6 March 2026
EMA/PRAC/42166/2026
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 9-12 March 2026

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

09 March 2026, 09:30 – 19:30, via teleconference

10 March 2026, 08:30 – 19:30, via teleconference

11 March 2026, 08:30 – 19:30, via teleconference

12 March 2026, 08:30 – 16:00, via teleconference

Organisational, regulatory and methodological matters (ORGAM)

26 March 2026, 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 9-12 March 2026. See March month 2026 PRAC minutes (to be published post April 2026 PRAC meeting).

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

Action: For adoption

1.3. Minutes of the previous meeting on 09-12 February 2026

Action: For adoption

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

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

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

3.1. Newly triggered procedure

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination 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. Gemcitabine (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

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

Action: For adoption

EPITT 20256 – New signal

Lead Member State(s): SE

4.1.2. Levonorgestrel intrauterine device 13.5 mg (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of increased risk of ectopic pregnancy

Action: For adoption

EPITT 20251 – 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

4.2. Signals follow-up and prioritisation

4.2.1. Galantamine (NAP)

Applicant(s): various

PRAC Rapporteur: Karin Bolin

Scope: Signal of nightmares

Action: For adoption

EPITT 20196 – Follow-up to September 2025

4.2.2. Chikungunya vaccine (live) - IXCHIQ (CAP) - EMEA/H/C/000829/SDA/013

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Dirk Mentzer

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

Action: For adoption

EPITT 20250 – Follow up to February 2026

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. Allogeneic faecal microbiota, pooled (CAP MAA) - EMEA/H/C/006678, Orphan

Scope (pre D-180 phase): Treatment of adult patients with acute-graft-versus-host disease (aGvHD)

Action: For adoption

5.1.2. Autologous melanoma-derived tumor infiltrating lymphocytes, ex vivo-expanded (CAP MAA) - EMEA/H/C/006563

ATMP

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

Action: For adoption

5.1.3. Camizestrant (CAP MAA) - EMEA/H/C/006494

Scope (pre D-180 phase): Treatment of adults with locally advanced or metastatic breast cancer

Action: For adoption

5.1.4. *Clostridium botulinum*, serotype E, neurotoxin (150 kDa) (CAP MAA) - EMEA/H/C/006420

Scope (pre D-180 phase): Temporary improvement in the appearance of moderate to severe lines between the eyebrows

Action: For adoption

5.1.5. Linerixibat (CAP MAA) - EMEA/H/C/006241, Orphan

Scope (pre D-180 phase): Treatment of cholestatic pruritus in adult patients with primary biliary cholangitis

Action: For adoption

5.1.6. Zopapogene imadenovec (CAP MAA) - EMEA/H/C/006508, Orphan

ATMP

Scope (pre D-120 phase): Treatment of respiratory papillomatosis in adults

Action: For adoption

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

5.2.1. 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

5.2.2. 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

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

Applicant: Sanofi-Aventis Deutschland GmbH

PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

5.2.4. Lenalidomide – LENALIDOMIDE KRKA (CAP); NAP – EMA/VR/0000310403

Applicants: KRKA tovarna zdravil d.d. Novo mesto, various

PRAC Rapporteur: Tiphaine Vaillant

Scope: C.I.11.z - to update Annex IID and the RMP following the outcome of the renewal procedure (EMA/R/0000272358). The RMP has been updated in accordance with the changes to the reference product's RMP as requested.

Action: For adoption

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

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: A grouped application consisting of:

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

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

Action: For adoption

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

5.3.1. Beclometasone / Formoterol / Glycopyrronium bromide – TRIMBOW (CAP) – EMA/VR/0000315173

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include treatment of asthma for TRIMBOW 88/5/9 mcg DPI, based on existing data from the development of Trimbow 87/5/9 mcg pressurised metered dose inhaler in COPD and Asthma, Trimbow 172/5/9 mcg pressurised metered dose inhaler in Asthma and Trimbow 88/5/9 mcg Dry powder inhale in COPD, as well as on new data coming from the PK 2 study (CLI-05993BB1-01) and on the interim results of the ongoing PASS (TRIBE) study in COPD. As a consequence, sections 4.1, 4.2, 4.4, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 11.1 of the RMP has also been submitted.

Action: For adoption

5.3.2. Bulevirtide – HEPCLUDEX (CAP) – EMA/VR/0000320140

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application consisting of:

C.I.4: Update of section 4.8 of the SmPC in order to remove a statement regarding bile acid elevations based on results from study MYR301, listed as a Category 3 study in the RMP. This is a Multicenter, Open-label, Randomized Phase 3 Clinical Study to Assess Efficacy and Safety of Bulevirtide in Patients With Chronic Hepatitis Delta to address the safety concern of 'Long-term safety of bile acid elevations' (Missing information). The RMP version 7.1 has also been submitted.

C.I.11.b: Submission of an updated RMP version 7.1 in order to propose the removal of Study GS-US-589-6206 as a Category 3 Pharmacovigilance Commitment from the RMP for safety concern of 'Long-term safety of bile acid elevations' (Missing information).

Action: For adoption

5.3.3. Datopotamab deruxtecan – DATROWAY (CAP) – EMA/VR/0000316654

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include, as monotherapy, the first-line treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy for DATROWAY, based on final results from study D926PC00001 (TROPION-Breast02). This is a Phase 3, randomised, open-label, 2 arm, multicentre, international study assessing the efficacy and safety of Dato-DXd compared with investigator's choice chemotherapy in participants with locally recurrent inoperable or

metastatic TNBC who are not candidates for PD-1/PD-L1 inhibitor therapy. 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 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.4. Delgocitinib – ANZUPGO (CAP) – EMA/VR/0000315280

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include treatment of adolescents 12 years and older with moderate to severe chronic hand eczema (CHE) for whom topical corticosteroids are inadequate or inappropriate for ANZUPGO, based on final results from study LP0133-1426 (DELTA TEEN); this is a phase 3 pivotal clinical trial to evaluate efficacy and safety of twice-daily applications of delgocitinib cream compared with cream vehicle for a 16-week treatment period in adolescents 12-17 years of age with moderate to severe chronic hand eczema. The trial is a randomized, double-blind, vehicle-controlled study. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 1.1 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.

Action: For adoption

5.3.5. 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

5.3.6. Dimethyl fumarate – TECFIDERA (CAP) – EMA/VR/0000320745

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Dennis Lex

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

Action: For adoption

5.3.7. Glecaprevir / Pibrentasvir – MAVIRET (CAP) – EMA/VR/0000316551

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension of indication to include treatment of Acute HCV for MAVIRET, based on final results from study M20-350; this is a multicenter, single-arm prospective study to evaluate safety and efficacy of GLE/PIB 8-week treatment in adults and adolescents with acute hepatitis C virus (HCV) infection. 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 10.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.8. Ipilimumab – YERVOY (CAP); Nivolumab – OPDIVO (CAP) – EMA/VR/0000319172

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add 'Myocarditis-Myositis-Myasthenia Gravis Overlap Syndrome' to the list of adverse drug reactions (ADRs) with frequency 'Uncommon' based on postmarketing data and literature. The Package Leaflet is updated accordingly. The RMP version 46 and 52 respectively, had also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

Action: For adoption

5.3.9. 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

5.3.10. Ivacaftor / Tezacaftor / Elexacaftor – KAFTRIO (CAP) – EMA/VR/0000320413

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Dennis Lex

Scope: Submission of Part A (week 96) clinical study report for study VX21-445-125 (study 125). This is a Phase 3, open-label study to evaluate the long-term safety, tolerability, efficacy, and pharmacodynamics of elexacaftor/tezacaftor/ivacaftor (ELX/TEZ/IVA) in cystic fibrosis (CF) subjects ≥6 years of age who have qualifying non-F508del ELX/TEZ/IVA-responsive CFTR mutations. RMP version 10.3 has also been submitted.

Action: For adoption

5.3.11. Lumacaftor / Ivacaftor – ORKAMBI (CAP) – EMA/VR/0000320822

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Eamon O Murchu

Scope: Submission of the final report from study VX18-809-128 (study 128), listed as an obligation in the Annex II of the Product Information. This is a 6-year, observational, post-authorization efficacy study (PAES) in young children with cystic fibrosis (CF) aged 1 through 5 years at the time of Orkambi initiation. This study evaluated disease progression and safety using observational cohorts of children receiving therapy in a "real-world" setting. The Annex II and the RMP version 12.0 are updated accordingly.

Action: For adoption

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

Applicant: Novartis Europharm Limited

PRAC Rapporteur: John Joseph Borg

Scope: Extension of indication to include treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after having progressed on androgen receptor pathway inhibitor (ARPI) and for whom chemotherapy is not yet clinically indicated for PLUVICTO, based on interim results from study CAAA617B12302 (PSMAfore); this is a phase III, open-label, multi-center, randomized study comparing 177Lu-PSMA-617 vs. a change of androgen receptor-directed therapy in the treatment of taxane naïve men with progressive metastatic castrate resistant prostate cancer; As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted to include clinical data from the PSMAfore study to support the addition of the new therapeutic indication.

Action: For adoption

5.3.13. Maralixibat – LIVMARLI (CAP) – EMA/VR/0000320544

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application consisting of:

C.I.13: Submission of the final report from study MRX- 503 listed as category 3 study in the RMP. This is a phase 3 study to Evaluate the Long-Term Safety and Efficacy of Maralixibat in the Treatment of Subjects with Progressive Familial Intrahepatic Cholestasis (PFIC). The RMP version 7.2 has also been submitted.

C.I.13: Submission of the final report for a retrospective study titled ''Analysis of Clinical Outcomes in PFIC: Comparison of Maralixibat from Studies MRX-502/503 and MRX-801 versus Natural History (NAtural course and Prognosis of PFIC and Effect of biliary Diversion [NAPPED])''.

Action: For adoption

5.3.14. Meningococcal Group A, C, W and Y conjugate vaccine – MENQUADFI (CAP) – EMA/VR/0000281377

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Jean-Michel Dogné

Scope: Extension of indication for MENQUADFI to include the active immunisation of patients from 6 weeks of age based on final results from study MET58 and additional supportive clinical studies. Study MET58 is a Phase 3, immunogenicity and Safety Study of an Investigational Quadrivalent Meningococcal Conjugate Vaccine when Administered Concomitantly with Routine Pediatric Vaccines in Healthy Infants and Toddlers in Europe. 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. An updated Risk Management Plan (RMP) version 4.0 is also included.

Action: For adoption

5.3.15. 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

5.3.16. Osilodrostat – ISTURISA (CAP) – EMA/VR/0000315678

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include the treatment of endogenous Cushing's syndrome in adolescents and children aged 6 years and older for ISTURISA, based on results from study CLCI699C2203; this is a Phase II, multicenter, open-label, non-comparative study to evaluate the pharmacokinetics, pharmacodynamics, and tolerability of osilodrostat in children and adolescent patients with Cushing's disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted.

Action: For adoption

5.3.17. Palbociclib – IBRANCE (CAP) – EMA/VR/0000316536

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include, in combination with anti-HER2 and endocrine therapies, the maintenance treatment of adult patients with HR-positive, HER2-positive locally advanced or metastatic breast cancer (MBC) following induction treatment for IBRANCE, based on the interim results from the open-label Phase 3 study PATINA (AFT-38/WI215662). This is a randomized, open-label Phase 3 study evaluating the efficacy and safety of IBRANCE (palbociclib) in combination with anti-HER2 therapy and endocrine therapy compared to anti-HER2 therapy and endocrine therapy alone as a first-line maintenance therapy (following induction chemotherapy treatment) for patients with HR positive, HER2-positive MBC. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. RMP version 1.10 has also been submitted.

Action: For adoption

5.3.18. Pembrolizumab – KEYTRUDA (CAP) – EMA/VR/0000316576

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: A grouped application consisting of:

C.I.6. Extension of indication for KEYTRUDA for subcutaneous use to include treatment of melanoma for adolescents aged 12 years and older based on an extrapolation approach from

adults to adolescents using pharmacokinetics modelling and simulation. 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 52.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to implement some minor editorial and formatting changes in the PI.

C.I.6. Extension of indication for KEYTRUDA for subcutaneous use to include treatment of classical Hodgkin lymphoma for adolescents aged 12 years and older based on an extrapolation approach from adults to adolescents using pharmacokinetics modelling and simulation. 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.

Action: For adoption

5.3.19. 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

5.3.20. Pirtobrutinib – JAYPIRCA (CAP) – EMA/VR/0000316267

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of adult patients with chronic lymphocytic leukaemia (CLL) for JAYPIRCA, based on interim results from studies LOXO-BTK-20023 (BRUIN-CLL-313) and LOXO-BTK-20030 (BRUIN-CLL-314). Study 20023 is a phase 3 open-label, randomized study of pirtobrutinib (LOXO-305) versus bendamustine plus rituximab in untreated patients with CLL/SLL. Study 20030 is a phase 3 open-label, randomized study of pirtobrutinib (LOXO-305) versus ibrutinib in patients with CLL/SLL. As a consequence, sections 4.1, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted.

Action: For adoption

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

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Jean-Michel Dogné

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

Action: For adoption

5.3.22. Respiratory syncytial virus mRNA vaccine (nucleoside modified) – MRESVIA (CAP) – EMA/VR/0000320244

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update clinical efficacy and safety information on the use of mRESVIA in immunocompromised individuals 18 years of age and older, based on interim results from study mRNA-1345-P303 Part B; this is a Phase 3 study to evaluate the immunogenicity and safety of mRNA-1345, an mRNA vaccine targeting respiratory syncytial virus, in high-risk adults. The updated RMP version 6.0 has also been submitted.

Action: For adoption

5.3.23. Ruxolitinib – OPZELURA (CAP) – EMA/VR/0000313318

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of moderate atopic dermatitis in adult patients who are inadequately controlled with, have a contraindication to, or are intolerant to topical corticosteroids and topical calcineurin inhibitors for OPZELURA, based on the results of the pivotal Phase III study INCB 18424-326 and the two supportive Phase III studies INCB 18424-303 and INCB 18424-304. INCB 18424-326 is a Phase 3b, double-blind, multicenter, randomized, vehicle-controlled, efficacy, and safety study of ruxolitinib cream in adults with moderate atopic dermatitis. 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 1.0 of the RMP has also been submitted.

Action: For adoption

5.3.24. Serplulimab – HETRONIFLY (CAP) – EMA/VR/0000282407

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include HETRONIFLY in combination with carboplatin and pemetrexed is indicated for the first-line treatment of adult patients with locally advanced or

metastatic non-squamous non-small cell lung carcinoma who do not have EGFR or ALK positive mutations based on interim results from study HLX10-002-NSCLC301; this is a pivotal Phase III clinical study. As a consequence, sections 4.1, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.

Action: For adoption

5.3.25. Serplulimab – HETRONIFLY (CAP) – EMA/VR/0000284402

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include, in combination with fluoropyrimidine- and platinum-based chemotherapy, the first-line treatment of adult patients with unresectable, locally advanced/recurrent or metastatic oesophageal squamous cell carcinoma whose tumours express PD-L1 with a CPS ≥ 1 for HETRONIFLY, based on results from study HLX10-007-EC301; this is a randomized, double-blind, multi-center, phase III clinical study comparing the clinical efficacy and safety of HLX10 or placebo combined with chemotherapy in first-line treatment of locally advanced/metastatic esophageal squamous cell carcinoma (ESCC) patients. 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 1.2 of the RMP has also been submitted.

Action: For adoption

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

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Dennis Lex

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

Action: For adoption

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

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

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

Action: For adoption

5.3.28. Ustekinumab – STELARA (CAP) – EMA/VR/0000316205

Applicant: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of ulcerative colitis in paediatric patients from the age of 2 years and older for STELARA, based on results from study CNTO1275PUC3001; this is a Phase 3 Study of the Efficacy, Safety and Pharmacokinetics of Ustekinumab as Open-label Intravenous Induction Treatment Followed by Randomized Double-blind Subcutaneous Ustekinumab Maintenance in Pediatric Participants (2 to <18 Years of Age) with Moderately to Severely Active Ulcerative Colitis. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 32.2 of the RMP has also been submitted.

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. Agalsidase beta – FABRAZYME (CAP) – EMA/PSUR/0000311185

Applicant: Sanofi B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000070/202507)

Action: For adoption

6.1.2. Belzutifan – WELIREG (CAP) – EMA/PSUR/0000311168

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011107/202508)

Action: For adoption

6.1.3. Catumaxomab – KORJUNY (CAP) – EMA/PSUR/0000311171

Applicant: Atnahs Pharma Netherlands B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011108/202508)

Action: For adoption

6.1.4. Chikungunya vaccine (recombinant, adsorbed) – VIMKUNYA (CAP) – EMA/PSUR/0000311187

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011118/202508)

Action: For adoption

6.1.5. Ciltacabtagene autoleucel – CARVYKTI (CAP) – EMA/PSUR/0000311150

Applicant: Janssen Cilag International

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00011000/202508)

Action: For adoption

6.1.6. Crovalimab – PIASKY (CAP) – EMA/PSUR/0000311169

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011071/202508)

Action: For adoption

6.1.7. Dapivirine – DAPIVIRINE VAGINAL RING 25 MG (Art 58) – EMA/PSUR/0000313080

Applicant: International Partnership For Microbicides

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUV Dapivirine)

Action: For adoption

6.1.8. Daunorubicin / Cytarabine – VYXEOS LIPOSOMAL (CAP) – EMA/PSUR/0000311133

Applicant: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010701/202508)

Action: For adoption

6.1.9. Dengue tetravalent vaccine (live, attenuated) – QDENGA (CAP) – EMA/PSUR/0000311184

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011034/202508)

Action: For adoption

6.1.10. Dengue tetravalent vaccine (live, attenuated) – DENGUE TETRAVALENT VACCINE (LIVE, ATTENUATED) TAKEDA (Art 58) – EMA/PSUR/0000308360

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUV dengue tetravalent vaccine)

Action: For adoption

6.1.11. Difelikefalin – KAPRUVIA (CAP) – EMA/PSUR/0000311151

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010995/202508)

Action: For adoption

6.1.12. Dronedarone – MULTAQ (CAP) – EMA/PSUR/0000311124

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001180/202507)

Action: For adoption

6.1.13. Efanesoctocog alfa – ALTUVOCT (CAP) – EMA/PSUR/0000311177

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00011062/202508)

Action: For adoption

6.1.14. Elranatamab – ELREXFIO (CAP) – EMA/PSUR/0000311115

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00000225/202508)

Action: For adoption

6.1.15. Epinephrine – EURNEFFY (CAP) – EMA/PSUR/0000311165

Applicant: Alk-Abello A/S

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011081/202508)

Action: For adoption

6.1.16. Fedratinib – INREBIC (CAP) – EMA/PSUR/0000311144

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010909/202508)

Action: For adoption

6.1.17. Fosdenopterin – NULIBRY (CAP) – EMA/PSUR/0000311166

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011017/202508)

Action: For adoption

6.1.18. Glecaprevir / Pibrentasvir – MAVIRET (CAP) – EMA/PSUR/0000311147

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010620/202507)

Action: For adoption

6.1.19. Imlifidase – IDEFIRIX (CAP) – EMA/PSUR/0000311139

Applicant: Hansa Biopharma AB

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010870/202508)

Action: For adoption

6.1.20. Lefamulin – XENLETA (CAP) – EMA/PSUR/0000311158

Applicant: Venipharm

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00010872/202508)

Action: For adoption

6.1.21. Lenacapavir – SUNLENCA (CAP); YEYTUO (CAP) – EMA/PSUR/0000311172

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00011012/202508)

Action: For adoption

6.1.22. Lenacapavir – LENACAPAVIR GILEAD (Art 58) – EMA/PSUR/0000310870

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUV lenacapavir)

Action: For adoption

6.1.23. Lonapegsomatropin – SKYTROFA (CAP) – EMA/PSUR/0000311154

Applicant: Ascendis Pharma Endocrinology Division A/S

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010969/202508)

Action: For adoption

6.1.24. Mirdametinib – EZMEKLY (CAP) – EMA/PSUR/0000311173

Applicant: Springworks Therapeutics Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011161/202508)

Action: For adoption

6.1.25. Odronextamab – ORDSPONO (CAP) – EMA/PSUR/0000311164

Applicant: Regeneron Ireland Designated Activity Company

PRAC Rapporteur: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00011074/202508)

Action: For adoption

6.1.26. Omaveloxolone – SKYCLARYS (CAP) – EMA/PSUR/0000311117

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000245/202508)

Action: For adoption

6.1.27. Patisiran – ONPATTRO (CAP) – EMA/PSUR/0000311137

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00010715/202508)

Action: For adoption

6.1.28. Pegaspargase – ONCASPAR (CAP) – EMA/PSUR/0000311176

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010457/202507)

Action: For adoption

6.1.29. Perampanel – FYCOMPA (CAP) – EMA/PSUR/0000311160

Applicant: Eisai GmbH

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00009255/202507)

Action: For adoption

6.1.30. Polihexanide – AKANTIOR (CAP) – EMA/PSUR/0000311167

Applicant: SIFI S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011082/202508)

Action: For adoption

6.1.31. Pretomanid – DOVPRELA (CAP) – EMA/PSUR/0000311186

Applicant: Mylan IRE Healthcare Limited

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010863/202508)

Action: For adoption

6.1.32. Risdiplam – EVRYSDI (CAP) – EMA/PSUR/0000311153

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010925/202508)

Action: For adoption

6.1.33. Seladelpar lysine dihydrate – LYVDELZI (CAP) – EMA/PSUR/0000311174

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00011119/202508)

Action: For adoption

6.1.34. Sofosbuvir / Velpatasvir / Voxilaprevir – VOSEVI (CAP) – EMA/PSUR/0000311119

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010619/202507)

Action: For adoption

6.1.35. Sotrovimab – XEVUDY (SRD[3]) – EMA/PSUR/0000311183

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010973/202508)

Action: For discussion

6.1.36. Sparsentan – FILSPARI (CAP) – EMA/PSUR/0000311163

Applicant: Vifor France

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011060/202508)

Action: For adoption

6.1.37. Talquetamab – TALVEY (CAP) – EMA/PSUR/0000311118

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00000099/202508)

Action: For adoption

6.1.38. Teclistamab – TECVAYLI (CAP) – EMA/PSUR/0000311141

Applicant: Janssen Cilag International

PRAC Rapporteur: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00011010/202508)

Action: For adoption

6.1.39. Tiratricol – EMCITATE (CAP) – EMA/PSUR/0000311170

Applicant: Rare Thyroid Therapeutics International AB

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00011114/202508)

Action: For adoption

[3] European Commission (EC) decision on the withdrawal of the marketing authorisation for XEVUDY dated 18 February 2026

6.1.40. Tisagenlecleucel – KYMRIAH (CAP) – EMA/PSUR/0000311179

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010702/202508)

Action: For adoption

6.1.41. Upadacitinib – RINVOQ (CAP) – EMA/PSUR/0000311064

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010823/202508)

Action: For adoption

6.1.42. Valoctocogene roxaparvovec – ROCTAVIAN (CAP) – EMA/PSUR/0000311159

Applicant: Biomarin International Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011009/202508)

Action: For adoption

6.1.43. Vosoritide – VOXZOGO (CAP) – EMA/PSUR/0000311145

Applicant: Biomarin International Limited

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00010952/202508)

Action: For adoption

6.1.44. Voxelotor – OXBRYTA (CAP) – EMA/PSUR/0000311152

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00010983/202508)

Action: For adoption

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

6.2.1. Human protein C – CEPROTIN (CAP); NAP – EMA/PSUR/0000311155

Applicants: Takeda Manufacturing Austria AG, various

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00002563/202507)

Action: For adoption

6.2.2. Lamivudine – ZEFFIX (CAP); NAP – EMA/PSUR/0000311149

Applicants: Glaxosmithkline Trading Services Limited, various

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00001824/202507)

Action: For adoption

6.2.3. Leuprorelin – CAMCEVI (CAP); NAP – EMA/PSUR/0000311157

Applicants: Accord Healthcare S.L.U., various

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010877/202507)

Action: For adoption

6.2.4. Palonosetron – ALOXI (CAP); NAP – EMA/PSUR/0000311140

Applicants: Helsinn Birex Pharmaceuticals Limited, various

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00002268/202507)

Action: For adoption

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

6.3.1. Ademetionine (NAP) – EMA/PSUR/0000310823

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000061/202508)

Action: For adoption

6.3.2. Amoxicillin / clarithromycin / pantoprazole (NAP) – EMA/PSUR/0000311136

Applicants: various

PRAC Lead: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00002286/202508)

Action: For adoption

6.3.3. Anastrozole (NAP) – EMA/PSUR/0000311116

Applicants: various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00000210/202508)

Action: For adoption

6.3.4. Beclometasone / formoterol (inhalative application) (NAP) – EMA/PSUR/0000311156

Applicants: various

PRAC Lead: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010068/202507)

Action: For adoption

6.3.5. Buclizine / codeine / paracetamol (NAP); acetylsalicylic acid / codeine / paracetamol (NAP); caffeine / codeine / paracetamol (NAP) – EMA/PSUR/0000311120

Applicants: various

PRAC Lead: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00000448/202508)

Action: For adoption

6.3.6. Cetalkonium / choline salicylate (NAP) – EMA/PSUR/0000311121

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00000626/202508)

Action: For adoption

6.3.7. Cetylpyridinium / lysozyme (NAP); lysozyme / pyridoxine (NAP) – EMA/PSUR/0000311122

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00000640/202508)

Action: For adoption

6.3.8. Cisatracurium (NAP) – EMA/PSUR/0000311123

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00000777/202507)

Action: For adoption

6.3.9. Copper chloride dihydrate / manganese chloride tetrahydrate / potassium iodide / sodium fluoride / sodium selenite anhydrous / zinc chloride (NAP) – EMA/PSUR/0000311161

Applicants: various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00010803/202508)

Action: For adoption

6.3.10. Diclofenac / misoprostol (NAP) – EMA/PSUR/0000311125

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00001040/202507)

Action: For adoption

6.3.11. Dimetindene / phenylephrine (NAP) – EMA/PSUR/0000311126

Applicants: various

PRAC Lead: Jana Pecherova

Scope: Evaluation of a PSUSA procedure (PSUSA/00001102/202507)

Action: For adoption

6.3.12. Epinephrine (except for nasal use) (NAP) – EMA/PSUR/0000311134

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00001232/202507)

Action: For adoption

6.3.13. Escherichia coli lysate (NAP) – EMA/PSUR/0000311128

Applicants: various

PRAC Lead: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00001263/202507)

Action: For adoption

6.3.14. Flutrimazole (NAP) – EMA/PSUR/0000311129

Applicants: various

PRAC Lead: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00001456/202508)

Action: For adoption

6.3.15. Fosphenytoin (NAP) – EMA/PSUR/0000311127

Applicants: various

PRAC Lead: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00001476/202508)

Action: For adoption

6.3.16. Glyceryl trinitrate (NAP) – EMA/PSUR/0000311175

Applicants: various

PRAC Lead: Polona Golmajer

Scope: Evaluation of a PSUSA procedure (PSUSA/00001552/202507)

Action: For adoption

6.3.17. Human plasma protease C1 inhibitor (NAP) – EMA/PSUR/0000311178

Applicants: various

PRAC Lead: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010163/202508)

Action: For adoption

6.3.18. Hydrocortisone / natamycin / neomycine sulphate (NAP) – EMA/PSUR/0000311130

Applicants: various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001672/202508)

Action: For adoption

6.3.19. Iodine (^{123}I) iobenguane (NAP) – EMA/PSUR/0000311135

Applicants: various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00001763/202508)

Action: For adoption

6.3.20. Octenidine (NAP) – EMA/PSUR/0000311148

Applicants: various

PRAC Lead: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010748/202507)

Action: For adoption

6.3.21. Pethidine (NAP) – EMA/PSUR/0000311131

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00002357/202508)

Action: For adoption

6.3.22. Piretanide / ramipril (NAP); piretanide (NAP) – EMA/PSUR/0000311146

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00002434/202508)

Action: For adoption

6.3.23. Pitavastatin (NAP) – EMA/PSUR/0000311143

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010502/202507)

Action: For adoption

6.3.24. Poliovirus type 1 / poliovirus type 2 / poliovirus type 3 vaccine (oral, live, attenuated) (NAP); poliovirus type 1 / poliovirus type 3 vaccine (oral, live, attenuated) (NAP); poliovirus type 1 (oral, live, attenuated) vaccine (NAP); poliovirus type 2 (oral, live, attenuated) vaccine (NAP); poliovirus type 3 (oral, live, attenuated) vaccine (NAP) – EMA/PSUR/0000311142

Applicants: various

PRAC Lead: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010801/202507)

Action: For adoption

6.3.25. Ziprasidone (NAP) – EMA/PSUR/0000311138

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00003146/202507)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

None

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Apalutamide - ERLEADA (CAP) – EMA/VR/0000319048

Applicants: Janssen Cilag International

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of section 4.5 of the SmPC in order to include information regarding apalutamide interference with a digoxin laboratory test based on a cumulative safety review, following the PRAC request in procedure PSUSA/00010745/202502. 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

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

Applicants: 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 subtrates 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[4]

None

7. Post-authorisation safety studies (PASS)

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

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

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Veronika Macurova

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

Action: For adoption

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

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

Applicant: Merck Europe B.V.

PRAC Rapporteur: Carla Torre

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

Action: For adoption

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

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

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

7.2.3. Galcanezumab – EMGALITY (CAP) – EMA/PAM/0000322252

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: PAM MEA to present a protocol substantial amendment to the category 3 PASS "A retrospective cohort study to assess drug utilisation and long-term safety of galcanezumab in European patients in the course of routine clinical care." Study identifier:I5Q-MC-B002.

Action: For adoption

7.2.4. Metreleptin – MYALEPTA (CAP) – EMA/PAM/0000319187

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Protocol amendment for Metreleptin effectiveness and safety registry (MEASURE): a non-interventional, multicenter, prospective, observational study of patients initiating treatment with metreleptin for lipodystrophy in the US and EEA.

Action: For adoption

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

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Sonja Radowan

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

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

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

Action: For adoption

7.2.6. Ravulizumab – ULTOMIRIS (CAP) – EMA/PAM/0000321330

Applicant: Alexion Europe

PRAC Rapporteur: Kimmo Jaakkola

Scope: Post-authorization measure to amend the protocol for Study M11-001, an observational, non-interventional, multi-center, multi-national study of patients with Atypical Hemolytic-Uremic syndrome. This is a Category 3 study (required additional pharmacovigilance activity). The main revision to the M11-001 protocol (amendment 7 dated 08 Dec 2025) is as follows: The registry will transition from a disease-based design to a drug-based design aligned with current risk management plan objectives and ongoing pharmacovigilance needs following fulfilment of the EMEA/H/C/000791/MEA/062.3 on 25 July 2024.

Action: For adoption

7.2.7. Romosozumab – EVENITY (CAP) – EMA/PAM/0000320086

Applicant: UCB Pharma

PRAC Rapporteur: Tiphaine Vaillant

Scope: Protocol amendment for PASS No. OP0005: European non-interventional PASS related to adherence to the risk minimization measures.

Action: For adoption

7.2.8. Tisagenlecleucel – KYMRIAH (CAP) – EMA/PAM/0000258545

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of protocol of the MEA Category 3 PASS CCTL019B2402 study entitiled 'A Non-Interventional Study (NIS) PASS to characterize secondary malignancies of T-cell origin following tisagenlecleucel therapy'

Action: For adoption

7.2.9. Vorasidenib – VORANIGO (CAP) – EMA/PAM/0000320338

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Jo Robays

Scope: To assess the safety of vorasidenib in paediatric patients 12 years of age and older based on a clinical trial in paediatric patients following exposure to vorasidenib - Final protocol for study (S095032-236) "A Phase 2, single arm, open-label study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of vorasidenib in pediatric participants aged 12 to < 18 years old with Grade 2 astrocytoma or oligodendroglioma with an IDH1 or IDH2 mutation".

Action: For adoption

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

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

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Veronika Macurova

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

Action: For adoption

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

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

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: A grouped application consisting of:

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

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

Action: For adoption

7.4.2. Dapagliflozin – EDISTRIDE (CAP); FORXIGA (CAP); Dapagliflozin / Metformin – EBYMECT (CAP); XIGDUO (CAP); Saxagliptin / Dapagliflozin – QTERN (CAP) – EMA/VR/0000308587

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Submission of the final report from the Cancer PASS study D1690R00007 listed as a category 3 study in the RMP. This is a post-authorisation observational study, final (120-month) report: comparison of the risk of cancer between patients with type 2 diabetes exposed to dapagliflozin and those exposed to other antidiabetic treatments. The RMP versions 32.0 for Forxiga & Edistride, 16.0 for Xigduo & Ebymect and 11.0 for Qtern have also been submitted.

Action: For adoption

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

7.4.3. Dexmedetomidine – DEXDOR (CAP) – EMA/VR/0000316395

Applicant: Orion Corporation

PRAC Rapporteur: Karin Bolin

Scope: Submission of the final report from study ANZIC-RC/YS003 listed as a category 3 PASS in the RMP. It concerns sedation practice in intensive care evaluation [SPICE] III, early goal directed sedation compared with standard care in mechanically ventilated patients in intensive care. The RMP version 10.0 has also been submitted.

Action: For adoption

7.4.4. Ivacaftor / Tezacaftor / Elexacaftor – KAFTRIO (CAP) – EMA/VR/0000319887

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Dennis Lex

Scope: Submission of the final report from the 5-year Post Authorisation Safety Study (PASS) VX20-445-120, listed as a category 3 study in the RMP. This is a longitudinal, registry based study evaluating the real-world effects and utilisation patterns of elexacaftor, tezacaftor, and ivacaftor combination therapy (ELX/TEZ/IVA) in patients with cystic fibrosis (CF). The RMP version 10.2 has also been submitted.

Action: For adoption

7.4.5. *Plasmodium falciparum* and hepatitis B vaccine (recombinant, adjuvanted) – MOSQUIRIX (CAP) – EMA/VR/0000319297

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Jean-Michel Dogné

Scope: A grouped application consisting of:

C.I.13: Submission of the final report from post authorisation safety study EPI-MAL-005 listed as a category 3 study in the RMP. This is an epidemiology study to assess *Plasmodium falciparum* parasite prevalence and malaria control measures in catchment areas of two interventional studies pre- and post RTS,S/AS01E introduction (EPI-MAL-002 and EPI-MAL-003) to assess, in field conditions, vaccine benefit:risk in children in sub-Saharan Africa. RMP version 7.0 has also been submitted.

C.I.13: Submission of the final report from post authorisation safety study EPI-MAL-010 listed as a category 3 study in the RMP. This is a phase IV, longitudinal, cross-sectional, retrospective, ancillary epidemiology study of the EPI-MAL-005 study to evaluate the genetic diversity in the *Plasmodium falciparum* parasite circumsporozoite sequences before and after the implementation of the RTS,S/AS01E vaccine in malaria-positive subjects ranging from 6 months to less than 5 years of age.

Action: For adoption

7.4.6. Ponesimod – PONVORY (CAP) – EMA/VR/0000320506

Applicant: Laboratoires Juvise Pharmaceuticals

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the final report from non-interventional post authosiration safety study PCSNSP003693 listed as a category 3 study in the RMP. This is a Survey to Assess the Effectiveness of Ponvory Educational Materials for Additional Risk Minimization Measures in the European Union.

Action: For adoption

7.4.7. Romosozumab – EVENITY (CAP) – EMA/VR/0000320170

Applicant: UCB Pharma

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of the final report of the EU PASS study OP0006 listed as a category 3 study in the RMP. The OP0006 EU PASS study is a European non-interventional post authorization safety study related to serious infections for romosozumab. The RMP version 3.0 has also been submitted.

Action: For adoption

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

7.5.1. COVID-19 vaccine (recombinant, adjuvanted) – NUVAXOVID (CAP) – EMA/PAM/0000317252

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Dirk Mentzer

Scope: Third Interim Report for PASS 2019nCoV-404: US Post-authorisation safety study to evaluate the pooled risk of selected Adverse Events of Special Interest (AESI) within specified time periods after vaccination with Nuvaxovid using a claim and/or EHR database.

Action: For adoption

7.5.2. COVID-19 vaccine (recombinant, adjuvanted) – NUVAXOVID (CAP) – EMA/PAM/0000317251

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Dirk Mentzer

Scope: Revised Third Interim Report for PASS 2019nCoV-402: UK A Study Using the Clinical Practice Research Datalink (CPRD): A surveillance study to characterise the safety profile of Nuvaxovid in adults aged 18 years and older in the real-world setting using the UK CPRD.

Action: For adoption

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

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: An interim report for the non-interventional post-authorisation safety study (PASS) titled: A Patient Registry of Patients with High-Risk Neuroblastoma Being Treated with the Monoclonal Antibody Dinutuximab Beta" (EUSA DB 0001)

Action: For adoption

7.5.4. Dupilumab – DUPIXENT (CAP) – EMA/PAM/0000320087

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: [Interim Report #2 for PASS Study CSA0014]: A registry-based non-interventional post- authorization safety study (PASS) to evaluate the long-term safety of dupilumab in children aged ≥6 months to <6 years with moderate-to-severe atopic dermatitis using the PEDISTAD registry.

Action: For adoption

7.5.5. Filgotinib – JYSELECA (CAP) – EMA/PAM/0000319177

Applicant: Alfasigma S.p.A.

PRAC Rapporteur: Petar Mas

Scope: Progress report for Study GLPG0634-CL-413: a non-interventional, post-authorisation safety study of filgotinib in patients with moderately to severely active ulcerative colitis - a European multi registry-based study.

Action: For adoption

7.5.6. Fingolimod – GILENYA (CAP) – EMA/PAM/0000320326

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: 6th Annual Interim Report of Study CFTY720D2311: A two-year, double-blind, randomized, multicenter, active-controlled Core Phase study to evaluate the safety and efficacy of fingolimod administered orally once daily versus interferon β-1a i.m. once weekly in pediatric patients with multiple sclerosis with five-year fingolimod Extension Phase.

Action: For adoption

7.5.7. Guselkumab – TREMFYA (CAP) – EMA/PAM/0000320084

Applicant: Janssen Cilag International

PRAC Rapporteur: Dirk Mentzer

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

Action: For adoption

7.5.8. Guselkumab – TREMFYA (CAP) – EMA/PAM/0000320085

Applicant: Janssen Cilag International

PRAC Rapporteur: Dirk Mentzer

Scope: Interim study results for PSOLAR - A Multicenter, Open Registry of Patients with Psoriasis Who Are Candidates for Systemic Therapy Including Biologics.

Action: For adoption

7.5.9. Neratinib – NERLYNX (CAP) – EMA/PAM/0000319826

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Bianca Mulder

Scope: Interim report for the primary endpoint of the category 3 PASS DIANER study (PUMA-NER-6202): a randomized phase II study to evaluate the incidence of discontinuations due to diarrhoea at 3 cycles in patients with early stage HER2-positive (HER2+), Hormone Receptor-positive (HR+) breast cancer treated with neratinib plus loperamide prophylaxis versus neratinib with initial dose escalation plus PRN loperamide prophylaxis versus neratinib plus loperamide plus colesevelam prophylaxis.

Action: For adoption

7.5.10. Nirmatrelvir / Ritonavir – PAXLOVID (CAP) – EMA/PAM/0000320342

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Dennis Lex

Scope: The second interim (31 December 2025) report for study PASS C4671037, Safety of Paxlovid During Pregnancy.

Action: For adoption

7.5.11. Octocog alfa – KOVALTRY (CAP) – EMA/PAM/0000324429

Applicant: Bayer AG

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of the 17th Annual EUHASS Report (reporting end: 31 Dec 2024) and the product specific report for Kovaltry as interim results for RMP registry study 14149. PAM MEA: Kovaltry EMEA/H/C/003825/MEA/004.9

Action: For adoption

7.5.12. Ofatumumab – KESIMPTA (CAP) – EMA/PAM/0000321410

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Fourth interim study report for PASS Study COMB157G2407: Evaluation of pregnancy and infant outcomes in Kesimpta patients using Pregnancy outcomes Intensive Monitoring (PRIM) data – The Kesimpta-PRIM study.

Action: For adoption

7.5.13. Pegvaliase – PALYNZIQ (CAP) – EMA/PAM/0000319850

Applicant: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: First interim report for study BM 165-503: a multicenter, prospective, longitudinal study evaluating immunologic, inflammatory, and laboratory parameters associated with long-term Palynziq (pegvaliase) treatment in subjects with phenylketonuria (PKU) in the United States.

Action: For adoption

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

Applicant: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

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

Action: For adoption

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

Applicant: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

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

Action: For adoption

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

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

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

Action: For adoption

7.5.17. Respiratory syncytial virus vaccine (bivalent, recombinant) – ABRYSVO (CAP) – EMA/PAM/0000321444

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of 2nd progress report for PASS study C3671026 - A post-authorisation safety study of Abrysvo in pregnant women and their offspring in a real world setting in Europe and UK

Action: For adoption

7.5.18. Romosozumab – EVENITY (CAP) – EMA/PAM/0000319563

Applicant: UCB Pharma

PRAC Rapporteur: Tiphaine Vaillant

Scope: Seventh interim report for PASS No. OP0004: European non-interventional post-authorisation safety study (PASS) related to serious cardiovascular adverse events of myocardial infarction and stroke for romosozumab by the EU-ADR Alliance to evaluate potential differences in terms of serious cardiovascular adverse events between romosozumab and currently available therapies used in comparable patients in real-world conditions.

Action: For adoption

7.5.19. Ruxolitinib – OPZELURA (CAP) – EMA/PAM/0000317014

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Submission of the first study progress report for study INCB 88888-037: an observational post-authorisation study assessing the long-term risk of Non-Melanoma Skin Cancer (NMSC) among new users of Opzelura (ruxolitinib) cream in a vitiligo patient population.

Action: For adoption

7.5.20. Sotatercept – WINREVAIR (CAP) – EMA/PAM/0000319268

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Annual Report Data Cutoff Date: 14-APR-2025. An Open-label Long-term Follow-up Study to Evaluate the Effects of Sotatercept When Added to Background Pulmonary Arterial Hypertension (PAH) Therapy for the Treatment of PAH (MK-7962-004). This stand alone MEA is submitted to address the Additional Pharmacovigilance Activity in the RMP approved at the time of the Marketing Authorization (MA).

Action: For adoption

7.5.21. Tildrakizumab – ILUMETRI (CAP) – EMA/PAM/0000321412

Applicant: Almirall S.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Interim study results for the PASS M14745-40 of tildrakizumab in European Psoriasis Registries

Action: For adoption

7.5.22. Upadacitinib – RINVOQ (CAP) – EMA/PAM/0000320093

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Progress report for study P21-824: a study of growth and development in adolescents with atopic dermatitis who receive upadacitinib.

Action: For adoption

7.5.23. