tiphaine Vaillant

Scope: PRAC consultation on a worksharing variation procedure (FR/H/xxxx/WS/558) to update the product information regarding foetal death secondary to cardiopulmonary and/or renal toxicity after nonsteroidal anti-inflammatory drugs (NSAID) exposure after the second trimester of pregnancy and the risk of formation of intestinal diaphragm-like strictures, at request of France.

Action: For adoption

11.1.3. Levofloxacin (intravenous and oral use) (NAP) - DE/H/5119/001-003/II/117/G

Applicant(s): Sanofi-Aventis Deutschland GmbH (Tavanic)

PRAC Lead: Martin Huber

Scope: PRAC consultation on a variation procedure (DE/H/5119/001-003/II/117/G) to update the product information regarding cerebellar syndrome and Guillain-Barré syndrome following the conclusions of PSUSA/00010767/202310, at request of Germany.

Action: For adoption

11.1.4. Tramadol (NAP) - DE/H/xxxx/WS/2290; DE/H/0639/001-004/II/040

Applicants: Ethypharm, Mylan Germany GmbH, Viatris Healthcare GmbH

PRAC Lead: Martin Huber

Scope: PRAC consultation on two worksharing variation procedures (DE/H/xxxx/WS/2290 and DE/H/0639/001-004/II/040) to update the product information to include a warning on

the use of prolonged-/modified-release opioids for acute post-operative pain owing to increased risk of persistent post-operative opioid use (PPOU) and opioid-induced ventilatory impairment (OIVI), at request of Germany.

Action: For adoption

11.2. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC membership

Action: For information

12.1.2. Vote by proxy

Action: For information

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. Scientific Advice Working Party (SAWP) - SAWP composition - re-examination exercise

Action: For discussion

12.4. Cooperation within the EU regulatory network

12.4.1. Health threats and EMA Emergency Task Force (ETF) activities - update

Action: For discussion

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

12.7.1. PRAC work plan 2026

PRAC lead: Ulla Wändel Liminga, Liana Martirosyan

Action: For discussion

12.8. Planning and reporting

None

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

12.10.5. Revisions of the Questions and Answers for assessors on Periodic safety update reports (PSUSA), PSUSA assessment report template and Explanatory Note to Good Pharmacovigilance Practice (GVP) Module VII.

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.11. Signal management

12.11.1. Signal management – feedback from Signal Management Review Technical (SMART) Working Group

PRAC lead: Martin Huber

Action: For discussion

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. Draft Good Pharmacovigilance Practice (GVP) Module V and RMP template rev 3.0

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.14.2. Risk management systems

None

12.14.3. 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

None

12.21. Others

12.21.1. Real World Evidence (RWE) and Data analysis and real-world interrogation network (DARWIN EU®) – update

Action: For discussion

12.21.2. Lactose used as excipient in medicinal products – revised information for the labelling and package leaflet

Action: For information

12.21.3. Patient Registries 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/