9 February 2026
EMA/PRAC/15618/2026
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 09-12 February 2026

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

09 February 2026, 13:00 – 19:30, room 2C

10 February 2026, 08:30 – 19:30, room 2C

11 February 2026, 08:30 – 19:30, room 2C

12 February 2026, 08:30 – 16:00, room 2C

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 12-15 January 2026. See February month 2026 PRAC minutes (to be published post March 2026 PRAC meeting).

1.2. Agenda of the meeting on 09-12 February 2026

Action: For adoption

1.3. Minutes of the previous meeting on 12-15 January 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

3.3.1. 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

3.4. 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. Chikungunya vaccine (live) - IXCHIQ (CAP)

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Signal of new aspect of the known risk of aseptic meningitis

Action: For adoption

EPITT 20250 – New signal

Lead Member State(s): DE

4.1.2. Omalizumab – OMLYCLO (CAP); XOLAIR (CAP)

Applicant: Celltrion Healthcare Hungary Kft., Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: Signal of acquired haemophilia

[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

Action: For adoption

EPITT 19385 – New signal

Lead Member State: SE

4.2. Signals follow-up and prioritisation

4.2.1. Risankizumab – SKYRIZI (CAP) - EMEA/H/C/004759/SDA/011

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Signal of pemphigoid

Action: For adoption

EPITT 20192 – Follow-up to September 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. Alpelisib (CAP MAA) - EMEA/H/C/006539, Orphan

Scope (pre D-180 phase): Treatment of adult and paediatric patients aged 2 years and older with severe or life-threatening manifestations of PIK3CA-related overgrowth spectrum (PROS)

Action: For adoption

5.1.2. Clesrovimab - ENFLONSIA (CAP MAA) - EMEA/H/C/006497

Applicant: Merck Sharp & Dohme B.V.

Scope (initial application in the decision making phase): Prevention of infections with respiratory syncytial virus (RSV) and lower respiratory tract disease (LRTD)

Action: For adoption

5.1.3. Colchicine (CAP MAA) - EMEA/H/C/006653

Scope (pre D-180 phase): Indicated to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in patients with atherosclerotic disease or with multiple risk factors for cardiovascular disease.

Action: For adoption

5.1.4. Diazoxide choline (CAP MAA) - EMEA/H/C/006576, Orphan

Scope (pre D-180 phase): Treatment of adult and paediatric patients with Prader-Willi syndrome (PWS)

Action: For adoption

5.1.5. Lerodalcibep (CAP MAA) - EMEA/H/C/006694, PUMA

Scope (pre D-180 phase): Is indicated in adults with primary hypercholesterolaemia (heterozygous familial (HeFH) and non-familial) or mixed dyslipidaemia as an adjunct to diet

Action: For adoption

5.1.6. Nerandomilast (CAP MAA) - EMEA/H/C/006405

Scope (pre D-180 phase): Treatment of adult patients with Idiopathic Pulmonary Fibrosis (IPF) and adult patients with Progressive Pulmonary Fibrosis (PPF)

Action: For adoption

5.1.7. Onasemnogene abeparvovec (CAP MAA) - EMEA/H/C/006498, Orphan

Scope (pre D-180 phase): Treatment of 5q spinal muscular atrophy (SMA)

Action: For adoption

5.1.8. Palbociclib (CAP MAA) - EMEA/H/C/006624

Scope (pre D-180 phase): Treatment of breast cancer factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer:
- in combination with an aromatase inhibitor;
- in combination with fulvestrant in women who have received prior endocrine therapy .

Action: For adoption

5.1.9. Plozasiran (CAP MAA) - EMEA/H/C/006579, Orphan

Scope (pre D-180 phase): Treatment of familial chylomicronaemia syndrome (FCS).

Action: For adoption

5.1.10. Ranibizumab (CAP MAA) - EMEA/H/C/006634

Scope (pre D-180 phase): Treatment of adults with neovascular (wet) age-related macular degeneration (AMD), visual impairment and other retinopathies

Action: For adoption

5.1.11. Sasanlimab (CAP MAA) - EMEA/H/C/006641

Scope (pre D-180 phase): Treatment of bladder cancer indicated for the treatment of adult

Action: For adoption

5.1.12. Tarlatamab (CAP MAA) - EMEA/H/C/006451, Orphan

Scope (pre D-180 phase): Treatment of extensive-stage small cell lung cancer

Action: For adoption

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

5.2.1. Durvalumab – IMFINZI (CAP); Olaparib – LYNPARZA (CAP) – EMA/VR/0000296305

Applicant: AstraZeneca AB

PRAC Rapporteur: Amelia Cupelli

Scope: To extend the due date for the phase III PAES study D9311C00001 (DUO-E) from December 2026 to November 2028 in the RMP and Annex II of the SmPC. In addition, the MAH has taken this opportunity to correct an error identified for the DUO-E study involving a raw data mapping issue that affected the COVID-19 study disruption data and impacts the COVID-19 tables in the CSR. As there is no change in the interpretation or the overall conclusion this has exceptionally been included as part of this type IB.

Action: For adoption

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

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

Applicant: 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

5.3.2. Atezolizumab – TECENTRIQ (CAP) – EMA/VR/0000315105

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: A grouped application consisting of:

C.I.4: Update of section 4.4 of the SmPC to enhance the text to explicitly advise healthcare professionals to monitor for signs of Immune-mediated myocarditis/myositis/myasthenia gravis overlap syndrome based on postmarketing data. The Package Leaflet is updated accordingly. The RMP version 33.0 has also been submitted.

C.I.4: Update of section 4.8 of the SmPC to add hypoalbuminemia, hypophosphatemia, hypocalcaemia, and gamma-glutamyltransferase increased as adverse drug reactions for atezolizumab based on postmarketing data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.

Action: For adoption

5.3.3. Atogepant – AQUIPTA (CAP) – EMA/VR/0000310717

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: A grouped application comprised of 1 Type II Variation and 3 Type I Variations, as follows:

Type II (C.I.6): Extension of indication to include acute treatment of migraine with or without aura in adults, based on interim results from study M24-305; this is a 24-week, global, Phase 3, multicenter, randomized, double blind, placebo-controlled, multiple-migraine attack study with an open label period to evaluate the safety and efficacy of atogepant in adult participants for the acute treatment of migraine (ECLIPSE). 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 2.2 of the RMP has also been submitted.

