24 October 2025
EMA/PRAC/316561/2025 Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 27 - 30 October 2025

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

27 October 2025, 09:30 – 19:30, via teleconference

28 October 2025, 08:30 – 19:30, via teleconference

29 October 2025, 08:30 – 19:30, via teleconference

30 October 2025, 08:30 – 16:00, via teleconference

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 27 - 30 October 2025. See November month 2025 PRAC minutes (to be published post December 2025 PRAC meeting).

1.2. Agenda of the meeting on 27 - 30 October 2025

Action: For adoption

1.3. Minutes of the previous meeting on 29 September – 2 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

None

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. Nemolizumab – NEMLUVIO (CAP)

Applicant: Galderma International

PRAC Rapporteur: Liana Martirosyan

Scope: Signal of erythema multiforme

Action: For adoption

EPITT 20207 – New signal

Lead Member State(s): NL

4.1.2. Selumetinib – KOSELUGO (CAP)

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Signal of photosensitivity reaction

Action: For adoption

EPITT 20208 – New signal

Lead Member State(s): SE

[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

4.2. Signals follow-up and prioritisation

4.2.1. Adalimumab – AMGEVITA (CAP); AMSPARITY (CAP); HEFIYA (CAP); HUMIRA (CAP) - EMEA/H/C/000481/SDA/128; HUKYNDRA (CAP); HULIO(CAP); HYRIMOZ (CAP); IDACIO (CAP); IMRALDI (CAP); LIBMYRIS (CAP); YUFLYMA (CAP)

Applicant: AbbVie Deutschland GmbH & Co. KG (Humira), Amgen Europe B.V. (Amgevita), Biosimilar Collaborations Ireland (Hulio), Celltrion Healthcare Hungary Kft. (Yuflyma), Fresenius Kabi Deutschland GmbH (Idacio), Pfizer Europe MA EEIG (Amsparity), Samsung Bioepis NL B.V. (Imraldi), Sandoz GmbH (Hefiya, Hyrimoz), STADA Arzneimittel AG (Hukyndra, Libmyris)

PRAC Rapporteur: Karin Bolin

Scope: Signal of morphoea

Action: For adoption

EPITT 20166 – Follow-up to May 2025

4.2.2. Bosutinib - BOSULIF (CAP) - EMEA/H/C/002373/SDA/018; NAP

Applicant: Pfizer Europe MA EEIG, various

PRAC Rapporteur: Martin Huber

Scope: Signal of cutaneous vasculitis

Action: For adoption

EPITT 20184 – Follow-up to July 2025

4.2.3. Datopotamab deruxtecan - DATROWAY (CAP) - EMEA/H/C/006547/SDA/002

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Mari Thorn

Scope: Signal of anaphylactic reaction

Action: For adoption

EPITT 20181 – Follow-up to July 2025

4.2.4. Epcoritamab - TEPKINLY (CAP) - EMEA/H/C/005985/SDA/005

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Signal of hypogammaglobulinaemia

Action: For adoption

EPITT 20174 – Follow-up to June 2025

4.2.5. Sulfasalazine (NAP)

Applicant(s): various

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Signal of idiopathic intracranial hypertension (Pseudotumor cerebri)

Action: For adoption

EPITT 20188 – Follow-up to July 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. Acellular pertussis vaccine - (CAP MAA) - EMEA/H/C/006304

Scope (pre D-210 phase): Indicated for booster immunisation against pertussis of individuals 12 years of age and older, passive protection against pertussis in early infancy following maternal immunisation during pregnancy

Action: For adoption

5.1.2. Estetrol - (CAP MAA) - EMEA/H/C/006213

Scope (pre D-180 phase): Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women

Action: For adoption

5.1.3. Iloperidone - (CAP MAA) - EMEA/H/C/006561

Scope (pre D-210 phase): Treatment of schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder

Action: For adoption

5.1.4. Semaglutide - (CAP MAA) - EMEA/H/C/006426

Scope (pre D-180 phase): Treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis with liver fibrosis

Action: For adoption

5.1.5. Teriparatide - (CAP MAA) - EMEA/H/C/006688

Scope (pre D-180 phase): Treatment of osteoporosis

Action: For adoption

5.1.6. Trivalent influenza vaccine (recombinant, prepared in cell culture) - (CAP MAA) - EMEA/H/C/006674

Scope (pre D-180 phase): Immunisation for the prevention of influenza disease

Action: For adoption

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

5.2.1. Aripiprazole – ARIPIPRAZOLE SANDOZ (CAP); NAP – EMA/VR/0000272677

Applicants: Sandoz GmbH, various

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: To update the RMP in line with the reference product of Aripiprazole Sandoz. In addition, the MAH has taken the opportunity to include the 20 mg tablets to the RMP in line with the approved SmPC and to reflect the change in MAH.

Action: For adoption

5.2.2. Ceftazidime / Avibactam – ZAVICEFTA (CAP) – EMA/VR/0000287802

Applicant: Pfizer Ireland Pharmaceuticals Unlimited Company

PRAC Rapporteur: Rugile Pilviniene

Scope: Submission of an updated RMP version 3.4 in order to propose the reclassification of the following safety concerns: Removal of 'Bacterial resistance development' as an Important potential risk and the removal of Missing Information 'Pregnancy exposure', 'Lactation exposure', and 'Immunocompromised population exposure.'

Action: For adoption

5.2.3. Denosumab – PROLIA (CAP) – EMA/VR/0000288149

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Mari Thorn

Scope: Submission of an updated RMP version 33.0 in order to remove and reclassify important identified risks, potential risks, and to remove completed category 3 Study 20090522. Update in RMP of the information about Patient reminder cards for osteonecrosis of the jaw have been reflected in Annex II of the PI.

Action: For adoption

5.2.4. Emtricitabine / Tenofovir disoproxil – TRUVADA (CAP) – EMA/VR/0000280828

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: A grouped application consisting of:

C.I.11: Submission of an updated RMP version 19.1 in order to remove targeted questionnaires (related to tenofovir disoproxil fumarate) concerning (1) Renal events including tubulopathy, and (2) Bone events due to proximal renal tubulopathy/loss of bone mineral density.

C.I.11: Submission of an updated RMP version 19.1 in order to remove missing information concerning Safety in pregnancy and lactation (related to tenofovir disoproxil fumarate), and consequently remove ‘Antiretroviral Pregnancy Registry’ listed as a Category 3 Additional Pharmacovigilance Activity.

Action: For adoption

5.2.5. Ipilimumab - YERVOY (CAP); nivolumab – OPDIVO (CAP) – EMA/VR/0000285155

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Bianca Mulder

Scope: To extend the due date related to the PAES study CA2098Y8, listed in the Product Information (PI) Annex II and in the RMP from 26.02.2026 to 28.02.2027.

Action: For adoption

5.2.6. Leflunomide – ARAVA (CAP) – EMA/VR/0000264105

Applicant: Sanofi-Aventis Deutschland GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of an updated RMP version 6.0 in order to address query raised by PRAC EMEA/H/C/PSUSA/00001837/202309 on the effectiveness and usefulness of the additional risk minimization measures (aRMMs) specifically related to the safety concerns hepatic reactions, blood cytopenia, and infections.

Action: For adoption

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

Applicant: 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

5.2.8. Ocrelizumab – OCREVUS (CAP) – EMA/VR/0000291534

Applicant: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of an updated RMP version 13.0 in order to add non-infectious colitis as an important potential risk along with an additional pharmacovigilance activity in the form of a voluntary Category 3 non-interventional post-authorization study to further characterize this risk.

Action: For adoption

5.2.9. Tenofovir disoproxil – VIREAD (CAP) – EMA/VR/0000280825

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Zoubida Amimour

Scope: Submission of an updated RMP version 26.2 in order to remove missing information concerning Safety in pregnancy and lactation, to remove 'Antiretroviral Pregnancy Registry' listed as a Category 3 Additional Pharmacovigilance Activity, and to implement PRAC agreed changes during procedure EMEA/H/C/PSUSA/00002892/202303 in relation to safety concerns associated with renal and bone adverse events.

Action: For adoption

5.2.10. Valoctocogene roxaparvovec – ROCTAVIAN (CAP) – EMA/VR/0000294531

Applicant: Biomarin International Limited

PRAC Rapporteur: Bianca Mulder

Scope: Submission of an updated RMP version 1.6 in order to remove the Biodistribution study investigating vertical transmission of the AAV5 vector in female mice listed as category 3 study in RMP.

Action: For adoption

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

5.3.1. 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

5.3.2. Bempedoic acid – NILEMDO (CAP); bempedoic acid / ezetimibe - NUSTENDI (CAP) – EMA/VR/0000284929

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Kimmo Jaakkola

Scope: Update of section 4.6 of the SmPC in order to update information on breast-feeding and lactation, based on final results from study 1002FDC-075. This is an open-label, phase 4, postmarketing milk-only lactation study to evaluate the concentration of bempedoic acid and bempedoic acid and ezetimibe in the breast milk of healthy lactating women administered therapeutic doses of bempedoic acid or bempedoic acid/ezetimibe fixed combination drug product (FCDP). The Package Leaflet is updated accordingly. The updated RMP version 8.1 has also been submitted.

Action: For adoption

5.3.3. 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

5.3.4. Darunavir / Cobicistat / Emtricitabine / Tenofovir alafenamide – SYMTUZA (CAP) – EMA/X/0000248421

Applicant: Janssen Cilag International

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension application to add a new strength of 675 mg/150 mg/20mg/10 mg film-coated tablets grouped with an Extension of indication (C.I.6) to include treatment of human immunodeficiency virus type 1 (HIV 1) infection in paediatric patients (aged 6 years and older with body weight at least 25 kg) for SYMTUZA, based on the 24-week interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicenter, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1, 6.3, 6.4, 6.5 and 8 of the SmPC are updated. The Annex II, Labelling and Package Leaflet are updated accordingly. Version 9.1 of the RMP has also been submitted. Furthermore, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.5. Dupilumab – DUPIXENT (CAP) – EMA/VR/0000248778

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of adults with bullous pemphigoid (BP) for DUPIXENT, based on final results from study R668-BP-1902 (LIBERTY-BP ADEPT); this is a phase 2/3, multicenter, randomized, double blind, placebo-controlled, parallel group study to assess the efficacy and safety of dupilumab in adult patients with bullous pemphigoid; 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 12.0 of the RMP has also been submitted.

Action: For adoption

5.3.6. Durvalumab – IMFINZI (CAP) – EMA/VR/0000289524

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Extension of indication for IMFINZI in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adults with BCG-naive, high-risk non-muscle-invasive bladder cancer (NMIBC), based on results from the POTOMAC study. POTOMAC is a phase 3, randomized multi-centre, open-label, global study to determine the efficacy and safety of durvalumab + BCG (induction + maintenance) combination therapy vs BCG (induction + maintenance) alone, and durvalumab + BCG (induction only) combination therapy vs BCG (induction + maintenance) alone for the treatment of patients with high-risk NMIBC. 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 with the SmPC. In addition, the Applicant took the

opportunity to implement editorial changes to SmPC sections 4.2 and 5.1. Version 15 (Succession 1) of the RMP has also been submitted.

Action: For adoption

5.3.7. Efgartigimod alfa – VYVGART (CAP) – EMA/VR/0000291882

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Quality

Action: For adoption

5.3.8. Eltrombopag – REVOLADE (CAP) – EMA/VR/0000288153

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study CETB115E2201, listed as a category 3 study in the RMP. This is a paediatric phase II, open-label, uncontrolled, intra-patient dose escalation study to characterise the pharmacokinetics after oral administration of eltrombopag in paediatric patients with refractory, relapsed severe aplastic anaemia or recurrent aplastic anemia. The RMP version 57.0 has also been submitted.

Action: For adoption

5.3.9. Epinephrine – EURNEFFY (CAP) – EMA/X/0000248440

Applicant: Alk-Abello A/S

PRAC Rapporteur: Terhi Lehtinen

Scope: Extension application to introduce a new strength (1 mg nasal spray, solution). The new strength is indicated for children with a body weight of 15 kg to less than 30 kg.

Action: For adoption

5.3.10. Finerenone – KERENDIA (CAP) – EMA/X/0000248026

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Extension application to introduce a new strength 40 mg for film-coated tablets grouped with a type II variations C.I.6: Extension of indication to include the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in adults for KERENDIA, based on final results from the phase 3 study FINEARTS-HF (20103); this is a randomized, double-blind, placebo-controlled phase 3 study evaluating the efficacy and safety of finerenone on morbidity and mortality in participants with symptomatic heart failure with left ventricular ejection fraction (LVEF) ≥40%.; Type II variation C.I.13: Submission of the final report from non-clinical study T105281-7, R-14405 - Juvenile toxicology study in rats; Type IB variation C.I.z: Minor correction of numbers in the currently approved SmPC due to a previously communicated GCP violation affecting the FIDELIO-DKD and FIGARO-DKD trials.

As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.1, 6.6 and 8 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and administrative changes to the PI and to bring it in line with the latest QRD template version 10.4.

Action: For adoption

5.3.11. Ganaxolone - ZTALMY (CAP) - EMEA/H/C/005825/II/0015/G, Orphan

Applicant: Immedica Pharma AB

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application consisting of five Type II variations, as follows:

C.I.13: Submission of the final report from non-clinical study 1022-9241 listed as a category 3 study in the RMP. This is a 26-Week Toxicity Study of Ganaxolone Metabolite, M2, by Oral Gavage in the Sprague-Dawley rat with a 2-Week Recovery Period. The RMP version 3 has also been submitted.

C.I.13: Submission of the final report from non-clinical study 20447815 listed as a category 3 study in the RMP. This is a An Oral (Gavage) Study of the Effects of M2 (Ganaxolone Metabolite) Administration on Embryo/Fetal Development in CD (Sprague Dawley) IGS Rat. The RMP version 3 has also been submitted.

C.I.13: Submission of the final report from Weight of Evidence (WoE) assessment to evaluate the need for a 2-year carcinogenicity study in rats with GNX, listed as a category 3 study in the RMP.

C.I.13: Submission of the final report from WoE assessment to evaluate the need for a 2-year carcinogenicity study in rats with M2, listed as a category 3 study in the RMP.

C.I.13: Submission of the final report from WoE assessment to evaluate the need for a juvenile toxicity study with M2, listed as a category 3 study in the RMP.

Action: For adoption

5.3.12. Ganaxolone – ZTALMY (CAP) – EMA/VR/0000263646

Applicant: Immedica Pharma AB

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application consisting of:

C.I.4: Update of section 5.3 of the SmPC in order to update non-clinical information based on final results from a transgenic mouse carcinogenicity study listed as a category 3 study in the RMP; this is a 26-week Oral Gavage Carcinogenicity Study of Ganaxolone in Hemizygous CByB6F1-Tg(HRAS)2Jic Mice; The RMP version 3.2 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

C.I.4: Update of section 5.3 of the SmPC in order to update non-clinical information based on final results from non-clinical study for juvenile toxicity in M2 (metabolite) listed as a category 3 study in the RMP; this is an Oral (Gavage) administration juvenile toxicity study of M2 (Ganaxolone Metabolite) in CD (Sprague Dawley) IGS Rats.

Action: For adoption

5.3.13. Hydrocortisone – EFMODY (CAP) – EMA/VR/0000282500

Applicant: Neurocrine Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of adrenal insufficiency (AI) in adolescents aged 12 years and over and adults for Efmody, based on final results from study DIUR-016-AI; this is a double-blind, double-dummy, two-way cross-over, randomised, phase II study of efficacy, safety and tolerability of modified-release hydrocortisones: Chronocort (Efmody) versus Plenadren, in AI. Consequently, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, e-mail of MAH was updated. Version 2.0 of the RMP has also been submitted.

Action: For adoption

5.3.14. Idecabtagene vicleucel – ABECMA (CAP) – EMA/VR/0000293201

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Mari Thorn

Scope: Update of sections 4.2, 4.4, and 4.7 of the SmPC in order to change the post-approval safety monitoring requirements after administration of Abecma; Annex II and the Package Leaflet are updated accordingly. The RMP version 5.0 has also been submitted.

Action: For adoption

5.3.15. Imipenem / Cilastatin / Relebactam – RECARBRIO (CAP) – EMA/VR/0000265089

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to extend the approved adult indications for RECARBRIO to include treatment of paediatric population from birth to <18 years of age, based on final results from two paediatric studies (MK-7655A-021 and MK-7655A-020); phase 2/3 study MK-7655A-021 addressed safety, tolerability, efficacy and PK, and phase 1b study MK-7655A-020 addressed PK, safety, and tolerability of MK-7655A in paediatric subjects from birth to less than 18 years of age with confirmed or suspected gram-negative infections. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 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 implement minor editorial corrections.

Action: For adoption

5.3.16. Isatuximab – SARCLISA (CAP) – EMA/X/0000281242

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (1400 mg) and a new route of administration (subcutaneous use). The RMP (version 3.0) is updated in accordance.

Action: For adoption

5.3.17. 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

5.3.18. Lutetium (^{177}Lu) vipivotide tetraxetan – PLUVICTO (CAP) – EMA/VR/0000288073

Applicant: Novartis Europharm Limited

PRAC Rapporteur: John Joseph Borg

Scope: Extension of indication to include treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after having progressed on androgen receptor pathway inhibitor (ARPI) and for whom chemotherapy is not yet clinically indicated for PLUVICTO, based on interim results from study CAAA617B12302 (PSMAfore); this is a phase III, open-label, multi-center, randomized study comparing 177Lu-PSMA-617 vs. a change of androgen receptor-directed therapy in the treatment of taxane naïve men with progressive metastatic castrate resistant prostate 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 3.0 of the RMP has also been submitted to include clinical data from the PSMAfore study to support the addition of the new therapeutic indication.

Action: For adoption

5.3.19. Mavacamten – CAMZYOS (CAP) – EMA/VR/0000294573

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: A grouped application consisting of:

C.I.4: Update of section 4.2 of the SmPC in order to remove the Week 8 echocardiography monitoring and associated down-titration opportunity based on the modelling and simulation analyses along with safety data from two studies conducted in Japan (HORIZON-HCM; CV027004) and China (EXPLORER-CN; CV0271097/LB2001301). The updated RMP version 7.0 has also been submitted.

C.I.4: Update of sections 4.2, and 4.5 of the SmPC in order modify maximum dose requirement from 5 mg to 15 mg for CYP2C19 poor metabolisers (PM), in alignment with the requirement for non-PM based on the modelling and simulation analyses along with safety data from two studies conducted in Japan (HORIZON-HCM; CV027004) and China (EXPLORER-CN; CV0271097/LB2001301). The updated RMP version 7.0 has also been submitted.

Action: For adoption

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

Applicant: 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

5.3.21. Nusinersen - SPINRAZA (CAP) - EMEA/H/C/004312/X/0038, Orphan

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Karin Bolin

Scope: Extension application to add a new strength of 28 mg and 50 mg.
The RMP (version 12.x) is updated in accordance (version 12.2 is under assessment in procedure EMEA/H/C/004312/II/0034/G).

Action: For adoption

5.3.22. Osilodrostat – ISTURISA (CAP) – EMA/VR/0000290393

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the final report from study CLCI699C2X01B listed as a category 3 study in the RMP. This is a Phase IIb, Open-label, Multi-centre, Roll-over Study to Assess Long Term Safety in Patients with Endogenous Cushing's Syndrome who have Completed a Prior Novartis-sponsored Osilodrostat (LCI699) Study and are Judged by the Investigator to

Benefit from Continued Treatment with Osilodrostat. The RMP version 3.1 has also been submitted.

Action: For adoption

5.3.23. Ozanimod – ZEPOSIA (CAP) – EMA/VR/0000291324

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Update of section 5.1 of the SmPC in order to update efficacy and safety information based on the final results from study RPC01-3102, listed as a category 3 study in RMP. This is a Phase 3, multicenter, open-label extension trial of oral RPC1063 as therapy for moderate to severe ulcerative colitis. The RMP version 11.0 has also been submitted.

Action: For adoption

5.3.24. Ponatinib – ICLUSIG (CAP) – EMA/VR/0000263550

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of adult patients with newly-diagnosed Ph+ ALL for ICLUSIG, based on interim results from study Ponatinib-3001 (PhALLCON); this is a phase 3, randomized, open-label, multicenter study comparing ponatinib versus imatinib, administered in combination with reduced intensity chemotherapy, in patients with newly diagnosed Ph+ ALL; supportive data were derived from two single-arm, open-label clinical studies (AP24534 11 001 in combination with chemotherapy and INCB 84344-201 as monotherapy). 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 23.2 of the RMP has also been submitted. In addition, earlier approved updates were incorporated to the PI.

Action: For adoption

5.3.25. Selinexor – NEXPOVIO (CAP) – EMA/VR/0000291736

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Bianca Mulder

Scope: A grouped application consisting of:

C.I.4: Update of sections 4.2, and 5.2 of the SmPC in order to include the recommended dose adjustment strategy in patients with severe hepatic impairment, and update pharmacokinetic, information based on interim results from study KCP-330-027; this is an open-label, phase 1/2, interventional study assessing the effect of hepatic impairment on selinexor pharmacokinetics; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI.

C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information with strong CYP3A4 and UGT inducer carbamazepine based on final results from study XPORT-HV-045; this is a phase 1 drug-drug interaction study in healthy volunteers to evaluate the effect of carbamazepine (a strong CYP3A4 inducer) on the pharmacokinetics of selinexor.

Action: For adoption

5.3.26. Serplulimab – HETRONIFLY (CAP) – EMA/VR/0000291455

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

Scope: Update of sections 4.4 and 4.8 of SmPC in order to include myasthenia gravis and myasthenic syndrome as part of the warning section and to add them to the list of adverse drug reactions (ADRs) with frequency not known, based on a signal assessment report. The Package Leaflet is updated accordingly. The updated RMP version 1.4 has also been submitted.

Action: For adoption

5.3.27. Serplulimab – HETRONIFLY (CAP) – EMA/VR/0000290021

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include HETRONIFLY in combination with carboplatin and nab-paclitaxel is indicated for the first-line treatment of adult patients with unresectable, locally advanced or metastatic squamous non-small cell lung carcinoma based on final results from study HLX10-004-NSCLC303; this is a randomized, double-blind, multi-center, phase III pivotal study, was conducted to compare the clinical efficacy and safety of serplulimab combined with chemotherapy (carboplatin and nab-paclitaxel) versus placebo combined with chemotherapy (carboplatin and nab-paclitaxel). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP Version 1.3 has been submitted.

Action: For adoption

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

Applicant: Rhythm Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Anna Mareková

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

5.3.29. Tasimelteon - HETLIOZ (CAP) - EMEA/H/C/003870/II/0040, Orphan

Applicant: Vanda Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include the treatment of nighttime sleep disturbances in adults with Smith Magenis Syndrome (SMS) for HETLIOZ, based on results from study VP-VEC-162-2401. This is a double-blind, randomized, two-period crossover study evaluating the effects of tasimelteon vs. placebo on sleep disturbances of individuals with Smith-Magenis Syndrome (SMS). As a consequence, sections 4.1, 4.5, 5.1, 5.2 and 5.3 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. The RMP version 5.0 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

5.3.30. Tasimelteon - HETLIOZ (CAP) - EMEA/H/C/003870/X/0039, Orphan

Applicant: Vanda Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to introduce a new pharmaceutical form associated with new

strength (4 mg/ml oral solution). The new formulation is indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in paediatric patients 3 to 15 years of age. The RMP (version 5.0) is updated in accordance.

Action: For adoption

5.3.31. Tedizolid phosphate – SIVEXTRO (CAP) – EMA/X/0000282136

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension application to introduce a new pharmaceutical form (powder for oral suspension, 200 mg). The RMP (version 8.1) is updated in accordance. Additionally, the marketing authorisation holder took the opportunity to align the PI with the latest QRD template.

Action: For adoption

5.3.32. Tirzepatide - MOUNJARO (CAP) - EMEA/H/C/005620/II/0038

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of symptomatic chronic heart failure with preserved ejection fraction (HFpEF) in adults with obesity for MOUNJARO, based on results from the Phase 3 trial I8F-MC-GPID (SUMMIT). SUMMIT was a randomized, multicenter, international, placebo-controlled, double-blind, parallel-arm study in participants with HFpEF and obesity. The study was designed to evaluate the effect of tirzepatide compared with placebo on both clinical and symptomatic or functional outcomes. As a consequence, sections 4.1, 4.8, and 5.1 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

5.3.33. Tucatinib – TUKYSA (CAP) – EMA/VR/0000280202

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Submission of the final report from study SGNTUC-016 listed as a category 3 study in the RMP. This is a randomized, double blind, phase 3 study of Tucatinib or Placebo in combination with Ado-Trastuzumab Emtansine (T-DM1) for subjects with unresectable locally advanced or metastatic HER2+ Breast Cancer. Primary objective is to compare progression-

free survival (PFS) by investigator per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 between treatment arms. The RMP version 2.0 has also been submitted.

Action: For adoption

5.3.34. Ustekinumab – STEQEYMA (CAP) – EMA/VR/0000292238

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Quality

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Action: For adoption

5.3.35. Ustekinumab – QOYVOLMA (CAP) – EMA/VR/0000292065

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Quality

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Action: For adoption

5.3.36. Ustekinumab – YESINTEK (CAP) – EMA/VR/0000290373

Applicant: Biosimilar Collaborations Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Quality

Action: For adoption

5.3.37. Ustekinumab – STELARA (CAP) – EMA/VR/0000290099

Applicant: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of moderately to severely active Crohn's disease in paediatric patients from the age of 2 years and older, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy, for STELARA, based on final results from the Phase 3 open-label CNTO1275CRD3004 study and the supportive results from the Phase 1 PK CNTO1275CRD1001 study. Study CNTO1275CRD3004 is a Phase 3 study of the efficacy, safety, and pharmacokinetics of ustekinumab as open-label intravenous induction treatment followed by randomized double-blind subcutaneous ustekinumab maintenance in pediatric participants 2 to <18 years of age with moderately to severely active Crohn's disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are being updated. The Package Leaflet is updated accordingly. The RMP version 32.1 has also been submitted. In addition, the MAH took the opportunity to introduce editorial, formatting and administrative changes to the PI, bringing it in line with the latest QRD template. In addition, the MAH updated the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.38. Vonicog alfa – VEYVONDI (CAP) – EMA/VR/0000264863

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of haemorrhage in children aged less than 18 years for VEYVONDI, based on results from studies 071102 and SHP677-304. Study 071102 is a phase 3, prospective, multicenter, uncontrolled, open-label clinical study to determine the efficacy, safety, and tolerability of the recombinant von Willebrand factor (rVWF) with or without ADVATE (octocog alfa) in the treatment and control of bleeding episodes, the efficacy and safety of rVWF in elective and emergency surgeries, and the pharmacokinetics (PK) of rVWF in children diagnosed with severe von Willebrand disease (VWD); study SHP677-304 is a phase 3B, prospective, open-label, uncontrolled, multicenter study on long term safety and efficacy of vonicog alfa in pediatric and adult subjects with severe VWD. 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 accordingly. Version 6.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI.

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. Apremilast – OTEZLA (CAP) – EMA/PSUR/0000282235

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00010338/202503)

Action: For adoption

6.1.2. Atogepant – AQUIPTA (CAP) – EMA/PSUR/0000282279

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00000100/202503)

Action: For adoption

6.1.3. Avacopan – TAVNEOS (CAP) – EMA/PSUR/0000282275

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010967/202503)

Action: For adoption

6.1.4. Cangrelor – KENGREXAL (CAP) – EMA/PSUR/0000282280

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010360/202503)

Action: For adoption

6.1.5. Cinacalcet – MIMPARA (CAP) – EMA/PSUR/0000282225

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00000756/202502)

Action: For adoption

6.1.6. Concizumab – ALHEMO (CAP) – EMA/PSUR/0000282246

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011105/202503)

Action: For adoption

6.1.7. COVID-19 vaccine (recombinant, adjuvanted) – BIMERVAX (CAP) – EMA/PSUR/0000282290

Applicant: Hipra Human Health S.L.

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00011045/202503)

Action: For adoption

6.1.8. Dimethyl fumarate – TECFIDERA (CAP); diroximel fumarate - VUMERITY (CAP) – EMA/PSUR/0000282247

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010143/202503)

Action: For adoption

6.1.9. Dimethyl fumarate – SKILARENCE (CAP) – EMA/PSUR/0000282230

Applicant: Almirall S.A.

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010647/202503)

Action: For adoption

6.1.10. Dupilumab – DUPIXENT (CAP) – EMA/PSUR/0000282220

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010645/202503)

Action: For adoption

6.1.11. Duvelisib – COPIKTRA (CAP) – EMA/PSUR/0000282286

Applicant: Secura Bio Limited

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010939/202503)

Action: For adoption

6.1.12. Enalapril maleate – AQUMELDI (CAP) – EMA/PSUR/0000282217

Applicant: Proveca Pharma Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00000201/202503)

Action: For adoption

6.1.13. Epcoritamab – TEPKINLY (CAP) – EMA/PSUR/0000282231

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00000107/202503)

Action: For adoption

6.1.14. Erdafitinib – BALVERSA (CAP) – EMA/PSUR/0000282264

Applicant: Janssen Cilag International

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011072/202504)

Action: For adoption

6.1.15. Etrasimod – VELSIPITY (CAP) – EMA/PSUR/0000282221

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00000273/202504)

Action: For adoption

6.1.16. Fingolimod – GILENYA (CAP) – EMA/PSUR/0000282248

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00001393/202502)

Action: For adoption

6.1.17. Fostamatinib – TAVLESSE (CAP) – EMA/PSUR/0000282287

Applicant: Instituto Grifols S.A.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010819/202504)

Action: For adoption

6.1.18. Futibatinib – LYTGOBI (CAP) – EMA/PSUR/0000282216

Applicant: Taiho Pharma Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00000068/202503)

Action: For adoption

6.1.19. Glofitamab – COLUMVI (CAP) – EMA/PSUR/0000282293

Applicant: Roche Registration GmbH

PRAC Rapporteur: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00000067/202503)

Action: For adoption

6.1.20. Idecabtagene vicleucel – ABECMA (CAP) – EMA/PSUR/0000282288

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010954/202503)

Action: For adoption

6.1.21. Isatuximab – SARCLISA (CAP) – EMA/PSUR/0000282274

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00010851/202503)

Action: For adoption

6.1.22. Lapatinib – TYVERB (CAP) – EMA/PSUR/0000282260

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00001829/202503)

Action: For adoption

6.1.23. Lorlatinib – LORVIQUA (CAP) – EMA/PSUR/0000282241

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00010760/202503)

Action: For adoption

6.1.24. Lutetium (^{177}Lu) vipivotide tetraxetan – PLUVICTO (CAP) – EMA/PSUR/0000282271

Applicant: Novartis Europharm Limited

PRAC Rapporteur: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00011031/202503)

Action: For adoption

6.1.25. Maralixibat – LIVMARLI (CAP) – EMA/PSUR/0000282276

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011032/202503)

Action: For adoption

6.1.26. Marstacimab – HYMPAVZI (CAP) – EMA/PSUR/0000282253

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011101/202504)

Action: For adoption

6.1.27. *Meningococcal* group a, c, w135 and y conjugate vaccine – MENVEO (CAP) – EMA/PSUR/0000282240

Applicant: Glaxosmithkline Vaccines S.r.l.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00001969/202503)

Action: For adoption

6.1.28. Methylnaltrexone bromide – RELISTOR (CAP) – EMA/PSUR/0000282262

Applicant: Bausch Health Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00002023/202503)

Action: For adoption

6.1.29. Mirikizumab – OMVOH (CAP) – EMA/PSUR/0000282215

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000049/202503)

Action: For adoption

6.1.30. Nemolizumab – NEMLUVIO (CAP) – EMA/PSUR/0000282252

Applicant: Galderma International

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011111/202503)

Action: For adoption

6.1.31. Nintedanib – OFEV (CAP) – EMA/PSUR/0000282233

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00010319/202504)

Action: For adoption

6.1.32. Niraparib – ZEJULA (CAP) – EMA/PSUR/0000282222

Applicant: Glaxosmithkline (Ireland) Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010655/202503)

Action: For adoption

6.1.33. Olipudase alfa – XENPOZYME (CAP) – EMA/PSUR/0000282268

Applicant: Sanofi B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00011003/202503)

Action: For adoption

6.1.34. Pemigatinib – PEMAZYRE (CAP) – EMA/PSUR/0000282272

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010923/202504)

Action: For adoption

6.1.35. Retifanlimab – ZYNYZ (CAP) – EMA/PSUR/0000282291

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011059/202503)

Action: For adoption

6.1.36. Rezafungin – REZZAYO (CAP) – EMA/PSUR/0000282237

Applicant: Mundipharma GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000221/202503)

Action: For adoption

6.1.37. Risankizumab – SKYRIZI (CAP) – EMA/PSUR/0000282229

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010765/202503)

Action: For adoption

6.1.38. Selinexor – NEXPOVIO (CAP) – EMA/PSUR/0000282278

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010926/202503)

Action: For adoption

6.1.39. Selumetinib – KOSELUGO (CAP) – EMA/PSUR/0000282270

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010936/202504)

Action: For adoption

6.1.40. Serplulimab – HETRONIFLY (CAP) – EMA/PSUR/0000282289

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011112/202503)

Action: For adoption

6.1.41. Sodium zirconium cyclosilicate – LOKELMA (CAP) – EMA/PSUR/0000282227

Applicant: AstraZeneca AB

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010675/202503)

Action: For adoption

6.1.42. Sotatercept – WINREVAIR (CAP) – EMA/PSUR/0000282250

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00011076/202503)

Action: For adoption

6.1.43. Tepotinib – TEPMETKO (CAP) – EMA/PSUR/0000282273

Applicant: Merck Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010979/202503)

Action: For adoption

6.1.44. Tucatinib – TUKYSA (CAP) – EMA/PSUR/0000282281

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010918/202504)

Action: For adoption

6.1.45. Velmanase alfa – LAMZEDE (CAP) – EMA/PSUR/0000282224

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010677/202503)

Action: For adoption

6.1.46. Vibegron – OBGEMSA (CAP) – EMA/PSUR/0000282266

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011068/202503)

Action: For adoption

6.1.47. Vilobelimab – GOHIBIC (CAP) – EMA/PSUR/0000282277

Applicant: InflaRx GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011103/202504)

Action: For adoption

6.1.48. Yttrium (90Y) chloride – YTTRIGA (CAP) – EMA/PSUR/0000282267

Applicant: Eckert & Ziegler Radiopharma GmbH

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00003137/202503)

Action: For adoption

6.1.49. Zilucoplan – ZILBRYSQ (CAP) – EMA/PSUR/0000282282

Applicant: UCB Pharma

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000169/202503)

Action: For adoption

6.1.50. Zolbetuximab – VYLOY (CAP) – EMA/PSUR/0000282259

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011095/202503)

Action: For adoption

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

6.2.1. Germanium (^{68}Ge) chloride / Gallium (^{68}Ga) chloride – GALLIAPHARM (CAP); NAP – EMA/PSUR/0000282223

Applicants: Eckert & Ziegler Radiopharma GmbH, various

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00010364/202503)

Action: For adoption

6.2.2. Gozetotide – LOCAMETZ (CAP); NAP – EMA/PSUR/0000282269

Applicants: Novartis Europharm Limited, various

PRAC Rapporteur: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00011030/202503)

Action: For adoption

6.2.3. Hepatitis B vaccine (rDNA) – HBVAXPRO (CAP); NAP – EMA/PSUR/0000282244

Applicants: Merck Sharp & Dohme B.V., various

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00001597/202502)

Action: For adoption

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

6.3.1. Alprazolam (NAP) – EMA/PSUR/0000282218

Applicants: various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00000109/202503)

Action: For adoption

6.3.2. Cefaclor (NAP) – EMA/PSUR/0000282255

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00000583/202503)

Action: For adoption

6.3.3. Chlorhexidine (NAP) – EMA/PSUR/0000282226

Applicants: various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00000662/202503)

Action: For adoption

6.3.4. Clobetasol (NAP) – EMA/PSUR/0000282239

Applicants: various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00000799/202502)

Action: For adoption

6.3.5. Clomipramine (NAP) – EMA/PSUR/0000282228

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000811/202503)

Action: For adoption

6.3.6. Clotrimazole (NAP) – EMA/PSUR/0000282284

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00000829/202503)

Action: For adoption

6.3.7. Clozapine (NAP) – EMA/PSUR/0000282232

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000836/202503)

Action: For adoption

6.3.8. Codeine / paracetamol (NAP) – EMA/PSUR/0000282209

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00000851/202503)

Action: For adoption

6.3.9. Cyamemazine (NAP) – EMA/PSUR/0000282261

Applicants: various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00000886/202503)

Action: For adoption

6.3.10. Diazepam (NAP) – EMA/PSUR/0000282242

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00001029/202503)

Action: For adoption

6.3.11. Doxycycline (NAP) – EMA/PSUR/0000282238

Applicants: various

PRAC Lead: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00001173/202503)

Action: For adoption

6.3.12. Erythromycin (systemic use) (NAP) – EMA/PSUR/0000282208

Applicants: various

PRAC Lead: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00010808/202503)

Action: For adoption

6.3.13. Ethinylestradiol (NAP) – EMA/PSUR/0000282265

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00001306/202503)

Action: For adoption

6.3.14. Ethyl loflazepate (NAP) – EMA/PSUR/0000282236

Applicants: various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00001317/202503)

Action: For adoption

6.3.15. Flucytosine (NAP) – EMA/PSUR/0000282257

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00001405/202503)

Action: For adoption

6.3.16. Fomepizole (NAP) – EMA/PSUR/0000282234

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00001466/202503)

Action: For adoption

6.3.17. Gentamicin (topical use) (NAP) – EMA/PSUR/0000282256

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00001522/202503)

Action: For adoption

6.3.18. Mannitol (all indications apart from cystic fibrosis) (NAP) – EMA/PSUR/0000282283

Applicants: various

PRAC Lead: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010005/202502)

Action: For adoption

6.3.19. Metoprolol (NAP) – EMA/PSUR/0000282258

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00002039/202503)

Action: For adoption

6.3.20. Prazepam (NAP) – EMA/PSUR/0000282243

Applicants: various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00002502/202503)

Action: For adoption

6.3.21. Rifampicin (NAP) – EMA/PSUR/0000282245

Applicants: various

PRAC Lead: Maria Popova-Kiradjieva

Scope: Evaluation of a PSUSA procedure (PSUSA/00002640/202503)

Action: For adoption

6.3.22. Rocuronium (NAP) – EMA/PSUR/0000282292

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00002656/202502)

Action: For adoption

6.3.23. Selegiline (NAP) – EMA/PSUR/0000282210

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00002688/202503)

Action: For adoption

6.3.24. Thiamazole (NAP) – EMA/PSUR/0000282251

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00002922/202503)

Action: For adoption

6.3.25. Trandolapril / verapamil (NAP) – EMA/PSUR/0000282249

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00003005/202503)

Action: For adoption

6.3.26. Tranexamic acid (NAP) – EMA/PSUR/0000282254

Applicants: various

PRAC Lead: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00003006/202503)

Action: For adoption

6.3.27. Urokinase (NAP) – EMA/PSUR/0000282263

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00003083/202503)

Action: For adoption

6.3.28. Varicella vaccine (live) (NAP) – EMA/PSUR/0000282219

Applicants: various

PRAC Lead: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010473/202503)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

None

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Ixekizumab – TALTZ (CAP) – EMA/PAM/0000262763

Applicant: Eli Lilly and Co (Ireland) Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Response to the PRAC request for a LEG for a cumulative review on MACE using data from clinical trials, post-marketing sources and literature adopted on 31 October 2024 following an assessment of EMEA/H/C/PSUSA/00010493/202403 (ixekizumab PSUR 11 - covering period 23 March 2021 to 22 March 2024) and to be submitted within 6 months.

Action: For adoption

6.6. Expedited summary safety reviews[3]

None

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

7. Post-authorisation safety studies (PASS)

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

7.1.1. Blinatumomab – BLINCYTO (CAP) – EMA/PASS/0000263976

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Veronika Macurova

Scope: PASS amendment [107o]: Substantial amendment to an observational PASS of long-term safety in paediatric patients with B-precursor acute lymphoblastic leukaemia (ALL) who have been treated with either blinatumomab or chemotherapy, followed by transplantation

Action: For adoption

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

7.2.1. Delgocitinib – ANZUPGO (CAP) – EMA/PAM/0000291999

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of a revised protocol for the non-imposed non-interventional PASS "Delgocitinib cream 20 mg/g in moderate to severe chronic hand eczema and risk of non-melanoma skin cancer: a nationwide registry based long-term post-authorisation safety study", as requested as part of MEA 003.

Action: For adoption

7.2.2. Mirikizumab – OMVOH (CAP) – EMA/PAM/0000292275

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Following Omvoh line extension procedure EMEA/H/C/005122/X/0006/G to include Crohn's Disease (CD) as a new indication:

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

Protocol amendment to I6T-MC-B003: Observational Study of Pregnancy and Infant Outcomes Among Women Exposed to Mirikizumab During Pregnancy in US-based Administrative Claims Data.

Protocol amendment to I6T-MC-B004: Observational Secondary Database Study to Assess the Long-Term Safety of Mirikizumab in Routine Clinical Practice Using US Administrative Claims Data.

Action: For adoption

7.2.3. Selexipag – UPTRAVI (CAP) – EMA/PAM/0000256686

Applicant: Janssen Cilag International

PRAC Rapporteur: Zoubida Amimour

Scope: Amendment of the EXPOSURE (AC-065A401) protocol (amendment 7 version 8 dated 17 February 2025). The protocol was amended to update the milestones of the study and to include OPSYNVI/YUVANCI into the list of PAH-specific marketed products from the MAH. In addition, the MAH proposes a reduction of the sample size planned for both cohorts of the study.

Action: For adoption

7.2.4. Tofacitinib – XELJANZ (CAP) – EMA/PAM/0000261850

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the third interim study reports for the four Rheumatoid Arthritis (RA) Registry Post-Authorization Safety Studies (PASSs) in line with protocol milestones for A3921312 (v3.0), A3921314 (v4.0), A3921316 (v3.0) & A3921317 (v5.0) for Xeljanz (tofacitinib).

- A3921312: UK, British Society for Rheumatology Biologics Register-Rheumatoid Arthritis (BSRBR-RA)
- A3921314: Sweden (SE), Anti Rheumatic Treatment in Sweden (ARTIS) register.
- A3921316: Spain (ES), Registry of Adverse Events of Biological Therapies and Biosimilars in Rheumatoid Diseases (BIOBADASER)
- A3921317: Germany (DE), Registry Rheumatoide Arthritis: Beobachtung der Biologika-Therapie (RABBIT)

Submission of a revised PASS protocol version 4.0 (A3921312), version 5.0 (A3921314), version 4.0 (A3921316), and version 6.0 (A3921317) for Tofacitinib (Xeljanz). Follow on from MEA 8.7+9.7+10.7+11.8.

Action: For adoption

7.2.5. Valoctocogene roxaparvovec – ROCTAVIAN (CAP) – EMA/PAM/0000292813

Applicant: Biomarin International Limited

PRAC Rapporteur: Bianca Mulder

Scope: PASS NINI: Submission of the final protocol of the survey of haematologists to assess the effectiveness of the additional risk minimisation measures (aRMMs) for Roctavian (valoctocogene roxaparvovec).

Action: For adoption

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

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

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Veronika Macurova

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

Action: For adoption

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

7.4.1. Abatacept – ORENCIA (CAP) – EMA/VR/0000287898

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: A grouped application consisting of:

C.I.13: Submission of the final report from study IM101803 listed as a category 3 study in the RMP. This is a nationwide post-marketing study on the safety of abatacept treatment in Denmark using the DANBIO register. The RMP version 29.0 has also been submitted.

[6] In accordance with Article 107p-q of Directive 2001/83/EC
[7] In accordance with Article 61a (6) of Regulation (EC) No 726/2004, in line with the revised variations regulation for any submission as of 4 August 2013

C.I.13: Submission of the final report from study IM101816 listed as a category 3 study in the RMP. This is a nationwide post-marketing study on the safety of abatacept treatment in Sweden using the ARTIS Register. The RMP version 29.0 has also been submitted.

Action: For adoption

7.4.2. Brexucabtagene autoleucel - TECARTUS (CAP) - EMEA/H/C/005102/II/0051, Orphan

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Submission of the final study report for the non-interventional study KT-EU-472-5966 titled "Quantitative Testing of Health Care Professional Knowledge About Tecartus Risk Minimisation Measures'' listed as a category 3 study in the RMP.

Action: For adoption

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

7.5.1. Avapritinib – AYVAKYT (CAP) – EMA/PAM/0000292344

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Fourth progress report of study BLU-285-1406

Study BLU-285-1406: In order to further confirm the safety and efficacy of avapritinib in the treatment of adult patients with unresectable or metastatic GIST harbouring the PDGFRA D842V mutation, the MAH should submit the results of an observational safety and efficacy study in patients with unresectable or metastatic PDGFRA D842V-mutant GIST.

Action: For adoption

7.5.2. Ciltacabtagene autoleucel – CARVYKTI (CAP) – EMA/PAM/0000291466

Applicant: Janssen Cilag International

PRAC Rapporteur: Jo Robays

Scope: First Interim Report for study 68284528MMY4002 - Long-term Follow-up Study for Participants Previously Treated with Ciltacabtagene Autoleucel.

Action: For adoption

7.5.3. Givosiran – GIVLAARI (CAP) – EMA/PAM/0000292266

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Study ALN-AS1-006: ELEVATE, a global observational longitudinal prospective registry of patients with acute hepatic porphyria (AHP)

ALN-AS1-006, PAM Report #4.0 (4th Interim study result)

Action: For adoption

7.5.4. Pirtobrutinib – JAYPIRCA (CAP) – EMA/PAM/0000291872

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Submission of an integrated safety analysis of patients with hematologic malignancies treated with pirtobrutinib monotherapy at the 200mg daily dose in clinical trials and from post-marketing reports to further characterise the risk of second primary malignancies.

Action: For adoption

7.5.5. Venetoclax – VENCLYXTO (CAP) – EMA/PAM/0000262601

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: 7th Study Progress Report for Study P16-562: A prospective observational study to assess the long-term safety profile of venetoclax in a Swedish cohort of Chronic Lymphocytic Leukemia (CLL) Patients

Action: For adoption

7.6. New Scientific Advice

7.7. Ongoing Scientific Advice

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

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Evinacumab – EVKEEZA (CAP) – EMA/S/0000288394

Applicant: Ultragenyx Germany GmbH

PRAC Rapporteur: Mari Thorn

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.2. Lomitapide – LOJUXTA (CAP) – EMA/S/0000290089

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Bianca Mulder

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. Nelarabine – ATRIANCE (CAP) – EMA/S/0000285152

Applicant: Sandoz Pharmaceuticals d.d.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.4. Odevixibat – BYLVAY (CAP) – EMA/S/0000287370

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.5. rADAMTS13 – ADZYNMA (CAP) – EMA/S/0000288329

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Maia Uusküla

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.6. Smallpox and monkeypox vaccine (live modified vaccinia virus Ankara) – IMVANEX (CAP) – EMA/S/0000288022

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Dirk Mentzer

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.7. Tafamidis – VYNDAQEL (CAP) – EMA/S/0000287643

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Zoubida Amimour

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.8. Tofersen – QALSODY (CAP) – EMA/S/0000275049

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

8.2.1. Belzutifan – WELIREG (CAP) – EMA/R/0000290222

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Martin Huber

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

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

Applicant: Otsuka Novel Products GmbH

PRAC Rapporteur: Jo Robays

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.3. Etranacogene dezaparvovec – HEMGENIX (CAP) – EMA/R/0000288354

Applicant: CSL Behring GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Abiraterone acetate – ABIRATERONE ACCORD (CAP) – EMA/R/0000286405

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.2. Azacitidine – ONUREG (CAP) – EMA/R/0000289529

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.3. Bevacizumab – ABEVMY (CAP) – EMA/R/0000287528

Applicant: Biosimilar Collaborations Ireland Limited

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.4. Bevacizumab – ALYMSYS (CAP) – EMA/R/0000276471

Applicant: Mabxience Research S.L.

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Bevacizumab – OYAVAS (CAP) – EMA/R/0000278081

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. Drospirenone / Estetrol – LYDISILKA (CAP) – EMA/R/0000288429

Applicant: Estetra

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.7. Drospirenone / Estetrol – DROVELIS (CAP) – EMA/R/0000288412

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.8. Hydrocortisone – EFMODY (CAP) – EMA/R/0000288092

Applicant: Neurocrine Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.9. Icosapent ethyl – VAZKEPA (CAP) – EMA/R/0000275813

Applicant: Amarin Pharmaceuticals Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.10. Ofatumumab – KESIMPTA (CAP) – EMA/R/0000276182

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.11. Potassium citrate / Potassium hydrogen carbonate – SIBNAYAL (CAP) – EMA/R/0000284883

Applicant: Advicenne

PRAC Rapporteur: Adam Przybylkowski

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.12. Risdiplam – EVRYSDI (CAP) – EMA/R/0000275338

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.13. Tralokinumab – ADTRALZA (CAP) – EMA/R/0000288404

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Kimmo Jaakkola

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. Hydrocortisone (NAP); hydrocortisone sodium succinate (NAP); methylprednisolone (NAP); methylprednisolone acetate (NAP); methylprednisolone sodium succinate (NAP); prednisolone (NAP); dexamethasone sodium phosphate (NAP) - SE/H/xxxx/WS/873

Applicant: Pfizer AB (Cortef, Solu-Cortef, Medrol, Depo-Medrol, Solu-Medrol, Prednisolon Pfizer, Dexamethasone Phosphate)

PRAC Lead: Mari Thörn

Scope: PRAC consultation on a worksharing variation procedure (SE/H/xxxx/WS/873) to update the product information of all the systemic corticosteroids (methylprednisolone, prednisolone, hydrocortisone and dexamethasone) regarding panniculitis, at request of Sweden.

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. PRAC working group - Best practice guide on using PRAC plenary time efficiently and effectively – update on the implementation of quantitative goals – Q3 2025

Action: For discussion

12.1.3. 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. Methodology Working Party (MWP) - Guideline on predictive biomarker assay development in the context of medicinal product lifecycle

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

None

12.8. Planning and reporting

12.8.1. PRAC workload statistics – Q3 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 - 2025 CAP Inspection Programme Revision

Action: For discussion

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: **Action:** For discussion

12.10.3. PSURs repository

None

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

Action: For adoption

12.11. Signal management

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

PRAC lead: **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. 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. Introducing the new Early Notification System (ENS) portal

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/