12 January 2026
EMA/PRAC/388300/2025
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 12-15 January 2026

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

12 January 2026, 09:30 – 19:30, via teleconference

13 January 2026, 08:30 – 19:30, via teleconference

14 January 2026, 08:30 – 19:30, via teleconference

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

1.2. Agenda of the meeting on 12-15 January 2026

Action: For adoption

1.3. Minutes of the previous meeting on 24-27 November 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 procedure

None

3.2. Ongoing procedures

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

Applicants: various

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

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

Action: For adoption (revised timetable and list of participant for a scientific advisory group (SAG) meeting)

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. Atropine (eyedrops indicated for slowing the progression of myopia in paediatric patients) – RYJUNEA (CAP); NAP

Applicant: Santen Oy, various

PRAC Rapporteur: Martin Huber

Scope: Signal of strabismus

Action: For adoption of PRAC recommendation

EPITT 20244 – New signal

Lead Member State(s): DE

[1] Re-examination of PRAC recommendation under Article 32 of Directive 2001/83/EC
[2] Each signal refers to a substance or therapeutic class. The route of marketing authorisation is indicated in brackets (CAP for Centrally Authorised Products; NAP for Nationally Authorised Products including products authorised via Mutual Recognition Procedures and Decentralised Procedure). Product names are listed for reference Centrally Authorised Products (CAP) only. PRAC recommendations will specify the products concerned in case of any regulatory action required

4.1.2. Darolutamide – NUBEQA (CAP)

Applicant: Bayer AG

PRAC Rapporteur: Jan Neuhauser

Scope: Signal of angioedema

Action: For adoption of PRAC recommendation

EPITT 20237 – New signal

Lead Member State(s): BE

4.1.3. Oxacillin (NAP)

Applicant(s): various

PRAC Lead: To be appointed

Scope: Signal of drug reaction with eosinophilia and systemic symptoms (DRESS)

Action: For adoption of PRAC recommendation

EPITT 20223 – New signal

Lead Member State(s): CZ

4.1.4. Vortioxetine - BRINTELLIX (CAP)

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Jo Robays

Scope: Signal of acute pancreatitis

Action: For adoption of PRAC recommendation

EPITT 20234 – New signal

Lead Member State(s): BE

4.1.5. Zolbetuximab – VYLOY (CAP)

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Signal of protein-losing gastroenteropathy

Action: For adoption of PRAC recommendation

EPITT 20236 – New signal

Lead Member State(s): NL

4.1.6. Zuranolone – ZURZUVAE (CAP)

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Guðrún Stefánsdóttir

Scope: Signal of suicidal ideation

Action: For adoption of PRAC recommendation

EPITT 20232 – New signal

Lead Member State(s): IS

4.1.7. X-ray contrast agents: Iobitridol (NAP); Iodixanol (NAP); Iohexol (NAP); Iomeprol (NAP); Iopamidol (NAP); Iopromide (NAP); Ioversol (NAP)

Applicants: various

PRAC Lead: To be appointed

Scope: Signal of fixed drug eruption

Action: For adoption of PRAC recommendation

EPITT 20229 – New signal

Lead Member State(s): NO, IE, FR

4.2. Signals follow-up and prioritisation

4.2.1. Cefazolin (NAP); cefazolin/lidocaine hydrochloride (NAP)

Applicant(s): various

PRAC Lead: Sonja Radowan

Scope: Signal of Kounis syndrome

Action: For adoption

EPITT 20204 – Follow-up to September 2025

4.2.2. Erdafitinib - BALVERSA (CAP) - EMEA/H/C/006050/SDA/003

Applicant: Janssen Cilag International

PRAC Rapporteur: Bianca Mulder

Scope: Signal of growth accelerated

Action: For adoption

EPITT 20194 – Follow-up to September 2025

4.2.3. Pegylated liposomal doxorubicin – CAELYX PEGYLATED LIPOSOMAL (CAP) - EMEA/H/C/000089/SDA/022; CELDOXOME PEGYLATED LIPOSOMAL (CAP); ZOLSKETIL PEGYLATED LIPOSOMAL (CAP) - EMEA/H/C/005320/SDA/002; NAP

Applicants: Accord Healthcare S.L.U. (Zolsketil pegylated liposomal), Baxter Holding B.V. (Caelyx pegylated liposomal, Celdoxome pegylated liposomal), various

PRAC Rapporteur: Eva Jirsová

Scope: Signal of renal-limited thrombotic microangiopathy

Action: For adoption

EPITT 20193 – Follow-up to September 2025

4.2.4. Pemetrexed – ALIMTA (CAP) - EMEA/H/C/000564/SDA/028; ARMISARTE (CAP); PEMETREXED ACCORD (CAP); PEMETREXED FRESENUIS KABI (CAP); PEMETREXED MEDAC (CAP); PEMETREXED PFIZER (CAP); NAP

Applicants: Accord Healthcare S.L.U. (Pemetrexed accord), Actavis Group Ptc ehf. (Armisarte), Eli Lilly Nederland B.V. (Alimta), Fresenius Kabi Deutschland GmbH (Pemetrexed fresenuis kabi), Medac Gesellschaft für klinische Spezialpräparate mbH (Pemetrexed medac), Pfizer Europe MA EEIG (Pemetrexed pfizer), various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Signal of lupus erythematosus

Action: For adoption

EPITT 20185 – 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. Apitegromab (CAP MAA) - EMEA/H/C/005909, PRIME, Orphan

Applicant: Scholar Rock Netherlands B.V.

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

Action: For adoption

5.1.2. Liraglutide (CAP MAA) - EMEA/H/C/006620

Scope (pre D-180 phase): Treatment of diabetes and weight management

Action: For adoption

5.1.3. Liraglutide (CAP MAA) - EMEA/H/C/006615

Scope (pre D-180 phase): Treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise

Action: For adoption

5.1.4. Lurbinectedin (CAP MAA) - EMEA/H/C/006673, Orphan

Applicant: Pharma Mar S.A.

Scope (pre D-180 phase): Maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)

Action: For adoption

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

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

Action: For adoption

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

5.2.1. Acalabrutinib CALQUENCE (CAP) – EMA/VR/0000304591

Applicant: AstraZeneca AB

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Submission of an updated RMP version 9 in order to revise the list of safety concerns, based on the currently available post-marketing and clinical data.

Action: For adoption

5.2.2. Atazanavir – REYATAZ (CAP); Atazanavir / Cobicistat – EVOTAZ (CAP) – EMA/VR/0000288444

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of an updated RMP version 16 in order to propose the removal of the continued prospective monitoring via the Antiretroviral Pregnancy Registry (APR) as an additional pharmacovigilance activity.

Action: For adoption

5.2.3. Avatrombopag – DOPTELET (CAP) – EMA/VR/0000296242

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: A grouped application consisting of:

C.I.11 for RMP: Submission of an updated RMP version 4.0 to propose the removal of missing information Use in splenectomy patients with chronic liver disease, Use in patients receiving interferon products and Safety in patients undergoing invasive procedures.

C.I.11 for RMP: Submission of an updated RMP version 4.0 to propose to remove Targeted Medical Event Questionnaires.

C.I.11 for RMP: Submission of an updated RMP version 4.0 to update information on immune thrombocytopenia (ITP) PASS and chronic liver disease (CLD) PASS studies

Action: For adoption

5.2.4. Ciclosporin – IKERVIS (CAP); VERKAZIA (CAP) – EMA/VR/0000296156

Applicant: Santen Oy

PRAC Rapporteur: Jan Neuhauser

Scope: C.I.11.z - the MAH submitted a worksharing (WS) application to revise the ciclosporin Risk Management plan (PAES study completion). In addition the follow up form in the current RMP is revised to be in compliance with latest version of Guideline on specific adverse reaction follow-up questionnaires (Specific AR FUQ).

Action: For adoption

5.2.5. 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

5.2.6. Elvitegravir / Cobicistat / Emtricitabine / Tenofovir alafenamide – GENVOYA (CAP) – EMA/VR/0000308403

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Amelia Cupelli

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

C.I.11 for RMP: Submission of an updated RMP version 6.1 in order to propose the removal of the Important Identified Risk of 'Suicidal ideation/suicide attempt in patients with a preexisting history of depression or psychiatric illness'.

C.I.11 for RMP: Submission of an updated RMP version 6.1 in order to propose the removal of the Important Identified Risk of 'Concurrent use of drugs whose coadministration with Genvoya is contraindicated'.

C.I.11 for RMP: Submission of an updated RMP version 6.1 in order to propose the removal of the following Missing Information: 'Safety in patients with cardiac conduction disorders'.

Action: For adoption

5.2.7. Lecanemab – LEQEMBI (CAP) – EMA/VR/0000302769

Applicant: Eisai GmbH

PRAC Rapporteur: Eva Jirsová

Scope: Submission of an updated RMP version 1.1 in order to propose an update to PASS study deadlines. In addition, the MAH has taken the opportunity to update Annex II accordingly.

Action: For adoption

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

Applicant: Santen Oy

PRAC Rapporteur: Maria del Pilar Rayon

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

Action: For adoption

5.2.9. Reslizumab – CINQAERO (CAP) – EMA/VR/0000309197

Applicant: Teva B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of an updated RMP version 6.0 in order to remove follow-up questionnaires and routine antidrug antibody testing, remove an uninitiated PASS study for malignancy and update the list of safety concerns to remove the important identified risk of severe hypersensitivity reactions, as well as the important potential risks of malignancy and medication errors.

Action: For adoption

5.2.10. Zanubrutinib – BRUKINSA (CAP) – EMA/VR/0000301572

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Submission of an updated RMP version 6.1 in order to reclassify the risks of hepatotoxicity (including hepatic failure) and drug-drug interaction with CYP3A inducers.

Action: For adoption

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

5.3.1. Abemaciclib – VERZENIOS (CAP) – EMA/VR/0000307389

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Carla Torre

Scope: Update of section 5.1 of the SmPC in order to update efficacy information based on final OS data from study monarchE (I3Y-MC-JPCF) listed as a PAES in the Annex II; this is a randomized, open-label, phase 3 study of abemaciclib combined with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone in patients with high risk, node positive, early stage, hormone receptor positive, human epidermal receptor 2 negative, breast cancer. The Annex II and Package Leaflet are updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.2. Abiraterone acetate – ABIRATERONE MYLAN (CAP); NAP – EMA/VR/0000291298

Applicants: Mylan Pharmaceuticals Limited, various

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Grouped application comprising of 3 Extension of indication variations for ABIRATERONE MYLAN, as follows:

C.I.6: to update the currently approved indication for metastatic hormone sensitive prostate cancer (mHSPC) patients to also include non-high risk mHSPC

C.I.6: to include the treatment of newly diagnosed mHSPC in adult men in combination with androgen deprivation therapy (ADT) and docetaxel in patients who are fit for chemotherapy

C.I.6: to include the treatment of newly diagnosed high risk non-metastatic hormone sensitive prostate cancer (HSPC) in adult men in combination with ADT and radiotherapy

The variations are based on literature data. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted.

Action: For adoption

5.3.3. Adalimumab – HUMIRA (CAP) – EMA/VR/0000303439

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Karin Bolin

Scope: Submission of the final report from study M10-870 listed as a category 3 study in the RMP. This is a Phase 3, Multi-Center, Open-Label Study of the Human Anti-TNF Monoclonal Antibody Adalimumab to Evaluate Long-Term Safety and Tolerability of Repeated Administration of Adalimumab in Pediatric Subjects with Ulcerative Colitis Who Completed the Study M11-290. The RMP version 17.0 has also been submitted.

Action: For adoption

5.3.4. Belimumab – BENLYSTA (CAP) – EMA/VR/0000306408

Applicant: Glaxosmithkline (Ireland) Limited

PRAC Rapporteur: Karin Bolin

Scope: Submission of the final report from study analysis BEL116559 listed as a category 3 study in the RMP. This is a pooled analyses of elderly (aged ≥65 years) subpopulation treated in select belimumab clinical trials to evaluate the safety of belimumab treatment in elderly patients with systemic lupus erythematosus (SLE). The RMP version 47.0 has also been submitted.

Action: For adoption

5.3.5. Budesonide / Formoterol - BIRESP SPIROMAX (CAP) - EMEA/H/C/WS2806/G; Budesonide / Formoterol - DUORESP SPIROMAX (CAP) - EMEA/H/C/WS2806/G

Applicant: Teva Pharma B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: A grouped application consisting of:

C.I.6: Extension of the asthma indication to include the anti-inflammatory reliever (AIR) use for DuoResp Spiromax and BiResp Spiromax, based on the latest GINA report, the European Respiratory Society guidelines, and literature data. In addition, the Applicant referred to changes made for Symbicort (UK). As a consequence, sections 4.1, 4.2, 4.4, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI introduced editorial changes, and is brought in line with the latest QRD template version. The RMP version 4.0 has also been submitted.

C.I.2.a: To update sections 4.5 and 5.1 of the SmPC following assessment of the same change for the reference product Symbicort Turbohaler (SE/H/0229/001- 002) and also Symbicort (UK).

Action: For adoption

5.3.6. 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/ 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

5.3.7. Decitabine / Cedazuridine – INAQOVI (CAP) – EMA/VR/0000304730

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy for INAQOVI in combination with venetoclax, based on interim results from study ASTX727-07; this is a single-arm, open-label pharmacokinetic, safety, and efficacy study of ASTX727 in combination with venetoclax in adult patients with acute myeloid leukemia. 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 1.3 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 bring editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.8. Deucravacitinib – SOTYKTU (CAP) – EMA/VR/0000282554

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include, for SOTYKTU, alone or in combination with conventional synthetic disease modifying antirheumatic drugs (DMARDs), the treatment of active psoriatic arthritis (PsA) in adults who have had an inadequate response or who have been intolerant to a prior DMARD therapy, based on results from the following phase 3 studies: Study IM011-054 (POETYK PsA-1); this is a phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of deucravacitinib in participants with active psoriatic arthritis who are naïve to biologic disease-modifying anti-rheumatic drugs, and Study IM011-055 (POETYK PsA-2); this is a multi-center, randomized, double-blind, placebo-controlled phase 3 study to evaluate the efficacy and safety of BMS-986165 in participants with active psoriatic arthritis (PsA) who are naïve to biologic disease modifying anti-rheumatic drugs or had previously received TNFα inhibitor treatment. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, as well as introduce administrative changes to the PI.

Action: For adoption

5.3.9. Deucravacitinib – SOTYKTU (CAP) – EMA/VR/0000309456

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.6, 5.2 and 5.3 of the SmPC based on final results from study IM011-1123. This is a Phase 4, open-label, single-group, single-dose study evaluating deucravacitinib concentrations in the breast milk and plasma of healthy lactating female subjects. The updated RMP (version 4.0) has also been submitted.

Action: For adoption

5.3.10. Dupilumab – DUPIXENT (CAP) – EMA/VR/0000282164

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of moderate to severe chronic spontaneous urticaria (CSU) in children aged 2 to 11 years whose disease is inadequately controlled by H1 antihistamines and who are naive to anti-IgE therapy for CSU for DUPIXENT, based on the results from study PKM16982; this is a multi-center, single-arm study to investigate the pharmacokinetics and safety of dupilumab in male and female participants ≥2 years to <12 years of age with uncontrolled chronic spontaneous urticaria (CSU). Consequently, 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 14.0 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. Furthermore, the PI is brought in line with the latest QRD template.

Action: For adoption

5.3.11. Durvalumab – IMFINZI (CAP) – EMA/VR/0000282058

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Extension of indication for IMFINZI to include in combination with FLOT chemotherapy as neoadjuvant and adjuvant treatment, followed by adjuvant IMFINZI monotherapy, for the treatment of adults with resectable gastric or gastro-oesophageal junction adenocarcinoma , based on interim results from study MATTERHORN, (D910GC00001); this is a randomized, double-blind, placebo-controlled, phase 3 study of neoadjuvant-adjuvant durvalumab and FLOT chemotherapy followed by adjuvant durvalumab in patients with resectable gastric and gastroesophageal junction cancer (GC/GEJC). As a consequence, sections 4.1, 4.2, 4.5, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14.0 of the RMP has also been submitted.

Action: For adoption

5.3.12. 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

5.3.13. Encorafenib – BRAFTOVI (CAP) – EMA/VR/0000304994

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Rugile Pilviniene

Scope: Extension of indication to include, in combination with cetuximab and FOLFOX, the first line treatment of adult patients with metastatic colorectal cancer with a BRAF V600E mutation for BRAFTOVI, based on the interim results from the pivotal Study C4221015 (BREAKWATER). This is an open-label, multicenter, 3-arm, randomized Phase 3 study of encorafenib plus cetuximab (EC) alone or in combination with mFOLFOX6 versus standard of care chemotherapy in first-line participants with BRAF V600E-mutant mCRC. 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. The version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.3.14. 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

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

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

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

Action: For adoption

5.3.16. 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

5.3.17. 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

5.3.18. Ganaxolone - ZTALMY (CAP) - EMEA/H/C/005825/II/0004/G, Orphan

Applicant: Immedica Pharma AB

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application comprised of 8 Type II variations as follows:
1 Type II (C.I.4): Update of section 5.2 of the SmPC in order to update ganaxolone metabolite pattern at steady state based on re-analysis of 1042-TQT-1001 listed as a category 3 study in the RMP to evaluate the ganaxolone steady-state metabolite.
7 Type II (C.I.13): Submission of the final non-clinical study reports for the in vitro DDI potential and in vivo PK of the metabolite M17 listed as category 3 studies in the RMP.
The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to introduce updates to the PI that reflect clarifications and typographical corrections, including

to sections 4.2 and 4.4 of the SmPC.

Action: For adoption

5.3.19. 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

5.3.20. Gemtuzumab ozogamicin – MYLOTARG (CAP) – EMA/VR/0000304835

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include, in combination with mitoxantrone and cytarabine (AraC), the treatment of paediatric patients aged 1 year to less than 18 years with newly diagnosed CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL) for MYLOTARG, based on results from study MyeChild 01 (WI203680). This is a Phase 3, randomised, open-label, multicenter study incorporating an embedded dose finding study in children with newly diagnosed AML/high risk MDS/isolated myeloid sarcoma (de novo or secondary). 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 2.3 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

5.3.21. Human normal immunoglobulin – PRIVIGEN (CAP) – EMA/VR/0000304719

Applicant: CSL Behring GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: A grouped application consisting of:

C.I.6: Extension of indication to include treatment of patients with measles pre/post-exposure prophylaxis in whom active immunisation is contraindicated or not advised, for PRIVIGEN, in alignment with the IVIg core SmPC (EMA/CHMP/BPWP/94038/2007 Rev). As a consequence, sections 2, 4.1, 4.2 and 5.2 of the SmPC. The Package Leaflet is updated accordingly. The RMP version 9 has also been submitted.

Action: For adoption

5.3.22. 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

5.3.23. 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

5.3.24. Marstacimab – HYMPAVZI (CAP) – EMA/VR/0000304590

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include treatment of routine prophylaxis of bleeding episodes in patients 12 years of age and older with haemophilia A with factor VIII inhibitors or haemophilia B with factor IX inhibitors for HYMPAVZI, based on final results from study B7841005 and interim results from supportive study B7841007. Study B7841005 is an open-label study in adolescent and adult severe (coagulation factor activity ≤2%) with or

without inhibitors comparing standard treatment to PF-06741086 Prophylaxis. Study B7841007 is an open-label extension study to evaluate the long-term safety, tolerability, and efficacy of marstacimab prophylaxis in severe (coagulation factor activity <1%) hemophilia A participants with or without inhibitors or moderately severe to severe hemophilia B participants (coagulation factor activity ≤2%) with or without inhibitors. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted.

Action: For adoption

5.3.25. Methoxy polyethylene glycol-epoetin beta – MIRCERA (CAP) – EMA/VR/0000309070

Applicant: Roche Registration GmbH

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Update of section 4.4 of the SmPC in order to discontinue provision of free anti-erythropoietin antibody (AEAB) testing (or re-testing). The RMP version 13.0 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

5.3.26. Mexiletine – NAMUSCLA (CAP) – EMA/X/0000258210

Applicant: Lupin Europe GmbH

PRAC Rapporteur: Eva Jirsová

Scope: Extension application to add new strengths of 62 mg and 83 mg grouped with an Extension of indication to include the symptomatic treatment of myotonia in children and adolescents (from 6 to 18 years of age) with non-dystrophic myotonic disorders for NAMUSCLA, based on final results from study MEX-NM-301 as well as population pharmacokinetic analysis of mexiletine in healthy volunteers and myotonic patients; MEX-NM-301 is an open-label, multi-centre, single arm, interventional study to describe the steady-state PK, safety, and efficacy of mexiletine in pediatric patients (6 to <18 years of age) with myotonic disorders. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.27. Niraparib / Abiraterone acetate – AKEEGA (CAP) – EMA/VR/0000282377

Applicant: Janssen Cilag International

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include AKEEGA with prednisone or prednisolone for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and HRR-mutations (germline and/or somatic, based on interim results from study

67652000PCR3002 (AMPLITUDE); this is a phase 3 randomized, placebo-controlled, double-blind study of niraparib in combination with abiraterone acetate and prednisone versus abiraterone acetate and prednisone for the treatment of participants with deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-sensitive prostate cancer (mCSPC). 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 3.1 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. In addition, the MAH is requesting an additional year of market protection for a new indication.

Action: For adoption

5.3.28. Nivolumab – OPDIVO (CAP) – EMA/VR/0000282199

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication for OPDIVO to include treatment of paediatric and adult patients with relapsed/refractory classical Hodgkin Lymphoma, based on results from study CA209744; a phase 2, open-label study of nivolumab + brentuximab vedotin for children, adolescents, and young adults with R/R CD30+ classical Hodgkin lymphoma after failure of first-line therapy, followed by brentuximab vedotin + bendamustine for participants with a suboptimal response. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 44.0 of the RMP has also been submitted

Action: For adoption

5.3.29. Nivolumab – OPDIVO (CAP) – EMA/VR/0000304938

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include OPDIVO for the treatment of adults and adolescents 12 years of age and older with previously untreated Stage III or IV classical Hodgkin Lymphoma (cHL), based on results from the pivotal study CA2098UT (SWOG 1826), a Phase 3, randomized, open-label study of nivolumab (Opdivo) + AVD (N-AVD) versus brentuximab vedotin (Adcetris) + AVD (Bv-AVD) in patients (age ≥12 years) with newly diagnosed, advanced stage cHL. 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 51.0 of the RMP has also been submitted.

Action: For adoption

5.3.30. Nivolumab / Relatlimab – OPDUALAG (CAP) – EMA/VR/0000303785

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include patients with tumour cell PD-L1 expression ≥ 1% in the first-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older for OPDUALAG, based on updated descriptive 4-year data from pivotal Study CA224047; this is a randomized, double-blind phase 2/3 study of relatlimab combined with nivolumab versus nivolumab in participants with previously untreated metastatic or unresectable melanoma. 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. In addition, the Marketing authorisation holder (MAH) took the opportunity to remove Annex IV from the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.31. 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

5.3.32. Pegvaliase – PALYNZIQ (CAP) – EMA/VR/0000302032

Applicant: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

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

C.I.6: Extension of indication to include treatment of adolescent patients aged 12 to <16 years with phenylketonuria (PKU) for PALYNZIQ, based on interim results from study 165-306; this is a Phase 3 open label, randomized, controlled, 2-arm, multicenter study designed to evaluate the safety and efficacy of pegvaliase in adolescent participants 12 to <18 years old with PKU. 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. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the PI to include editorial changes and remove references to the route of administration of adrenaline (injection) to allow physicians to prescribe any approved adrenaline device.

C.I.4: Update of section 4.6 of the SmPC in order to update information on pregnancy based on a comprehensive assessment of all pregnancy and breastfeeding reports received from all sources.

The RMP version 5.0 has also been submitted.

Action: For adoption

5.3.33. Pertuzumab – PERJETA (CAP) – EMA/VR/0000307073

Applicant: Roche Registration GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Update of sections 4.8 and 5.1 of the SmPC in order to update safety and efficacy data, based on final results from post-authorisation efficacy study BO25126 (APHINITY) listed as a specific obligation in the Annex II; this is a phase III, randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer; the Package Leaflet and Annex II are updated accordingly. The RMP version 15.0 has also been submitted. In addition, the MAH took the opportunity to introduce editorials changes to the PI.

Action: For adoption

5.3.34. Regorafenib – STIVARGA (CAP) – EMA/VR/0000312922

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Update of sections 4.2 and 5.1 of the SmPC in order to update paediatric information based on results from paediatric Study 7. The RMP version 7.3 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

5.3.35. Risankizumab – SKYRIZI (CAP) – EMA/X/0000296763

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Extension application to introduce a new strength of 55 mg solution for injection grouped with a type II variation C.I.6.a to include treatment of paediatric plaque psoriasis (6 to < 18 years) for Skyrizi, based on final results from study M19-977 and interim results from study M19-973. M19-977 is a randomized, active-controlled, efficacy assessor-blinded study to evaluate pharmacokinetics, safety, and efficacy of risankizumab in patients from 6 to less than 18 years of age with moderate to severe plaque psoriasis; M19-973 is a phase 3 multicenter, single-arm, open-label extension study to assess the safety, tolerability, and efficacy of risankizumab in subjects with moderate to severe plaque psoriasis who have completed participation in study M19-977. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.4, 6.5, 6.6, and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.0 of the RMP has also been submitted.

Action: For adoption

5.3.36. Selpercatinib – RETSEVMO (CAP) – EMA/VR/0000282012

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include paediatric patients 2 years and older with: (1) Advanced RET fusion-positive thyroid cancer who are radioactive iodine-refractory, (2) Advanced RET-mutant medullary thyroid cancer, (3) Advanced RET fusion-positive solid tumours, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted, for RETSEVMO, based on final results from study J2G-OX-JZJJ (LOXO RET 18036, LIBRETTO-121); this is a multicentre, open-label Phase 1/2 study in paediatric patients with advanced solid or primary central nervous system (CNS) tumours harbouring an activating RET alteration. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.6 of the SmPC are updated. The Package Leaflet and labelling are updated in accordance. Version 15.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the information related to Quality part of the dossier.

Action: For adoption

5.3.37. Semaglutide – WEGOVY (CAP) – EMA/X/0000296344

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Extension application to introduce a new pharmaceutical form (tablet), associated with four new strengths (1.5 mg, 4 mg, 9mg and 25 mg) and a new route of administration (oral use).

Action: For adoption

5.3.38. Sipavibart – KAVIGALE (CAP) – EMA/VR/0000287106

Applicant: AstraZeneca AB

PRAC Rapporteur: Kimmo Jaakkola

Scope: Update of section 4.4 of the SmPC in order to add a new warning on cardiovascular and/or thrombo-embolic events, based on the currently available safety information including the updated post-authorisation data. The Package Leaflet is updated accordingly. The RMP version 2 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

5.3.39. Tirzepatide – MOUNJARO (CAP) – EMA/VR/0000271898

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Update of section 4.6 of the SmPC in order to include information on breast-feeding based on results from study I8F-MC-GPIN (GPIN); this was a Phase I, single-site, open-label, single-treatment arm, single-dose, lactation study, assessing pharmacokinetics of tirzepatide

in breastmilk and plasma in healthy lactating women. The Package Leaflet is also updated accordingly. The RMP version 6.1 has also been submitted.

Action: For adoption

5.3.40. Tolvaptan – JINARC (CAP) – EMA/VR/0000246866

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Update of sections 4.2 and 5.1 of the SmPC in order to update information based on final results from study 156-12-299 listed as a category 1 study in the RMP. This is a 7.5-year, Multicentre, Non-interventional, Post-authorisation Safety Study for Patients Prescribed JINARC for Autosomal Dominant Polycystic Kidney Disease. This study was intended to explore the safety profile and usage of Jinarc when used in the real-world setting in Europe, particularly with relation to the risk of liver injury. The Package Leaflet is updated accordingly. The RMP version 15.1 has also been submitted. In addition, the MAH took the opportunity to update Annex II section D, 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

5.3.41. Vedolizumab – ENTYVIO (CAP) – EMA/VR/0000255408

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Adam Przybylkowski

Scope: Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study MLN0002SC-3030 listed as a category 3 study in the RMP; this is a phase 3b open-label study to determine the long-term safety and efficacy of vedolizumab subcutaneous in subjects with ulcerative colitis and Crohn's disease; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted. In addition, 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, and to introduce changes to the PI that are pre-agreed in the previous procedures.

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. Acoramidis – BEYONTTRA (CAP) – EMA/PSUR/0000296585

Applicant: Bayer AG

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00011106/202505)

Action: For adoption

6.1.2. Adagrasib – KRAZATI (CAP) – EMA/PSUR/0000296576

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00000214/202506)

Action: For adoption

6.1.3. Alpelisib – PIQRAY (CAP) – EMA/PSUR/0000296587

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010871/202505)

Action: For adoption

6.1.4. Amivantamab – RYBREVANT (CAP) – EMA/PSUR/0000296559

Applicant: Janssen Cilag International

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010977/202505)

Action: For adoption

6.1.5. Anakinra – KINERET (CAP) – EMA/PSUR/0000296578

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000209/202505)

Action: For adoption

6.1.6. Arpraziquantel – ARPRAZIQUANTEL (Art 58) – EMA/PSUR/0000294554

Applicant: Merck Europe B.V.

PRAC Rapporteur: Adam Przybyłkowski

Scope: Evaluation of a PSUSA procedure (PSUV)

Action: For adoption

6.1.7. Artesunate – ARTESUNATE AMIVAS (CAP) – EMA/PSUR/0000296558

Applicant: Amivas Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010958/202506)

Action: For adoption

6.1.8. Atezolizumab – TECENTRIQ (CAP) – EMA/PSUR/0000296544

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010644/202505)

Action: For adoption

6.1.9. Bevacizumab gamma – LYTENAVA (CAP) – EMA/PSUR/0000296623

Applicant: Outlook Therapeutics Limited

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00011065/202505)

Action: For adoption

6.1.10. Sipavibart – KAVIGALE (CAP) – EMA/PSUR/0000296621

Applicant: AstraZeneca AB

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00011113/202506)

Action: For adoption

6.1.11. Binimetinib – MEKTOVI (CAP) – EMA/PSUR/0000296615

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010717/202506)

Action: For adoption

6.1.12. Cholera vaccine – VAXCHORA (CAP) – EMA/PSUR/0000296628

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010862/202506)

Action: For adoption

6.1.13. COVID-19 mRNA vaccine – KOSTAIVE (CAP) – EMA/PSUR/0000296565

Applicants: Seqirus Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011115/202505)

Action: For adoption

6.1.14. Dabrafenib – FINLEE (CAP); TAFINLAR (CAP) – EMA/PSUR/0000296502

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010084/202505)

Action: For adoption

6.1.15. Dantrolene sodium, hemiheptahydrate – AGILUS (CAP) – EMA/PSUR/0000296582

Applicant: Norgine B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011063/202505)

Action: For adoption

6.1.16. Datopotamab deruxtecan – DATROWAY (CAP) – EMA/PSUR/0000296568

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00011129/202506)

Action: For adoption

6.1.17. Dolutegravir / Rilpivirine – JULUCA (CAP) – EMA/PSUR/0000296626

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00010689/202505)

Action: For adoption

6.1.18. Dopamine hydrochloride – NEOATRICON (CAP) – EMA/PSUR/0000296599

Applicant: BrePco Biopharma Limited

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00011066/202505)

Action: For adoption

6.1.19. Drospirenone / Estetrol – DROVELIS (CAP); LYDISILKA (CAP) – EMA/PSUR/0000296619

Applicants: Estetra, Gedeon Richter Plc.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010938/202505)

Action: For adoption

6.1.20. Efmoroctocog alfa – ELOCTA (CAP) – EMA/PSUR/0000296496

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010451/202506)

Action: For adoption

6.1.21. Elacestrant – ORSERDU (CAP) – EMA/PSUR/0000296492

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000120/202506)

Action: For adoption

6.1.22. Eladocagene exuparvovec – UPSTAZA (CAP) – EMA/PSUR/0000296569

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011004/202506)

Action: For adoption

6.1.23. Elafibranor – IQIRVO (CAP) – EMA/PSUR/0000296570

Applicant: Ipsen Pharma

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00011092/202506)

Action: For adoption

6.1.24. Encorafenib – BRAFTOVI (CAP) – EMA/PSUR/0000296574

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00010719/202506)

Action: For adoption

6.1.25. Entrectinib – ROZLYTREK (CAP) – EMA/PSUR/0000296595

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010874/202506)

Action: For adoption

6.1.26. Etranacogene dezaparvovec – HEMGENIX (CAP) – EMA/PSUR/0000296612

Applicant: CSL Behring GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011037/202505)

Action: For adoption

6.1.27. Fenfluramine – FINTEPLA (CAP) – EMA/PSUR/0000296555

Applicant: UCB Pharma

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010907/202506)

Action: For adoption

6.1.28. Flortaucipir (^{18}F) – TAUVID (CAP) – EMA/PSUR/0000296625

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011073/202505)

Action: For adoption

6.1.29. Formoterol / Glycopyrronium bromide / Budesonide – RILTRAVA AEROSPHERE (CAP); TRIXEO AEROSPHERE (CAP) – EMA/PSUR/0000296609

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010908/202506)

Action: For adoption

6.1.30. Gadopiclenol – ELUCIREM (CAP); VUEWAY (CAP) – EMA/PSUR/0000296586

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

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000232/202504)

Action: For adoption

6.1.31. Givinostat – DUVYZAT (CAP) – EMA/PSUR/0000296566

Applicant: Italfarmaco S.p.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011141/202506)

Action: For adoption

6.1.32. Givosiran – GIVLAARI (CAP) – EMA/PSUR/0000296590

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010839/202505)

Action: For adoption

6.1.33. Glibenclamide – AMGLIDIA (CAP) – EMA/PSUR/0000296601

Applicant: AMMTek

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00010690/202505)

Action: For adoption

6.1.34. Human papillomavirus 9-valent Vaccine (Recombinant, adsorbed) – GARDASIL 9 (CAP) – EMA/PSUR/0000296500

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010389/202506)

Action: For adoption

6.1.35. Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) – GARDASIL (CAP) – EMA/PSUR/0000296551

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00001634/202505)

Action: For adoption

6.1.36. Hydroxycarbamide – SIKLOS (CAP); XROMI (CAP) – EMA/PSUR/0000296554

Applicants: Lipomed GmbH, Theravia

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00001692/202506)

Action: For adoption

6.1.37. Imetelstat – RYTELO (CAP) – EMA/PSUR/0000296613

Applicant: Geron Netherlands B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011117/202506)

Action: For adoption

6.1.38. Indacaterol / Glycopyrronium bromide / Mometasone – ENERZAIR BREEZHALER (CAP); ZIMBUS BREEZHALER (CAP) – EMA/PSUR/0000296547

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010861/202507)

Action: For adoption

6.1.39. Indacaterol / Mometasone – ATECTURA BREEZHALER (CAP); BEMRIST BREEZHALER (CAP) – EMA/PSUR/0000296553

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010850/202505)

Action: For adoption

6.1.40. Inebilizumab – UPLIZNA (CAP) – EMA/PSUR/0000296564

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010996/202506)

Action: For adoption

6.1.41. Insulin icodec – AWIQLI (CAP) – EMA/PSUR/0000296618

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011053/202505)

Action: For adoption

6.1.42. Iptacopan – FABHALTA (CAP) – EMA/PSUR/0000296594

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure (PSUSA/00011054/202506)

Action: For adoption

6.1.43. Larotrectinib – VITRAKVI (CAP) – EMA/PSUR/0000296535

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00010799/202505)

Action: For adoption

6.1.44. Latanoprost / Netarsudil – ROCLANDA (CAP) – EMA/PSUR/0000296556

Applicant: Santen Oy

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010905/202506)

Action: For adoption

6.1.45. Lazertinib – LAZCLUZE (CAP) – EMA/PSUR/0000296610

Applicant: Janssen Cilag International

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00011110/202505)

Action: For adoption

6.1.46. Levofloxacin – QUINSAIR (CAP) – EMA/PSUR/0000296515

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00010429/202505)

Action: For adoption

6.1.47. Lidocaine / Prilocaine – FORTACIN (CAP) – EMA/PSUR/0000296529

Applicant: Recordati Ireland Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00010110/202505)

Action: For adoption

6.1.48. Lonafarnib – ZOKINVY (CAP) – EMA/PSUR/0000296604

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011005/202505)

Action: For adoption

6.1.49. Lumacaftor / Ivacaftor – ORKAMBI (CAP) – EMA/PSUR/0000296584

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00010455/202505)

Action: For adoption

6.1.50. Luspatercept – REBLOZYL (CAP) – EMA/PSUR/0000296531

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00010860/202506)

Action: For adoption

6.1.51. Maribavir – LIVTENCITY (CAP) – EMA/PSUR/0000296562

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011024/202505)

Action: For adoption

6.1.52. Eplontersen – WAINZUA (CAP) – EMA/PSUR/0000296602

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011120/202506)

Action: For adoption

6.1.53. Mirabegron – BETMIGA (CAP) – EMA/PSUR/0000296505

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00010031/202506)

Action: For adoption

6.1.54. Mosunetuzumab – LUNSUMIO (CAP) – EMA/PSUR/0000296629

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010999/202506)

Action: For adoption

6.1.55. Onasemnogene abeparvovec – ZOLGENSMA (CAP) – EMA/PSUR/0000296536

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010848/202505)

Action: For adoption

6.1.56. Ozanimod – ZEPOSIA (CAP) – EMA/PSUR/0000296528

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00010852/202505)

Action: For adoption

6.1.57. Palopegteriparatide – YORVIPATH (CAP) – EMA/PSUR/0000296591

Applicant: Ascendis Pharma Bone Diseases A/S

PRAC Rapporteur: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure (PSUSA/00000173/202505)

Action: For adoption

6.1.58. Pandemic influenza vaccine (H5N1) (live attenuated, nasal) – PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) – EMA/PSUR/0000296545

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010501/202505)

Action: For adoption

6.1.59. Pegvaliase – PALYNZIQ (CAP) – EMA/PSUR/0000296541

Applicant: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00010761/202505)

Action: For adoption

6.1.60. Pertuzumab / Trastuzumab – PHESGO (CAP) – EMA/PSUR/0000296614

Applicant: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010906/202506)

Action: For adoption

6.1.61. Piflufolastat (^{18}F) – PYLCLARI (CAP) – EMA/PSUR/0000296490

Applicant: Curium Pet France

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00000097/202505)

Action: For adoption

6.1.62. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) – PREVENAR 20 (CAP) – EMA/PSUR/0000296603

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010981/202506)

Action: For adoption

6.1.63. Pneumococcal polysaccharide conjugate vaccine (21-valent) – CAPVAXIVE (CAP) – EMA/PSUR/0000296567

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00011121/202506)

Action: For adoption

6.1.64. Polatuzumab vedotin – POLIVY (CAP) – EMA/PSUR/0000296524

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010817/202506)

Action: For adoption

6.1.65. Quizartinib – VANFLYTA (CAP) – EMA/PSUR/0000296557

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00000176/202506)

Action: For adoption

6.1.66. Relugolix / Estradiol / Norethisterone acetate – RYEQO (CAP) – EMA/PSUR/0000296598

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010942/202505)

Action: For adoption

6.1.67. Respiratory syncytial virus mRNA vaccine (nucleoside modified) – MRESVIA (CAP) – EMA/PSUR/0000296622

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00011075/202505)

Action: For adoption

6.1.68. Respiratory syncytial virus vaccine (bivalent, recombinant) – ABRYSVO (CAP) – EMA/PSUR/0000296493

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000102/202505)

Action: For adoption

6.1.69. Rozanolixizumab – RYSTIGGO (CAP) – EMA/PSUR/0000296581

Applicant: UCB Pharma

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00000216/202506)

Action: For adoption

6.1.70. Satralizumab – ENSPRYNG (CAP) – EMA/PSUR/0000296560

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010944/202505)

Action: For adoption

6.1.71. Semaglutide – OZEMPIC (CAP); RYBELSUS (CAP); WEGOVY (CAP) – EMA/PSUR/0000296561

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010671/202505)

Action: For adoption

6.1.72. Sotorasib – LUMYKRAS (CAP) – EMA/PSUR/0000296611

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010970/202505)

Action: For adoption

6.1.73. Sugemalimab – CEJEMLY (CAP) – EMA/PSUR/0000296627

Applicant: Cstone Pharmaceuticals Ireland Limited

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00011080/202506)

Action: For adoption

6.1.74. Toripalimab – LOQTORZI (CAP) – EMA/PSUR/0000296630

Applicant: Topalliance Biosciences Europe Limited

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00011094/202506)

Action: For adoption

6.1.75. Trametinib – MEKINIST (CAP); SPEXOTRAS (CAP) – EMA/PSUR/0000296499

Applicant: Novartis Europharm Limited

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010262/202505)

Action: For adoption

6.1.76. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/PSUR/0000296589

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010894/202506)

Action: For adoption

6.1.77. Vadadustat – VAFSEO (CAP) – EMA/PSUR/0000296607

Applicant: Medice Arzneimittel Puetter GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00011050/202506)

Action: For adoption

6.1.78. Vutrisiran – AMVUTTRA (CAP) – EMA/PSUR/0000296597

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011021/202506)

Action: For adoption

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

6.2.1. Bromfenac – YELLOX (CAP); NAP – EMA/PSUR/0000296580

Applicants: Bausch + Lomb Ireland Limited, various

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000436/202505)

Action: For adoption

6.2.2. Human normal immunoglobulin – DEQSIGA (CAP); FLEBOGAMMA DIF (CAP); HIZENTRA (CAP); HYQVIA (CAP); KIOVIG (CAP); PRIVIGEN (CAP); NAP – EMA/PSUR/0000296525

Applicants: Takeda Manufacturing Austria AG, BAXALTA INNOVATIONS GmbH, CSL Behring GmbH, Instituto Grifols S.A., various

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00001633/202505)

Action: For adoption

6.2.3. Mycophenolate mofetil – CELLCEPT (CAP); MYCLAUSEN (CAP); MYCOPHENOLATE MOFETIL TEVA (CAP); MYFENAX (CAP); NAP – EMA/PSUR/0000296546

Applicants: Teva B.V., Roche Registration GmbH, Passauer Pharma GmbH, various

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00010550/202505)

Action: For adoption

6.2.4. Topotecan – HYCAMTIN (CAP); TOPOTECAN HOSPIRA (CAP); NAP – EMA/PSUR/0000296506

Applicants: Sandoz Pharmaceuticals d.d., Pfizer Europe MA EEIG, various

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00002997/202505)

Action: For adoption

6.2.5. Treprostinil sodium – TREPULMIX (CAP); NAP – EMA/PSUR/0000296507

Applicants: SciPharm S.a.r.l., various

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00003013/202505)

Action: For adoption

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

6.3.1. Amiloride (NAP); amiloride / furosemide (NAP); amiloride / hydrochlorothiazide (NAP); amiloride / hydrochlorthiazide / timolol (NAP); amiloride / bumetanide (NAP); amiloride / chlortalidone (NAP) – EMA/PSUR/0000296593

Applicants: various

PRAC Lead: Guðrún Stefánsdóttir

Scope: Evaluation of a PSUSA procedure (PSUSA/00000148/202506)

Action: For adoption

6.3.2. Azelaic acid (NAP) – EMA/PSUR/0000296491

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000276/202506)

Action: For adoption

6.3.3. Benzoyl peroxide / clindamycin phosphate (NAP) – EMA/PSUR/0000296608

Applicants: various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00000796/202505)

Action: For adoption

6.3.4. Bifonazole (NAP) – EMA/PSUR/0000296617

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000411/202505)

Action: For adoption

6.3.5. Caffeine / codeine / paracetamol / propyphenazone (NAP), acetylsalicylic acid / caffeine / codeine / paracetamol (NAP) – EMA/PSUR/0000296512

Applicants: various

PRAC Lead: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00002312/202506)

Action: For adoption

6.3.6. Calcipotriol (NAP) – EMA/PSUR/0000296620

Applicants: various

PRAC Lead: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00000492/202506)

Action: For adoption

6.3.7. Carmellose (eye preparation) (NAP) – EMA/PSUR/0000296572

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00000562/202506)

Action: For adoption

6.3.8. Cefixime (NAP) – EMA/PSUR/0000296579

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00000594/202506)

Action: For adoption

6.3.9. Ceftriaxone sodium / lidocaine hydrochloride (NAP) – EMA/PSUR/0000296550

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000614/202505)

Action: For adoption

6.3.10. Ciprofloxacin / dexamethasone (ear drops, suspension) (NAP) – EMA/PSUR/0000296519

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010012/202504)

Action: For adoption

6.3.11. Clotiazepam (NAP) – EMA/PSUR/0000296600

Applicants: various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00000827/202505)

Action: For adoption

6.3.12. Diphtheria / tetanus vaccines (adsorbed), diphtheria vaccines (adsorbed) (NAP) – EMA/PSUR/0000296575

Applicants: various

PRAC Lead: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00001128/202505)

Action: For adoption

6.3.13. Etamsylate (NAP) – EMA/PSUR/0000296606

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00001294/202506)

Action: For adoption

6.3.14. Etodolac (NAP) – EMA/PSUR/0000296549

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00001324/202505)

Action: For adoption

6.3.15. Fenticonazole (NAP) – EMA/PSUR/0000296592

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001371/202506)

Action: For adoption

6.3.16. Ferucarbotran (NAP) – EMA/PSUR/0000296616

Applicants: various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00001382/202506)

Action: For adoption

6.3.17. Flunisolide (NAP) – EMA/PSUR/0000296543

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00001417/202505)

Action: For adoption

6.3.18. Formoterol (NAP) – EMA/PSUR/0000296605

Applicants: various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00001469/202505)

Action: For adoption

6.3.19. Fotemustine (NAP) – EMA/PSUR/0000296596

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00001477/202506)

Action: For adoption

6.3.20. Fusidic acid (systemic use) (NAP) – EMA/PSUR/0000296498

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00010226/202505)

Action: For adoption

6.3.21. Gadobenic acid (NAP) – EMA/PSUR/0000296542

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00001500/202504)

Action: For adoption

6.3.22. Gadobutrol (NAP) – EMA/PSUR/0000296537

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00001502/202504)

Action: For adoption

6.3.23. Gadodiamide (NAP) – EMA/PSUR/0000296538

Applicants: various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00001503/202504)

Action: For adoption

6.3.24. Gadopentetic acid (NAP) – EMA/PSUR/0000296588

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00001504/202504)

Action: For adoption

6.3.25. Gadoteric acid (intra articular formulation) (NAP) – EMA/PSUR/0000296573

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001505/202504)

Action: For adoption

6.3.26. Gadoteric acid (IV and intravascular formulations) (NAP) – EMA/PSUR/0000296563

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001506/202504)

Action: For adoption

6.3.27. Gadoteridol (NAP) – EMA/PSUR/0000296571

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00001507/202504)

Action: For adoption

6.3.28. Gadoxetic acid disodium (NAP) – EMA/PSUR/0000296534

Applicants: various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00001509/202504)

Action: For adoption

6.3.29. Gemfibrozil (NAP) – EMA/PSUR/0000296533

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00001521/202505)

Action: For adoption

6.3.30. Hyoscine butylbromide / paracetamol (NAP) – EMA/PSUR/0000296523

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00002303/202505)

Action: For adoption

6.3.31. Indobufen (NAP) – EMA/PSUR/0000296521

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00001736/202505)

Action: For adoption

6.3.32. Ioversol (NAP) – EMA/PSUR/0000296526

Applicants: various

PRAC Lead: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00001775/202506)

Action: For adoption

6.3.33. Isradipine (NAP) – EMA/PSUR/0000296532

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00001797/202506)

Action: For adoption

6.3.34. Levofloxacin/dexamethasone (ocular use) (NAP) – EMA/PSUR/0000296624

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010881/202506)

Action: For adoption

6.3.35. Levomethadone (NAP) – EMA/PSUR/0000296494

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00001855/202505)

Action: For adoption

6.3.36. Levonorgestrel (for emergency contraception only) (NAP) – EMA/PSUR/0000296539

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010827/202505)

Action: For adoption

6.3.37. Levosulpiride (NAP); sulpiride (NAP) – EMA/PSUR/0000296527

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00001859/202506)

Action: For adoption

6.3.38. Lodoxamide (NAP) – EMA/PSUR/0000296522

Applicants: various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001898/202506)

Action: For adoption

6.3.39. Magnesium pidolate (NAP) – EMA/PSUR/0000296501

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00010041/202506)

Action: For adoption

6.3.40. Mebendazole (NAP) – EMA/PSUR/0000296583

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00001939/202505)

Action: For adoption

6.3.41. Methadone (NAP) – EMA/PSUR/0000296520

Applicants: various

PRAC Lead: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00002004/202505)

Action: For adoption

6.3.42. Methoxyflurane (NAP) – EMA/PSUR/0000296548

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010484/202505)

Action: For adoption

6.3.43. Metolazone (NAP) – EMA/PSUR/0000296530

Applicants: various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00002037/202506)

Action: For adoption

6.3.44. Misoprostol (gynaecological indication - labour induction) (NAP) – EMA/PSUR/0000296504

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010353/202505)

Action: For adoption

6.3.45. Nicardipine (NAP) – EMA/PSUR/0000296516

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00002149/202505)

Action: For adoption

6.3.46. Nicergoline (NAP) – EMA/PSUR/0000296517

Applicants: various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00002150/202505)

Action: For adoption

6.3.47. Ozenoxacin (NAP) – EMA/PSUR/0000296540

Applicants: various

PRAC Lead: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00010651/202505)

Action: For adoption

6.3.48. Pneumococcal polysaccharide vaccine (NAP) – EMA/PSUR/0000296552

Applicants: various

PRAC Lead: Pernille Harg

Scope: Evaluation of a PSUSA procedure (PSUSA/00002453/202505)

Action: For adoption

6.3.49. Rifaximin (NAP) – EMA/PSUR/0000296518

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00002642/202505)

Action: For adoption

6.3.50. Sertaconazole (NAP) – EMA/PSUR/0000296509

Applicants: various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00002694/202506)

Action: For adoption

6.3.51. Solifenacin (NAP) – EMA/PSUR/0000296513

Applicants: various

PRAC Lead: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00002769/202506)

Action: For adoption

6.3.52. Somatostatin (NAP) – EMA/PSUR/0000296510

Applicants: various

PRAC Lead: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00002771/202506)

Action: For adoption

6.3.53. Tamoxifen (NAP) – EMA/PSUR/0000296514

Applicants: various

PRAC Lead: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00002846/202504)

Action: For adoption

6.3.54. Ticlopidine (NAP) – EMA/PSUR/0000296508

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00002952/202505)

Action: For adoption

6.3.55. Torasemide (NAP) – EMA/PSUR/0000296503

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00002998/202506)

Action: For adoption

6.3.56. Valsartan (NAP) ; hydrochlorothiazide / valsartan (NAP) – EMA/PSUR/0000296497

Applicants: various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010396/202504)

Action: For adoption

6.3.57. Zotepine (NAP) – EMA/PSUR/0000296511

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00003154/202505)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

None

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Sapropterin – KUVAN (CAP) – EMA/VR/0000301983

Applicant: Biomarin International Limited

PRAC Rapporteur: Eamon O Murchu

Scope: Update of section 4.6 of the SmPC in order to update pregnancy information based on a cumulative pregnancy data analysis, following the PRAC request in the PSUR assessment for PSUR/0000257835. In addition, the MAH took the opportunity to introduce a minor editorial change to the PI.

Action: For adoption

6.5.2. Tafamidis – VYNDAQEL (CAP) – EMA/VR/0000297114

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Zoubida Amimour

Scope: Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on co-administration tafamidis meglumine/tafamidis and BCRP substrates, update drug-drug interaction information with BCRP sustrates following the PRAC PSUR assessment report for procedure no.: EMEA/H/C/PSUSA/00002842/202405. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the European Medicines Agency website address in line with the latest EU CP QRD template version 10.4.

Action: For adoption

6.6. Expedited summary safety reviews[3]

None

7. Post-authorisation safety studies (PASS)

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

None

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

7.2.1. Abaloparatide – ELADYNOS (CAP) – EMA/PAM/0000281538

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Karin Erneholm

Scope: Protocol amendment for Study EUPAS1000000613 (MEA 001: European non-interventional post-authorization safety study (PASS) to evaluate cardiovascular (CV) events in patients newly exposed to abaloparatide or teriparatide)

[3] Submission of expedited summary safety reports for review in addition to the requirements for submission of PSUR(s) falling within the pandemic period and requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC
[4] In accordance with Article 107n of Directive 2001/83/EC
[5] In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

Action: For adoption

7.2.2. Alemtuzumab – LEMTRADA (CAP) – EMA/PAM/0000303207

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the initial protocol and Statistical Analysis Plan for a substudy of LEMPASS (OBS13434/EUPAS7346): an external comparison cohort study to support the contextualization of the long-term safety profile of LEMTRADA® (alemtuzumab) in patients with relapsing forms of multiple sclerosis

Action: For adoption

7.2.3. Chikungunya vaccine (live) – IXCHIQ (CAP) – EMA/PAM/0000284934

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of the protocols for the post-authorisation safety studies VLA1553-403 (version 4.0) and VLA1553-406 (version 4.0) which are category 3 studies in the RMP. VLA1553-403 is an observational study to evaluate the safety of VLA1553 in pregnant women exposed to the vaccine in Brazil. VLA1553-406 is a prospective safety cohort study.

Action: For adoption

7.2.4. Chikungunya vaccine (recombinant, adsorbed) – VIMKUNYA (CAP) – EMA/PAM/0000276447

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the protocol for the post-authorisation safety study BN-CV-317-011 (version 1.0) which is a category 3 study in the RMP. BN-CV-317-011 is an observational prospective study to evaluate the safety of Vimkunya in pregnant women and their offspring.

Action: For adoption

7.2.5. COVID-19 mRNA vaccine – KOSTAIVE (CAP) – EMA/PAM/0000310312

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Protocol for PASS Category 3 study V206_06, a retrospective post-authorisation safety study to assess the risk of cardiac inflammatory and thromboembolic events following vaccination with sa-mRNA COVID-19 vaccine in adult individuals, reflected as a milestone in the Risk Management Plan.

Action: For adoption

7.2.6. COVID-19 vaccine (recombinant, adjuvanted) – BIMERVAX (CAP) – EMA/PAM/0000310979

Applicant: Hipra Human Health S.L.

PRAC Rapporteur: Zane Neikena

Scope: Submission of protocol version 3.0 for the non-imposed, non-interventional, category 3 post authorisation observational study to assess the safety of Bimervax using electronic health record (HER) databases in Europe (PASS VAC4EU).

Action: For adoption

7.2.7. Crovalimab – PIASKY (CAP) – EMA/PAM/0000281171

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Responses to the List of Questions raised in the assessment report of EMEA/H/C/006061/MEA/002 and submission of the revised draft non-interventional-PASS protocol MO45473. This is a post-authorization safety study (PASS) to characterize safety events and special conditions such as pregnancy and infant outcomes, in paroxysmal nocturnal hemoglobinuria (PNH) patients treated with crovalimab within the IPIG registry (Study MO45473).

Action: For adoption

7.2.8. Etranacogene dezaparvovec – HEMGENIX (CAP) – EMA/PAM/0000248926

Applicant: CSL Behring GmbH

PRAC Rapporteur: Bianca Mulder

Scope: The MAH submitted a PASS protocol (version 1.0), which covers a Healthcare Professional Survey (HCP) to assess the effectiveness of the additional Risk Minimization Measures (aRMM) for Hemgenix (etranacogene dezaparvovec).

Action: For adoption

7.2.9. Guselkumab – TREMFYA (CAP) – EMA/PAM/0000308163

Applicant: Janssen Cilag International

PRAC Rapporteur: Dirk Mentzer

Scope: Protocol update for PCSIMM001324 - A Retrospective Cohort Study Using Health Administrative Claims Databases to Assess Adverse Pregnancy and Infant Outcomes in Women Who Were Exposed to Guselkumab Versus Other Biologic Therapies During Pregnancy

Action: For adoption

7.2.10. Human thrombin / Human fibrinogen – TACHOSIL (CAP) – EMA/PAM/0000247840

Applicant: Corza Medical GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Revised protocol for PASS PasTel: Short- and long-term safety evaluation of TachoSil in paediatric population

Action: For adoption

7.2.11. Miglustat – OPFOLDA (CAP) – EMA/PAM/0000303344

Applicant: Amicus Therapeutics Europe Limited

PRAC Rapporteur: Mari Thorn

Scope: Submission of protocol for POM-005 Registry, a global prospective observational registry of patients with Pompe disease.

Action: For adoption

7.2.12. Respiratory syncytial virus vaccine (bivalent, recombinant) – ABRYSVO (CAP) – EMA/PAM/0000303298

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Study protocol (Version 2.0) and first progress report for PASS C3671038, a post-authorisation safety study of ABRYSVO in immunocompromised, or renally or hepatically impaired older adults aged 60 years and older in a real world setting in Europe and UK.

Action: For adoption

7.2.13. Risankizumab – SKYRIZI (CAP) – EMA/PAM/0000309550

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Protocol amendment for Study P16-751: Pregnancy Exposures and Outcomes in Women with Psoriasis Treated with Risankizumab: A Cohort Study Utilizing Large Electronic Healthcare Databases with Mother-Baby Linkage in the United States.

Action: For adoption

7.2.14. Risankizumab – SKYRIZI (CAP) – EMA/PAM/0000310075

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Protocol amendment for study P23-653: Pregnancy Exposures and Outcomes in Women with Inflammatory Bowel Disease Treated with Risankizumab.

Action: For adoption

7.2.15. Semaglutide – RYBELSUS (CAP) – EMA/PAM/0000301197

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Protocol amendment for study NN9535-4447: Epidemiological assessment of the risk for pancreatic cancer associated with the use of semaglutide in patients with type 2 diabetes - A cohort study based on Nordic registry data.

Action: For adoption

7.2.16. Semaglutide – OZEMPIC (CAP) – EMA/PAM/0000295858

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Protocol amendment for Study NN9535-4447: Epidemiological assessment of the risk for pancreatic cancer associated with the use of semaglutide in patients with type 2 diabetes - A cohort study based on Nordic registry data.

Action: For adoption

7.2.17. Teprotumumab – TEPEZZA (CAP) – EMA/PAM/0000310214

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Draft protocol for PASS (non-imposed) 20250081: Drug utilization study to evaluate the effectiveness of teprotumumab aRMMs.

Action: For adoption

7.2.18. Vutrisiran – AMVUTTRA (CAP) – EMA/PAM/0000301789

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Amendment of the study protocol of Prospective observational study to monitor and assess the safety of Amvuttra® [vutrisiran] in a real-world cohort of ATTR amyloidosis patients Protocol version 2.0 dated 09 September 2025

Action: For adoption

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

7.3.1. Belimumab – BENLYSTA (CAP) – EMA/PASS/0000306411

Applicant: Glaxosmithkline (Ireland) Limited

PRAC Rapporteur: Karin Bolin

Scope: PASS results [107q]: A 5-Year prospective observational registry to assess adverse events of interest and effectiveness in adults with active, autoantibody-positive systemic Lupus erythematosus treated with or without BENLYSTA (belimumab)

Action: For adoption

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

7.4.1. Adalimumab – IMRALDI (CAP) – EMA/VR/0000282472

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Karin Bolin

Scope: A grouped application comprised of:

Type II (C.I.13): Submission of the final report from study (ARTIS) listed as a category 3 study in the RMP. This is a nation-wide safety monitoring of Imraldi treatment in patients with Rheumatic diseases in Sweden. The RMP version 8.0 has been updated accordingly.

Type II (C.I.13): Submission of the final report from study (BIOBADASER) listed as a category 3 study in the RMP. This is a Spanish register of adverse events with targeted DMARD therapies in rheumatic diseases. The RMP version 8.0 has been updated accordingly.

Type IB (C.I.11) for RMP: Submission of an updated RMP version 8.0 in order to reflect the changes made in the RMP of the reference product Humira.

Action: For adoption

7.4.2. Arsenic trioxide – TRISENOX (CAP) – EMA/VR/0000281747

Applicant: Teva B.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of section 4.8 of the SmPC to update the safety information based on the final results from PASS C18477-ONC-50025 listed as a category 3 study in the RMP; this is an observational Post-Authorisation Long-Term Retrospective Safety Cohort Study of Arsenic Trioxide in First Line Low-to-Intermediate-Risk Acute Promyelocytic Leukaemia (APL) Patients. The updated RMP version 3.0 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.

[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

Action: For adoption

7.4.3. COVID-19 mRNA vaccine – SPIKEVAX (CAP) – EMA/VR/0000264109

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: A grouped application consisting of:

C.I.4 Update of section 4.8 of the SmPC in order to update the frequency of the adverse reactions ''Anaphylaxis'' and ''Erythema multiforme'' from ''Not known'' to ''Rare'', based on final results from study mRNA-1273-P904 listed as a category 3 study in the RMP. This is a Non-Interventional, Post-Authorisation Active Surveillance Safety Study Using Secondary Data to Monitor Real-World Safety of the mRNA-1273 Vaccine in the EU. The Package leaflet is updated accordingly. An updated RMP (version 11.0) is also included.

C.I.13: Submission of the final report from study mRNA-1273-P905 (Monitoring safety of COVID-19 Vaccine Moderna in pregnancy: an observational study using routinely collected health data in five European countries) listed as a category 3 study in the RMP.

Action: For adoption

7.4.4. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/VR/0000302705

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final report, protocol amendment #6 and SAP amendment #5 for the non-interventional study C4591021, listed as a category 3 PASS in the RMP. This is a post conditional approval active surveillance study among individuals in Europe receiving the Pfizer BioNTech Coronavirus Disease 2019 (COVID-19) vaccine. The RMP version 15.1 has also been submitted.

Action: For adoption

7.4.5. Darbepoetin alfa – ARANESP (CAP) – EMA/VR/0000301503

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of the final report from study 20190404 listed as a category 3 PASS in the RMP. This is a retrospective, multicentre, observational chart review study to assess the use of erythropoiesis stimulating agents (ESAs) in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy in Europe. The RMP version 11.0 has also been submitted.

Action: For adoption

7.4.6. Emicizumab – HEMLIBRA (CAP) – EMA/VR/0000302494

Applicant: Roche Registration GmbH

PRAC Rapporteur: Amelia Cupelli

Scope: Submission of the final report from study MO40685 (PedNet) listed as a category 3 study in the RMP. This is a non-interventional, secondary data use post-authorization safety study (PASS) relying on data collected as part of the PedNet Registry. The RMP version 6.0 has also been submitted.

Action: For adoption

7.4.7. Laronidase – ALDURAZYME (CAP) – EMA/VR/0000282056

Applicant: Sanofi B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Submission of the final report from PASS study ALID01803 listed as a category 3 study in the RMP. This is an observational, open-label study of the effects of Aldurazyme (laronidase) treatment on lactation in postpartum women with Mucopolysaccharidosis Type I and their breastfed infants. This study is to determine whether laronidase activity was present in the breast milk of mothers with MPS I disease and whether Aldurazyme affected the growth, development, and immunologic response of breastfed infants. The RMP version 2.0 has also been submitted.

Action: For adoption

7.4.8. 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. Abrocitinib – CIBINQO (CAP) – EMA/PAM/0000310297

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: Submission of the first progress report for PASSB7451084, entitled 'An Active Surveillance Study to Monitor the Safety of Abrocitinib Among Real-World Patients with Atopic Dermatitis (AD) in the European Union (EU)'

Action: For adoption

7.5.2. Abrocitinib – CIBINQO (CAP) – EMA/PAM/0000310306

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: Submission of the first progress report for PASS B7451085, entitled 'A Drug Utilization Study to Evaluate the Effectiveness of Risk Minimization Measures (RMMs) for Abrocitinib in the EU Using Electronic Healthcare Data'

Action: For adoption

7.5.3. Bimekizumab – BIMZELX (CAP) – EMA/PAM/0000302071

Applicant: UCB Pharma

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the first annual recruitment report for PS0036; a Bimekizumab Pregnancy Exposure and Outcome Registry: An OTIS Autoimmune Diseases in Pregnancy Study. The objective of this study is to assess maternal, foetal and infant outcomes among people who become pregnant while exposed to bimekizumab relative to the outcomes in 2 matched comparator populations.

Action: For adoption

7.5.4. Ciltacabtagene autoleucel – CARVYKTI (CAP) – EMA/PAM/0000286337

Applicant: Janssen Cilag International, ATMP

PRAC Rapporteur: Jo Robays

Scope: Post-authorization Safety Study Survey (Study PCSONCA0014) to Evaluate the Effectiveness of the Ciltacabtagene Autoleucel HCP Educational Program and the Product Handling Training. Submission of first interim report.

Action: For adoption

7.5.5. COVID-19 mRNA vaccine – SPIKEVAX (CAP) – EMA/PAM/0000309160

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Submission of the fourth interim update for study mRNA-1273-P911 (long-term outcomes of myocarditis following administration of Spikevax) and the responses to the RSI adopted in procedure MEA/066.4 for Spikevax.

Action: For adoption

7.5.6. Damoctocog alfa pegol – JIVI (CAP) – EMA/PAM/0000303584

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Fourth interim report of study number 20904 (HA-SAFE), 'Observational study evaluating long-term safety of real-world treatment with damoctocog alfa pegol in previously treated patients with hemophilia A'. The HA-SAFE study is a post-authorisation measure defined in Annex II.D of the Jivi EU PI.

Action: For adoption

7.5.7. Daratumumab – DARZALEX (CAP) – EMA/PAM/0000310226

Applicant: Janssen Cilag International

PRAC Rapporteur: Carla Torre

Scope: Submission of Erratum PSUR/PBRER report for daratumumab, including data which were inadvertently omitted from the last submitted PSUR/PBRER report covering the period 16 November 2022 to 15 November 2024.

Action: For adoption

7.5.8. Difelikefalin – KAPRUVIA (CAP) – EMA/PAM/0000307833

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: Development Safety Update Report No.12 (23 August 2024 to 22 August 2025) for study CR845- 310601 - A 2-part, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy and Safety of Oral Difelikefalin for Moderate-to-Severe Pruritus in Adult Subjects With Notalgia Paresthetica.

This submission concerns DSUR v 12.0.

Action: For adoption

7.5.9. Dulaglutide – TRULICITY (CAP) – EMA/PAM/0000303057

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: EMEA/H/C/002825/MEA/006 - H9X-MC-B013 - Dulaglutide and Potential Risks of Pancreatic Cancer and Thyroid Cancer: A Non-Interventional Post-Authorisation Safety Study (PASS), 1st interim report

Action: For adoption

7.5.10. Emicizumab – HEMLIBRA (CAP) – EMA/PAM/0000307773

Applicant: Roche Registration GmbH

PRAC Rapporteur: Amelia Cupelli

Scope: 6th Interim clinical study report (CSR) of Hemlibra (emicizumab) EUHASS registry study, submitted as per the obligation set out in Article 46 of Regulation (EC) No 1901/2006 as a 'standalone' post-authorisation measure (PAM) application.

Action: For adoption

7.5.11. Enfortumab vedotin – PADCEV (CAP) – EMA/PAM/0000314208

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Final study report: A Non-Interventional Post-Authorization Safety Study (NI-PASS) as an Effectiveness Check of a Patient Card for Padcev™ (ISN: 7465-PV-0002)

Action: For adoption

7.5.12. Ketoconazole – KETOCONAZOLE ESTEVE (CAP) – EMA/PAM/0000312512

Applicant: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Petar Mas

Scope: Eighth Interim Annual Report covering the period from 01 September 2018 to 31 August 2025. - Study ERCUSYN

PASS EUPAS21731

Prospective, multi-country, observational registry to collect clinical information on patients with endogenous Cushing's syndrome exposed to Ketoconazole (using the existing European Registry on Cushing's Syndrome (ERCUSYN)), to assess drug utilization pattern and to document the safety (e.g. hepatotoxicity, QT prolongation) and effectiveness of Ketoconazole.

Action: For adoption

7.5.13. Neratinib – NERLYNX (CAP) – EMA/PAM/0000281194

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Bianca Mulder

Scope: Interim report of the NER7402 (NERLYFE) study, a category 3 PASS: a multicentre, multi-country, prospective, observational, post-authorisation safety study to describe the incidence of discontinuation due to diarrhoea within the first 3 months of a treatment with neratinib, in adult breast cancer patients treated in extended adjuvant in a real world setting.

Interim report for the combined NERLYFE/ELEANOR study, a category 3 PASS. The ELEANOR study is a multi-centric, multi-national, prospective, longitudinal, non-interventional study in

Austria, Germany and Switzerland conducted with neratinib in patients with HER2+ breast cancer.

Action: For adoption

7.5.14. Niraparib / Abiraterone acetate – AKEEGA (CAP) – EMA/PAM/0000302057

Applicant: Janssen Cilag International

PRAC Rapporteur: Jan Neuhauser

Scope: Interim Study report for PCSONCA0485: Post authorization safety study to characterize the risk of second primary malignancies (SPM) including MDS/AML among metastatic prostate cancer patients exposed to AKEEGA.

Action: For adoption

7.5.15. Ofatumumab – KESIMPTA (CAP) – EMA/PAM/0000308145

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: First Annual Interim Study Report for long-term PASS, study COMB157G2406 entitled Kesimpta long-term retrospective safety study utilizing real-world data from existing multiple sclerosis registries and databases from multiple countries

Action: For adoption

7.5.16. Patisiran – ONPATTRO (CAP) – EMA/PAM/0000306413

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: 5th Interim study report of Study ALN-TTR02-010

Description: Patisiran-LNP Pregnancy Surveillance Program.

To collect primary data on pregnant women from the US, the United Kingdom (UK), France, Spain, Italy, Portugal and Germany, and other potential countries, who have been exposed to patisiran during the exposure window, defined as 12 weeks prior to their last menstrual period (LMP), or at any time during pregnancy. Establish a worldwide Pregnancy Surveillance Program (PSP) to collect and analyze information pertaining to pregnancy complications and birth outcomes in women exposed to patisiran during pregnancy. The collection and analysis of data should continue for a minimum of 10 years.

Action: For adoption

7.5.17. Selumetinib – KOSELUGO (CAP) – EMA/PAM/0000302968

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: SOB, PASS category 2, Study number: D1346R00004.

Interim Report and APR3: Post-Authorisation Safety Study of Paediatric Patients Initiating Selumetinib: A Multiple-Country Prospective Cohort Study. As per Koselugo Study milestones listed in the RMP and PASS protocol, the interim report APR3 is due in Q3 2025.

Action: For adoption

7.5.18. Sutimlimab – ENJAYMO (CAP) – EMA/PAM/0000273920

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Jan Neuhauser

Scope: 3rd Annual interim report for the sutimlimab Cold Agglutinin Disease Real World Evidence Registry (CADENCE, OBS16454) a multinational, multi-center, observational, prospective, longitudinal disease registry; former MEA 003.2.

Action: For adoption

7.5.19. Upadacitinib – RINVOQ (CAP) – EMA/PAM/0000301869

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Annual progress report for PASS study P21-825: Drug Utilization Study Evaluating the Additional Risk Minimisation Measures for Upadacitinib in the Treatment of Atopic Dermatitis in Europe

Action: For adoption

7.5.20. Upadacitinib – RINVOQ (CAP) – EMA/PAM/0000301747

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Interim study report for PASS study P19-150: Long-term safety cohort studies of upadacitinib use for the treatment of RA in Europe

Action: For adoption

7.5.21. Upadacitinib – RINVOQ (CAP) – EMA/PAM/0000301931

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Annual progress report for PASS study P20-390: a cohort study of long-term safety of upadacitinib in the treatment of atopic dermatitis in Denmark and Sweden

Action: For adoption

7.5.22. Upadacitinib – RINVOQ (CAP) – EMA/PAM/0000303398

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Annual progress report for PASS study P24-344: Drug utilization study evaluating additional risk minimisation measures for upadacitinib in the treatment of Ulcerative Colitis in Europe

Action: For adoption

7.5.23. Ustekinumab – STELARA (CAP) – EMA/PAM/0000310166

Applicant: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Second interim report for an Observational Postauthorization Safety Study To Describe The Safety Of Ustekinumab and Other Biologic Treatments in a Cohort of Patients With Ulcerative Colitis or Crohn's Disease Using Compulsory Swedish Nationwide Healthcare Registers and the Independent Swedish National Quality Register for Inflammatory Bowel Disease (SWIBREG; PCSIMM002807); former MEA 047.

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. 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

8.1.2. Lonafarnib – ZOKINVY (CAP) – EMA/S/0000306613

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. Metreleptin – MYALEPTA (CAP) – EMA/S/0000302645

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.4. Odevixibat – KAYFANDA (CAP) – EMA/S/0000306639

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.5. Tocofersolan – VEDROP (CAP) – EMA/S/0000304509

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Melinda Palfi

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

8.2.1. Andexanet alfa – ONDEXXYA (CAP) – EMA/R/0000308136

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.2. 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

8.2.3. Pandemic influenza vaccine (H5N1) (live attenuated, nasal) – PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) – EMA/R/0000313191

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.4. Volanesorsen – WAYLIVRA (CAP) – EMA/R/0000308372

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Azathioprine – JAYEMPI (CAP) – EMA/R/0000296298

Applicant: Lipomed GmbH

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

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

Applicant: UCB Pharma

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.3. Odevixibat – BYLVAY (CAP) – EMA/R/0000306638

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.4. Pitolisant – OZAWADE (CAP) – EMA/R/0000304208

Applicant: Bioprojet Pharma

PRAC Rapporteur: Terhi Lehtinen

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Relugolix / Estradiol / Norethisterone acetate – RYEQO (CAP) – EMA/R/0000304469

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. Roxadustat – EVRENZO (CAP) – EMA/R/0000304810

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Jana Pecherova

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.7. 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

8.3.8. 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

8.3.9. Vericiguat – VERQUVO (CAP) – EMA/R/0000304275

Applicant: Bayer AG

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 Member States, CHMP or the EMA

10.1.1. Lithium sulphate (NAP) - SE/H/xxxx/WS/943

Applicant: Karo Pharma AB (Lithionit)

PRAC Lead: Karin Bolin

Scope: PRAC consultation on a worksharing variation procedure (SE/H/xxxx/WS/943) to update the product information regarding the development of Darier disease following administration of lithium containing products, at request of Sweden.

Action: For adoption

11. Scientific advice procedures

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

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC membership

Action: For information

12.1.2. Vote by proxy

Action: For information

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

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

None

12.4. Cooperation within the EU regulatory network

None

12.5. Cooperation with International Regulators

None

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

None

12.7. PRAC work plan

12.7.1. PRAC work plan 2026

PRAC lead: Ulla Wändel Liminga, Liana Martirosyan

Action: For adoption

12.8. Planning and reporting

12.8.1. Marketing authorisation applications (MAA) forecast for 2025 – planning update dated 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

12.11. Signal management

None

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. PRAC Risk Minimisation Alliance (PRISMA) - Mandate for operational phase

PRAC leads: Ulla Wändel Liminga, Liana Martirosyan

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)