Action: For adoption

5.3.4. Avelumab – BAVENCIO (CAP) – EMA/VR/0000314741

Applicant: Merck Europe B.V.

PRAC Rapporteur: Karin Erneholm

Scope: A grouped application comprised of 2 Type II Variations, as follows:

C.I.4: Update of section 4.4 of the SmPC in order to update the warning on 'immune mediated adverse reactions', particularly regarding myositis, myocarditis, and myasthenia

gravis (Triple-M syndrome), based on a safety review. The Package Leaflet is updated accordingly.

C.I.4: Update of section 4.8 of the SmPC in order to update the frequency of 'sarcoidosis' in the list of adverse drug reactions (ADRs) for avelumab monotherapy from 'uncommon' to 'rare', and to add it to the list of ADRs for avelumab in combination with axitinib with frequency 'not known', based on a safety review. The Package Leaflet is updated accordingly. The RMP version 9.3 has been submitted. In addition, the MAH took the opportunity to introduce alignment changes to the PI.

Action: For adoption

5.3.5. Axicabtagene ciloleucel – YESCARTA (CAP); Brexucabtagene autoleucel – TECARTUS (CAP) – EMA/VR/0000308229

Applicant: Kite Pharma EU B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Update of sections 4.2, 4.4, 4.5. 4.7 and 6.4 of the SmPC in order to modify the pre- and post-infusion monitoring recommendations and requirements related to the risk of CRS (cytokine release syndrome) and ICANS (immune effector cell-associated neurotoxicity syndrome) based on data from clinical trials, post-marketing experience and literature. The Package Leaflet is updated accordingly. The RMP version 7.1 has also been submitted. In addition, Annex II has been updated accordingly. Furthermore, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the PI.

Action: For adoption

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

Applicant: 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

5.3.7. Baricitinib – OLUMIANT (CAP) – EMA/VR/0000288098

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of adolescent patients (12 to less than 18 years) with severe alopecia areata for OLUMIANT, based on results from study I4V-MC-JAIO; this is a Phase 3, double-blind, randomised, placebo-controlled trial to evaluate the efficacy, safety, and pharmacokinetics of baricitinib in children from 6 years to less than 18 years of age with alopecia areata. 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 26.1 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 and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.8. Benralizumab – FASENRA (CAP) – EMA/VR/0000288520

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Extension of indication to include treatment of adults and adolescents with hypereosinophilic syndrome (HES) for FASENRA, based on interim results from study D3254C00001 (NATRON); this is a multicentre, randomised, double-blind, parallel-group, placebo-controlled, 24-week phase III study with an open-label extension to evaluate the efficacy and safety of benralizumab in patients with HES; 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 8 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial and administrative updates to the PI and to update the list of local representatives in the Package Leaflet. Furthermore, section 6.5 of the SmPC was updated.

Action: For adoption

5.3.9. Berotralstat – ORLADEYO (CAP) – EMA/X/0000268892

Applicant: Biocryst Ireland Limited

PRAC Rapporteur: Julia Pallos

Scope: Extension application to introduce a new pharmaceutical form associated with new strengths (78 mg, 96 mg,108 and 132 film - coated granules). The new presentations are indicated to include treatment for paediatric patients aged 2 to less than 12 years. The extension application is grouped with a type II clinical variation (C.I.4). 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 and Labelling are updated in accordance. Version 2.1 of the RMP has also been submitted.

Action: For adoption

5.3.10. COVID-19 vaccine (recombinant, adjuvanted) – BIMERVAX (CAP) – EMA/VR/0000316063

Applicant: Hipra Human Health S.L.

PRAC Rapporteur: Zane Neikena

Scope: Update of section 4.5 of the SmPC in order to add coadministration information with seasonal influenza vaccines based on final results from study HIPRA-HH-11. HIPRA-HH-11 was a Phase II randomized, double-blind, multi-centre trial to evaluate the safety and immunogenicity of BIMERVAX when coadministered with seasonal surface antigen, inactivated adjuvanted influenza vaccine (SIIV) in adults older than 65 years of age fully vaccinated against COVID-19. The Package Leaflet is updated accordingly. The RMP version

3.0 is also submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.

Action: For adoption

5.3.11. Darunavir / Cobicistat – REZOLSTA (CAP) – EMA/X/0000268372

Applicant: Janssen Cilag International

PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (600 mg darunavir/90 mg cobicistat dispersible tablet). The new presentation is indicated to include treatment for paediatric patients aged ≥ 3 years and older weighing at least 15 kg and less than 25 kg. The extension application is grouped with a type II clinical variation (C.I.4) to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 in order to add efficacy and PK data in children based on final results from study GS-US-215-0128; this is a Phase 2/3, Multicentre, Open-label, Multicohort Study Evaluating Pharmacokinetics (PK), Safety, and Efficacy of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 Infected, Virologically Suppressed Paediatric Participants. The Package Leaflet and Labelling are updated in accordance. Version 7.2 of the RMP has also been submitted.

Action: For adoption

5.3.12. Difelikefalin – KAPRUVIA (CAP) – EMA/VR/0000316094

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: A grouped application consisting of safety data from three studies of the oral difelikefalin formulation to support the safety of the intravenous difelikefalin formulation:

C.I.13: Submission of the final report from study CR845-310301 listed as a category 3 study in the RMP. This is a multicenter, randomized, double-blind, placebo-controlled 12-week study to evaluate the safety and efficacy of oral difelikefalin in advanced chronic kidney disease subjects with moderate-to-severe pruritus with an up to 52-week long-term extension. The RMP version 3.0 has also been submitted.

C.I.13: Submission of the final report from study CR845-310302 listed as a category 3 study in the RMP. This is a multicenter, randomized, double-blind, placebo-controlled 12-week study to evaluate the safety and efficacy of oral difelikefalin in advanced chronic kidney disease subjects with moderate-to-severe pruritus with an up to 52-week long-term extension

C.I.13: Submission of the final report from study CR845-310501 listed as a category 3 study in the RMP. This is a two-part, multicenter, randomized, double-blind study to evaluate the efficacy and safety of oral difelikefalin as adjunct therapy to a topical corticosteroid for moderate-to-severe pruritus in adult subjects with atopic dermatitis.

Action: For adoption

5.3.13. Dinutuximab beta – QARZIBA (CAP) – EMA/VR/0000316241

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: A grouped application, comprised of the following variations:

C.I.4: Update of sections 4.8 and 5.1 of the SmPC to introduce changes based on the final results from study APN311-304; this is a Phase II, interventional, single-arm, open-label study evaluating the anti-tumor activity and safety of dinutuximab beta (ch14.18/CHO) continuous infusion in pediatric patients with primary refractory or relapsed neuroblastoma. The Package Leaflet has been updated accordingly.

C.I.4: Update of sections 4.8 and 5.1 of the SmPC to introduce changes based on the final results from study APN311-202 V1/V2; this is a Phase I/II, interventional, multi-center, open-label study evaluating the tolerability, immunomodulatory efficacy, and anti-tumor activity of dinutuximab beta (ch14.18/CHO) administered as prolonged continuous infusion in combination with subcutaneous aldesleukin (IL-2) in pediatric patients with primary refractory or relapsed neuroblastoma. The Package Leaflet has been updated accordingly.

C.I.13: Submission of final results from study APN 311-201. This is a Phase II feasibility study using ch14.18/CHO antibody and subcutaneous interleukin 2 after haploidentical stem cell transplantation in children with relapsed neuroblastoma.

The RMP version 10.1 has also been submitted. In addition, the MAH took the opportunity to introduce changes to the PI for completion and to update excipient wording for polysorbates.

Action: For adoption

5.3.14. Enfortumab vedotin – PADCEV (CAP) – EMA/VR/0000312495

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include PADCEV, in combination with pembrolizumab, for use as neoadjuvant treatment and continued as adjuvant treatment following radical cystectomy, is indicated for the treatment of adult patients with muscle-invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy based on interim results from study EV-303/KN-905; this is a randomized phase 3 study evaluating cystectomy with perioperative pembrolizumab and cystectomy with perioperative enfortumab, vedotin and pembrolizumab versus cystectomy alone in participants who are cisplatin-ineligible or decline cisplatin with muscle-invasive bladder cancer. 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 5.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, and to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

5.3.15. Enzalutamide – XTANDI (CAP) – EMA/VR/0000313098

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Update of sections 4.8 and 5.1 of the SmPC to reflect the updated safety and efficacy data based on final results from 9785-CL-0335 (EMBARK) study; this is a phase 3, randomized, double-blind, placebo-controlled efficacy and safety study of enzalutamide plus androgen deprivation therapy (ADT) versus placebo plus ADT in patients with metastatic hormone sensitive prostate cancer (mHSPC); the Package Leaflet is updated accordingly. The RMP version 20.0 has also been submitted.

Action: For adoption

5.3.16. Epcoritamab – TEPKINLY (CAP) – EMA/VR/0000311043

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Extension of indication to include in combination with rituximab and lenalidomide treatment of patients with relapsed/refractory follicular lymphoma (FL) for Tepkinly, based on interim results from study M20-638; this is a Phase 3, open-label study to evaluate safety and efficacy of epcoritamab in combination with rituximab and lenalidomide (R2) compared to R2 in subjects with relapsed or refractory follicular lymphoma (EPCORE FL-1). 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 3.2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.17. Ferric maltol – FERACCRU (CAP) – EMA/VR/0000268118

Applicant: Norgine B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of paediatric population (adolescents aged 12 years and above) for FERACCRU, based on results from phase 1 study ST10-01-103, phase 3 study ST10-01-305 and a supportive phase 1 study ST10-01-104. 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 9.1 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 and to implement editorial changes to the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

Action: For adoption

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

Applicant: 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

5.3.19. Lazertinib – LAZCLUZE (CAP) – EMA/VR/0000315717

Applicant: Janssen Cilag International

PRAC Rapporteur: Petar Mas

Scope: Update of section 4.8 of the SmPC in order to add information regarding elevations in alkaline phosphatase and bilirubin with lazertinib monotherapy within the 'hepatotoxicity' subsection, based on a cumulative safety review. The RMP version 2.1 has also been submitted.

Action: For adoption

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

Applicant: 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

5.3.21. Lorlatinib – LORVIQUA (CAP) – EMA/VR/0000292366

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update dosing recommendations in patients with moderate and severe hepatic impairment based on final results from study B7461040 listed as a category 3 study in the RMP; this is a Phase 1,

Open-Label, Single-Dose, Parallel-Group Study to Evaluate the Plasma Pharmacokinetics and Safety of Lorlatinib in Participants with Moderate and Severe Hepatic Impairment Relative to Participants with Normal Hepatic Function. The Package Leaflet is updated accordingly. The RMP version 5.4 has also been submitted.

Action: For adoption

5.3.22. Mitapivat – PYRUKYND (CAP) – EMA/VR/0000315433

Applicant: Agios Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Submission of the final report from study AG348-C-011 listed as a category 3 study in the RMP. This is a Phase 3, Multicenter, Open-label, Long-term, Extension Study of Mitapivat in Adults with PK Deficiency Previously Treated in Studies AG348-C-006 or AG348-C-007. The RMP version 2.1 has also been submitted.

Action: For adoption

5.3.23. Nivolumab / Relatlimab – OPDUALAG (CAP) – EMA/VR/0000314728

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on Myocarditis-Myositis-Myasthenia Gravis Overlap Syndrome, and add Myocarditis-Myositis-Myasthenia Gravis Overlap Syndrome to the list of adverse drug reactions (ADRs) with frequency Uncommon based on postmarketing data and literature; the Package Leaflet is updated accordingly. The RMP version 5.0 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

5.3.24. Nivolumab – OPDIVO (CAP) – EMA/X/0000304427

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Extension application to add a new strength of 300 mg solution for injection.

Action: For adoption

5.3.25. Ocrelizumab – OCREVUS (CAP) – EMA/VR/0000309389

Applicant: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include treatment of paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (RRMS) for OCREVUS, based on primary analysis results from the pivotal phase III study (WN42086/Operetta 2) and primary and

updated results from a supportive phase II study (WA39085/Operetta 1). Operetta 1 is an open-label, parallel-group, dose-finding Phase II study to determine the dosing regimen of ocrelizumab to be further investigated in Operetta 2, and Operetta 2 is a Phase III, randomized, double-blind, double-dummy, parallel-group, multicenter, non-inferiority study to evaluate the efficacy and safety of intravenous ocrelizumab in comparison with fingolimod. As a consequence, sections 2, 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 15.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce updates to other sections of the SmPC and PL as per previous procedures: linguistic review comments (sodium, pH and osmolality), updates to comply with the Excipient Guideline (polysorbates), changes to the list of local representatives in the Package Leaflet, as well as editorial and clarification changes to the PI.

Action: For adoption

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

Applicant: 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

5.3.27. Pembrolizumab – KEYTRUDA (CAP) – EMA/VR/0000312515

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment of adults with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin containing chemotherapy for KEYTRUDA, based on interim results from study KEYNOTE-905, an open label, randomised, interventional phase 3 study. As consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 51.1 of the RMP has also been submitted.

Action: For adoption

5.3.28. Ponatinib – ICLUSIG (CAP) – EMA/X/0000296489

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength (5 mg hard capsule) grouped with an Extension of Indication to include treatment of paediatric patients aged 6 years and older with chronic phase chronic myeloid leukaemia (CP-CML) who are resistant or intolerant to at least one tyrosine kinase inhibitor for ICLUSIG,

based on interim results from study INCB 84344-102 and a final results from early-terminated study Ponatinib-1501; the first is an ongoing open-label, single-arm, Phase 1/2 study evaluating the safety and efficacy of ponatinib monotherapy for the treatment of R/R leukemias, lymphomas, or solid tumors in pediatric participants. The second is a Phase 1/2, single-arm, open-label, multicenter study designed to evaluate the safety, tolerability, PK, and efficacy of ponatinib when administered in combination with multiagent chemotherapy in pediatric patients with Ph+ ALL, Ph+ MPAL, or Ph-like ALL who had a relapse, were resistant or intolerant to at least 1 prior BCR-ABL1 TKI therapy, or had the T315I mutation. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1 and 6.5 of the SmPC are updated. Package Leaflet is updated accordingly. The RMP version 23.4 has also been submitted.

Action: For adoption

5.3.29. Respiratory syncytial virus mRNA vaccine (nucleoside modified) – mRESVIA (CAP) – EMA/VR/0000312911

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Extension of indication to include active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in all adults 18 years of age and older for mRESVIA, based on results from Study mRNA-1345-P101, Study mRNA-1345-P301, Study mRNA-1345-P303 Part A, and Study mRNA-1345-P302 Part A and Part B. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP has also been submitted.

Action: For adoption

5.3.30. Roflumilast – DAXAS (CAP) – EMA/VR/0000315545

Applicant: AstraZeneca AB

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Submission of the final report from study ROF-MD-07. This is a 52-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Roflumilast 500 µg on Exacerbation Rate in Patients With Chronic Obstructive Pulmonary Disease (COPD) Treated With a Fixed-Dose Combination of Long-Acting Beta Agonist and Inhaled Corticosteroid (LABA/ICS). The RMP version 24 succession 1 has also been submitted.

Action: For adoption

5.3.31. Sacituzumab govitecan – TRODELVY (CAP) – EMA/VR/0000312649

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication for treatment of adult patients with PD-L1-negative metastatic triple- negative breast cancer or PD-L1-positive metastatic triple-negative breast cancer previously treated with an anti-PD-(L)1 agent in the curative setting for Trodelvy, based on

results from study GS-US-592-6238 (ASCENT-03), which is a phase 3 study of sacituzumab govitecan (IMMU-132) versus treatment of physician's choice (TPC) in Patients With Previously Untreated, Locally Advanced, Inoperable or Metastatic Triple-Negative Breast Cancer Whose Tumors Do Not Express PD-L1 or in Patients Previously Treated With Anti-PD-(L)1 Agents in the Early Setting Whose Tumors Do Express PD-L1. As a consequence, sections 4.1, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted

Action: For adoption

5.3.32. Setmelanotide – IMCIVREE (CAP) – EMA/VR/0000288021

Applicant: Rhythm Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Miroslava Gocova

Scope: Extension of indication to include reduction in hunger (or hyperphagia) and BMI (Body Mass Index)/BMI z-score, improvement of metabolic parameters, and increase in energy expenditure in adults and children 4 years of age and above, following rapid and severe weight gain associated with hypothalamic injury and/or impairment for IMCIVREE, based on results from study RM-493-040 as well as supportive study RM-493-030. RM-493-040 is a phase 3, double blind, randomized, placebo-controlled trial to evaluate the efficacy and safety of setmelanotide in patients with acquired hypothalamic obesity, while RM-493-030 is a phase 2, open-label 20-week study to evaluate the safety and efficacy of setmelanotide in subjects with hypothalamic obesity. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are being updated. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to introduce editorial and administrative changes to the PI.

Action: For adoption

5.3.33. Smallpox and monkeypox vaccine (live modified vaccinia virus Ankara) – IMVANEX (CAP) – EMA/VR/0000316261

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Dirk Mentzer

Scope: A grouped application as follows:

Type II (C.I.4): Update of sections 4.8 and 5.1 in order to update clinical information based on the final clinical study report of study DMID 22-0020 stage 2, listed as a Specific Obligation in the Annex II. This is a Phase 2 randomized open label multisite trial to inform Public Health strategies involving the use of MVA-BN vaccine for Mpox. The Annex II and Package Leaflet are updated in accordance. The RMP version 11.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.

Type IA (A.6): To change the ATC Code from 'other viral vaccines, ATC code: J07BX' to 'smallpox and monkeypox vaccines, ATC code: J07BX01'

Action: For adoption

5.3.34. Sotatercept – WINREVAIR (CAP) – EMA/VR/0000315667

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Update of sections 4.4, 4.8, and 5.1 of the SmPC in order to update efficacy and safety information based on the final results from the study MK-7962-005 (HYPERION). MK-7962-005 (HYPERION) is a Phase 3, randomized, double-blind, placebo-controlled study designed to evaluate the effect of sotatercept in participants who had received the diagnosis less than 1 year earlier, had an intermediate or high risk of death, and were receiving double or triple background therapy. The RMP version 2.1 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

5.3.35. Tirzepatide – MOUNJARO (CAP) – EMA/VR/0000310637

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, or stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease for MOUNJARO, based on final results from study I8F-MC-GPGN (SURPASS-CVOT). SURPASS-CVOT was a Phase 3, event-driven, multicentre, international, randomized, double-blind, active-comparator, parallel-group study to assess the effect of tirzepatide versus dulaglutide on major adverse cardiovascular events in participants with type 2 diabetes. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI.

Action: For adoption

5.3.36. 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

5.3.37. Upadacitinib – RINVOQ (CAP) – EMA/VR/0000312506

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include the treatment of severe alopecia areata (AA) in adult and adolescents 12 years and older for RINVOQ, based on interim results from 2 pivotal, Phase 3 studies (M23-716 Study 1 and Study 2); those are randomized, double blind, placebo-controlled, multi-centre studies of Upadacitinib evaluating the efficacy and safety of Upadacitinib 15 mg QD and 30 mg QD versus placebo for the treatment of severe AA in subjects who are at least 12 years of age. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Annex II are updated in accordance. Version 18.0 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

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

Applicant: Fresenius Kabi Deutschland GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Quality

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. Aclidinium – BRETARIS GENUAIR (CAP); EKLIRA GENUAIR (CAP) – EMA/PSUR/0000305035

Applicant: Covis Pharma Europe B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00009005/202507)

Action: For adoption

6.1.2. Afamelanotide – SCENESSE (CAP) – EMA/PSUR/0000305040

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010314/202506)

Action: For adoption

6.1.3. Alectinib – ALECENSA (CAP) – EMA/PSUR/0000305041

Applicant: Roche Registration GmbH

PRAC Rapporteur: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00010581/202507)

Action: For adoption

6.1.4. Anifrolumab – SAPHNELO (CAP) – EMA/PSUR/0000305059

Applicant: AstraZeneca AB

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010980/202507)

Action: For adoption

6.1.5. Avapritinib – AYVAKYT (CAP) – EMA/PSUR/0000305025

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010878/202507)

Action: For adoption

6.1.6. Beclometasone / Formoterol / Glycopyrronium bromide – TRIMBOW (CAP); TRYDONIS (CAP) – EMA/PSUR/0000305048

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010617/202507)

Action: For adoption

6.1.7. Belatacept – NULOJIX (CAP) – EMA/PSUR/0000305012

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00000311/202506)

Action: For adoption

6.1.8. Brexucabtagene autoleucel – TECARTUS (CAP) – EMA/PSUR/0000305034

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010903/202507)

Action: For adoption

6.1.9. Budesonide – JORVEZA (CAP) – EMA/PSUR/0000305032

Applicant: Dr. Falk Pharma GmbH

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00010664/202507)

Action: For adoption

6.1.10. Bulevirtide – HEPCLUDEX (CAP) – EMA/PSUR/0000305044

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010873/202507)

Action: For adoption

6.1.11. C1 esterase inhibitor (human) – CINRYZE (CAP) – EMA/PSUR/0000305079

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010104/202506)

Action: For adoption

6.1.12. Cefepime / Enmetazobactam – EXBLIFEP (CAP) – EMA/PSUR/0000305019

Applicant: Advanz Pharma Limited

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000305/202506)

Action: For adoption

6.1.13. Cenegermin – OXERVATE (CAP) – EMA/PSUR/0000305014

Applicant: Dompe Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010624/202507)

Action: For adoption

6.1.14. Darolutamide – NUBEQA (CAP) – EMA/PSUR/0000305057

Applicant: Bayer AG

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010843/202507)

Action: For adoption

6.1.15. Decitabine / Cedazuridine – INAQOVI (CAP) – EMA/PSUR/0000305018

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000118/202507)

Action: For adoption

6.1.16. Eptacog beta (activated) – CEVENFACTA (CAP) – EMA/PSUR/0000305028

Applicant: Laboratoire Francais Du Fractionnement Et Des Biotechnologies

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011006/202507)

Action: For adoption

6.1.17. Finerenone – KERENDIA (CAP) – EMA/PSUR/0000305023

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010978/202507)

Action: For adoption

6.1.18. Garadacimab – ANDEMBRY (CAP) – EMA/PSUR/0000305046

Applicant: CSL Behring GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011109/202507)

Action: For adoption

6.1.19. Gefapixant – LYFNUA (CAP) – EMA/PSUR/0000305009

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000132/202507)

Action: For adoption

6.1.20. Glucagon – BAQSIMI (CAP); OGLUO (CAP) – EMA/PSUR/0000305033

Applicants: Amphastar France Pharmaceuticals, Strongbridge Dublin Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00010826/202507)

Action: For adoption

6.1.21. Glucarpidase – VORAXAZE (CAP) – EMA/PSUR/0000305021

Applicant: Serb

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010968/202507)

Action: For adoption

6.1.22. Guselkumab – TREMFYA (CAP) – EMA/PSUR/0000305076

Applicant: Janssen Cilag International

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010652/202507)

Action: For adoption

6.1.23. Inotersen – TEGSEDI (CAP) – EMA/PSUR/0000305036

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00010697/202507)

Action: For adoption

6.1.24. Lecanemab – LEQEMBI (CAP) – EMA/PSUR/0000305053

Applicant: Eisai GmbH

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00011132/202507)

Action: For adoption

6.1.25. Lomitapide – LOJUXTA (CAP) – EMA/PSUR/0000305062

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010112/202507)

Action: For adoption

6.1.26. Netarsudil – RHOKIINSA (CAP) – EMA/PSUR/0000305050

Applicant: Santen Oy

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00107812/202506)

Action: For adoption

6.1.27. Odevixibat – BYLVAY (CAP); KAYFANDA (CAP) – EMA/PSUR/0000305038

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010949/202507)

Action: For adoption

6.1.28. Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) – INCELLIPAN (CAP); Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) – CELLDEMIC (CAP) – EMA/PSUR/0000305049

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00011057/202507)

Action: For adoption

6.1.29. Phenylephrine / Ketorolac – OMIDRIA (SRD[3]) – EMA/PSUR/0000305058

Applicant: Rayner Surgical (Ireland) Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010419/202507)

Action: For discussion

[3] European Commission (EC) decision on the withdrawal of the marketing authorisation for OMIDRIA dated 10 November 2025

6.1.30. Pirtobrutinib – JAYPIRCA (CAP) – EMA/PSUR/0000305011

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000155/202507)

Action: For adoption

6.1.31. Remimazolam – BYFAVO (CAP) – EMA/PSUR/0000305045

Applicant: Paion Pharma GmbH

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00010924/202507)

Action: For adoption

6.1.32. Rotavirus vaccine, live – ROTARIX (CAP) – EMA/PSUR/0000305060

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00002665/202507)

Action: For adoption

6.1.33. Smallpox and monkeypox vaccine (live modified vaccinia virus Ankara) – IMVANEX (CAP) – EMA/PSUR/0000305075

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010119/202507)

Action: For adoption

6.1.34. Sofosbuvir / Velpatasvir – EPCLUSA (CAP) – EMA/PSUR/0000305055

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010524/202506)

Action: For adoption

6.1.35. Tafasitamab – MINJUVI (CAP) – EMA/PSUR/0000305027

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010951/202507)

Action: For adoption

6.1.36. Teprotumumab – TEPEZZA (CAP) – EMA/PSUR/0000305056

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011148/202507)

Action: For adoption

6.1.37. Tocofersolan – VEDROP (CAP) – EMA/PSUR/0000305051

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00002981/202507)

Action: For adoption

6.1.38. Voretigene neparvovec – LUXTURNA (CAP) – EMA/PSUR/0000305077

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010742/202507)

Action: For adoption

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

6.2.1. Dasatinib – SPRYCEL (CAP); NAP – EMA/PSUR/0000305016

Applicants: Bristol-Myers Squibb Pharma EEIG, various

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000935/202506)

Action: For adoption

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

6.3.1. Albendazole (NAP) – EMA/PSUR/0000305020

Applicants: various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000073/202507)

Action: For adoption

6.3.2. Alfacalcidol (NAP) – EMA/PSUR/0000305008

Applicants: various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000080/202506)

Action: For adoption

6.3.3. Amlodipine / irbesartan (NAP) – EMA/PSUR/0000305030

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00010876/202506)

Action: For adoption

6.3.4. Ascorbic acid / paracetamol / phenylephrine hydrochloride (NAP) – EMA/PSUR/0000305010

Applicants: various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00000255/202506)

Action: For adoption

6.3.5. Benzylpenicillin (NAP); benzathine benzylpenicillin (NAP); benzathine benzylpenicillin / lidocaine (NAP); procaine benzylpenicillin (NAP); benzathine benzylpenicillin / procaine benzylpenicillin (NAP) – EMA/PSUR/0000305013

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00000383/202506)

Action: For adoption

6.3.6. Bethanechol (NAP) – EMA/PSUR/0000305015

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000402/202506)

Action: For adoption

6.3.7. Calcifediol (NAP) – EMA/PSUR/0000305017

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000491/202506)

Action: For adoption

6.3.8. Clonazepam (NAP) – EMA/PSUR/0000305022

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00000812/202506)

Action: For adoption

6.3.9. Diphtheria / tetanus / pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed) (NAP); diphtheria / tetanus / pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) (NAP) – EMA/PSUR/0000305024

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001126/202507)

Action: For adoption

6.3.10. Ethinylestradiol / etonogestrel (NAP) – EMA/PSUR/0000305026

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001307/202507)

Action: For adoption

6.3.11. Ganciclovir (NAP) – EMA/PSUR/0000305047

Applicants: various

PRAC Lead: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00001516/202506)

Action: For adoption

6.3.12. Itopride (NAP) – EMA/PSUR/0000305039

Applicants: various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00010606/202506)

Action: For adoption

6.3.13. Magnesium sulfate (NAP) – EMA/PSUR/0000305052

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00009225/202506)

Action: For adoption

6.3.14. Metronidazole / miconazole (NAP); chlorquinaldol / metronidazole (NAP) – EMA/PSUR/0000305029

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00002042/202507)

Action: For adoption

6.3.15. Misoprostol (gastrointestinal indication) (NAP) – EMA/PSUR/0000305043

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010291/202506)

Action: For adoption

6.3.16. Mitoxantrone (NAP) – EMA/PSUR/0000305042

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00002076/202506)

Action: For adoption

6.3.17. Nitrous oxide (NAP); nitrous oxide / oxygen (NAP) – EMA/PSUR/0000305054

Applicants: various

PRAC Lead: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00010572/202506)

Action: For adoption

6.3.18. Rifabutin (NAP) – EMA/PSUR/0000305031

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00002639/202507)

Action: For adoption

6.3.19. Ropinirole (NAP) – EMA/PSUR/0000305037

Applicants: various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00002661/202507)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Ustekinumab – STELARA (CAP) – EMA/PAM/0000274988

Applicant: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Responses to the LEG 058 RSI adopted on 27 March 2025 - From PSUSA/00003085/202312: An updated cumulative review (clinical trial, registry, postmarketing, literature and other sources) of severe depression/suicidal ideation, using an appropriate SMQ (Depression and suicide/self injury) for all relevant data streams.

Action: For adoption

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Natalizumab – TYSABRI (CAP) – EMA/VR/0000315289

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Update of sections 4.2, 4.4 of the SmPC, and Annex II in order to align with the revised content of the additional risk minimisation materials in the RMP following the PRAC recommendation in EU PSUR 23 for the Tysabri (EMEA/H/C/PSUSA/00002127/202408). The Package Leaflet is updated accordingly. The RMP version 34.1 has been submitted; the due date for the provision of the final CSR for category 3 PASS study 101MS412 is also being revised.

Action: For adoption

6.6. Expedited summary safety reviews[4]

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[5]

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 dystrophic epidermolysis bullosa (DEB) wounds in a real-life clinical setting.

Action: For adoption

7.1.2. Ketoconazole – KETOCONAZOLE ESTEVE (CAP) – EMA/PASS/0000287667

Applicant: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Petar Mas

Scope: PASS amendment [107o]: Prospective, Multi-Country, Observational Registry to collect clinical information on patients with endogenous Cushing's syndrome (CS) exposed to Ketoconazole ESTEVE (using the existing European Registry on CS (ERCUSYN)), to assess drug utilization pattern and to document the safety (e.g. hepatotoxicity, QT prolongation) and effectiveness of Ketoconazole ESTEVE.

Action: For adoption

[4] 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

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

7.1.3. Odevixibat – KAYFANDA (CAP) – EMA/PASS/0000262884

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: PASS protocol [107n]: Prospective non-interventional study evaluating the long-term safety of odevixibat in patients with Alagille Syndrome (ALGS)

Action: For adoption

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[6]

7.2.1. Birch bark extract – FILSUVEZ (CAP) – EMA/PAM/0000316631

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Zane Neikena

Scope: Submission of an amended protocol for the non-imposed (category 3) Post-Authorisation Safety Study (PASS) Foster, "A long-term non-interventional study to assess the incidence of skin malignancies in patients with dystrophic and junctional epidermolysis bullosa receiving treatment with Filsuvez "

Action: For adoption

7.2.2. Concizumab – ALHEMO (CAP) – EMA/PAM/0000280062

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Submission of the category 3 PASS NN7415-7533 protocol: A registry-based observational cohort study to characterise the safety profile of concizumab in people with haemophilia in the real-world setting.

Action: For adoption

7.2.3. Dimethyl fumarate – SKILARENCE (CAP) – EMA/PAM/0000316578

Applicant: Almirall S.A.

PRAC Rapporteur: Karin Bolin

Scope: Submission of amended protocol for the non-imposed (category 3) Post Authorisation Safety Study (PASS) M-41008-40, “An Observational Post-Authorisation Safety Study of Skilarence in European Psoriasis Registers”; Protocol, version 3.0, dated 25 November 2025; former EMA/PAM/0000280214

Action: For adoption

[6] 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

7.2.4. Efanesoctocog alfa – ALTUVOCT (CAP) - EMA/PAM/0000269605

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Amelia Cupelli

Scope: Response to PRAC Rapporteur's Request for Supplementary Information of EMEA/H/C/005968/MEA/002. Updated protocol of the Observational Registry Study in Previously Untreated Patients (PUPs) with Hemophilia A (ATHN), a non-imposed non-interventional post-authorization safety study (NI-PASS)

Action: For adoption

7.2.5. Galcanezumab – EMGALITY (CAP) – EMA/PAM/0000309244

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: New PASS protocol addendum for ongoing non-interventional PASS I5Q-MC-B001: A Cohort Study to Assess Drug Utilisation and Long-Term Safety of Galcanezumab in US Patients in the Course of Routine Clinical Care (category 3 study in the RMP).

Action: For adoption

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

Applicant: 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.

Action: For adoption

7.2.7. Marstacimab – HYMPAVZI (CAP) – EMA/PAM/0000273932

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Submission of responses to questions following the submission of the PASS protocol for the category 3 post-authorisation study B7841016, a Post-Authorisation Safety Study to Evaluate the Safety of Marstacimab Among Patients with Severe Haemophilia A or B using Real-World Data in European Haemophilia Register

Action: For adoption

7.2.8. Tofacitinib – XELJANZ (CAP) – EMA/PAM/0000316639

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of amended protocols for the non-imposed (category 3) Post Authorisation Safety Study (PASS) - version 6.0 (A3921312), and version 6.0 (A3921316) for Tofacitinib (Xeljanz).

- A3921312: UK, British Society for Rheumatology Biologics Register-Rheumatoid Arthritis (BSRBR-RA)
- A3921316: Spain (ES), Registry of Adverse Events of Biological Therapies and Biosimilars in Rheumatoid Diseases (BIOBADASER)

Action: For adoption

7.3. Results of PASS imposed in the marketing authorisation(s)[7]

7.3.1. Eliglustat – CERDELGA (CAP) – EMA/PASS/0000287682

Applicant: Sanofi B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: PASS results [107q]: A prospective multicenter observational post-authorization safety sub-registry study (PASS) to characterize the long-term safety profile of commercial use of eliglustat (Cerdelga) in adult patients with Gaucher disease.

Action: For adoption

7.4. Results of PASS non-imposed in the marketing authorisation(s)[8]

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

Applicant: 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

7.4.2. Levofloxacin – QUINSAIR (CAP) – EMA/VR/0000310972

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Maria del Pilar Rayon

[7] In accordance with Article 107p-q of Directive 2001/83/EC
[8] 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

Scope: Submission of the amended final report for study CLI-LEVFLAA1-01. This is a post-marketing, observational safety study of Quinsair (levofloxacin hemihydrate) in patients with cystic fibrosis.

Action: For adoption

7.4.3. Linaclotide – CONSTELLA (CAP) – EMA/VR/0000281586

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Martin Huber

Scope: Submission of the final report from study EVM-18888 (P21-481) listed as a category 3 study in the RMP. The study, titled "Linaclotide Safety Study for the Assessment of Diarrhoea Complications and Associated Risk Factors in Selected European Populations with IBS-C," is an observational safety study. It assesses the risk of severe complications of diarrhoea (SCD) during treatment with linaclotide, as well as other risk factors among patients with IBS-C in the UK, Sweden, and Spain. The RMP version 11.2 has also been submitted.

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 PRegnancy outcomes Intensive Monitoring (PRIM) study.

Action: For adoption

7.4.5. Tocilizumab – ROACTEMRA (CAP) – EMA/VR/0000261482

Applicant: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of the final report for study ML28664 (RABBIT), listed as a category 3 study in the RMP. This was a non-interventional post-authorisation safety study aimed at collecting and analysing safety data related to the use of tocilizumab in rheumatoid arthritis patients in Germany. The RMP version 30.0 has also been submitted. In addition, the MAH removed the education materials from the RMP and PI as agreed by PRAC during procedure PSUSA/00002980/202204. Furthermore, the MAH took the opportunity to introduce editorial and formatting changes to the PI and to align the wording used for the pre-filled syringe and the pre-filled pen, as well as to update the list of local representatives in the Package Leaflet.

Action: For adoption

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

7.5.1. Axicabtagene ciloleucel – YESCARTA (CAP) – EMA/PAM/0000316955

Applicant: Kite Pharma EU B.V. ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Fifth annual safety Report for the non-interventional post authorisation safety study (PASS) for Yescarta: Study KT-EU-471-0117

Action: For adoption

7.5.2. Drospirenone / Estetrol – DROVELIS (CAP) – EMA/PAM/0000281181

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Martin Huber

Scope: Second interim study report with cut-off date of 21 April 2025 of PASS study titled "International Active Surveillance Study: Native Estrogen Estetrol (E4) Safety Study (INAS-NEES)"

Action: For adoption

7.5.3. Drospirenone / Estetrol – LYDISILKA (CAP) – EMA/PAM/0000281178

Applicant: Estetra

PRAC Rapporteur: Martin Huber

Scope: Second interim study report with cut-off date of 21 April 2025 of PASS study titled "International Active Surveillance Study: Native Estrogen Estetrol (E4) Safety Study (INAS-NEES)"

Action: For adoption

7.5.4. Exagamglogene autotemcel – CASGEVY (CAP) – EMA/PAM/0000316999

Applicant: Vertex Pharmaceuticals (Ireland) Limited, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: PASS Study (VX22-290-101) Annual Progress Report for Casgevy (exagamglogene autotemcel) covering the reporting period January to October 2025.

Action: For adoption

7.5.5. Galcanezumab – EMGALITY (CAP) – EMA/PAM/0000314992

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: Study Progress Reports for non-interventional studies I5Q-MC-B001, I5Q-MC-B002 and I5Q-MC-B003

Action: For adoption

7.5.6. Inotersen – TEGSEDI (CAP) – EMA/PAM/0000314977

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: TEG 005 = Pregnancy Surveillance Programme - covering the period from 17 Oct 2019 to 16 Oct 2025. Interim report.

Action: For adoption

7.5.7. Interferon beta-1a – AVONEX (CAP) – EMA/PAM/0000315762

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the Study Report for joint PASS INFORM - Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden.

Action: For adoption

7.5.8. Interferon beta-1b – BETAFERON (CAP) – EMA/PAM/0000309054

Applicant: Bayer AG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the Study Report for joint PASS INFORM - Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden.

Action: For adoption

7.5.9. Interferon beta-1a – REBIF (CAP) – EMA/PAM/0000315764

Applicant: Merck Europe B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the Study Report for joint PASS INFORM - Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden.

Action: For adoption

7.5.10. Ivosidenib – TIBSOVO (CAP) – EMA/PAM/0000316636

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Responses to PRAC List of Requests issued for the Post-Authorisation Measure (MEA 003.1) MEA/01297/1

PASS - IMPACTA - EUPAS1000000190

Patients survey study to assess the effectiveness of the additional risk minimisation measures.

Cross-sectional study to assess the effectiveness of the patients' alert card to inform on risk of differentiation syndrome in AML patients treated with TIBSOVO (Ivosidenib).

Action: For adoption

7.5.11. Peginterferon beta-1a – PLEGRIDY (CAP) – EMA/PAM/0000315767

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the Study Report for joint PASS INFORM - Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden.

Action: For adoption

7.5.12. Rimegepant – VYDURA (CAP) – EMA/PAM/0000314939

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Erneholm

Scope: The second progress report (MEA003) for the study entitled Post-Authorisation Safety Study of Rimegepant in Patients with Migraine and History of Cardiovascular Disease in European Countries.

Action: For adoption

7.5.13. Somapacitan – SOGROYA (CAP) – EMA/PAM/0000314915

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Martin Huber

Scope: Fifth study progress report with the data cut-off date of 31 Aug 2025 for PASS NN8640-4515: a multi-national, multi-centre, prospective, single-arm, observational, non-interventional post-authorisation safety study to investigate long-term safety of Sogroya® (somapacitan) in adults with growth hormone deficiency (AGHD) under routine clinical practice.

Action: For adoption

7.5.14. Somapacitan – SOGROYA (CAP) – EMA/PAM/0000316564

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Martin Huber

Scope: 1st interim report for PASS NN8640-4787 (REAL 10): a non-interventional, observational, register-based study to investigate long-term safety and clinical parameters of somapacitan treatment in paediatric patients with GHD in the setting of routine clinical practice.

Action: For adoption

7.5.15. Turoctocog alfa pegol – ESPEROCT (CAP) – EMA/PAM/0000314924

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Dirk Mentzer

Scope: 5th PASS progress report for Study NN7088-4029: A multinational, prospective, open labelled, non-controlled, non interventional post-authorisation study of turoctocog alfa pegol (N8-GP) during long-term routine prophylaxis and treatment of bleeding episodes in patients with haemophilia A.

Action: For adoption

7.5.16. Ustekinumab – STELARA (CAP) – EMA/PAM/0000316549

Applicant: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Third interim study report - An observational post authorization safety study to describe the safety of ustekinumab and other treatments of ulcerative colitis in a cohort of patients with ulcerative colitis using the independent French Nationwide Claims Database (SNDS; PCSIMM002659); former MEA 0048

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. Cholic acid – ORPHACOL (CAP) – EMA/S/0000310692

Applicant: Theravia

PRAC Rapporteur: Maria Poulianiti

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.2. Fosdenopterin – NULIBRY (CAP) – EMA/S/0000312759

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Martin Huber

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. Idebenone – RAXONE (CAP) – EMA/S/0000310527

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Amelia Cupelli

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

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

Applicant: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Terhi Lehtinen

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

8.2.1. Linvoseltamab – LYNOZYFIC (CAP) – EMA/R/0000306825

Applicant: Regeneron Ireland Designated Activity Company

PRAC Rapporteur: Veronika Macurova

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.2. Mosunetuzumab – LUNSUMIO (CAP) – EMA/R/0000314743

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.3. Selumetinib – KOSELUGO (CAP) – EMA/R/0000316378

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.4. Zanidatamab – ZIIHERA (CAP) – EMA/R/0000316461

Applicant: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Abiraterone acetate – ABIRATERONE MYLAN (CAP) – EMA/R/0000312706

Applicant: Mylan Pharmaceuticals Limited

PRAC Rapporteur: Maria del Pilar Rayon

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

Applicant: Fondazione Telethon Ets

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.3. Bimekizumab – BIMZELX (CAP) – EMA/R/0000304244

Applicant: UCB Pharma

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.4. Icatibant – ICATIBANT ACCORD (CAP) – EMA/R/0000300686

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Ranibizumab – BYOOVIZ (CAP) – EMA/R/0000312514

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. Setmelanotide – IMCIVREE (CAP) – EMA/R/0000302063

Applicant: Rhythm Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Miroslava Gocova

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

None

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. PRAC membership

Action: For information

12.1.2. Vote by proxy

Action: For information

12.1.3. PRAC working group - Best practice guide on using PRAC plenary time efficiently and effectively – update on the implementation of quantitative goals – Q4 2025

Action: For discussion

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 – new appointment of PRAC representative(s)

Action: For adoption

12.4. Cooperation within the EU regulatory network

None

12.5. Cooperation with International Regulators

12.5.1. International Conference on Harmonisation (ICH) E2D(R1) - Guideline

Action: For adoption

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. EU Pharmacovigilance system - annual workload measures and performance indicators – 2025

Action: For discussion

12.8.2. PRAC workload statistics – Q4 2025

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)

None

12.10.3. PSURs repository

None

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

Action: For adoption

12.10.1. Good Pharmacovigilance Practice (GVP) Module VIII - update

PRAC lead: Maria del Pilar Rayon, Patricia McGettigan

Action: For adoption

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

12.13.2. Changes to EudraVigilance

Action: For adoption

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

None

12.21. Others

12.21.1. DARWIN EU® study on the utilisation of commonly used benzodiazepines during pregnancy and the incidence of pregnancy losses - PRAC Sponsor's critical appraisal of feasibility assessment

PRAC lead: Tiphaine Vaillant

Action: For discussion

12.21.2. Scientific Explorer – update

Action: For discussion

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)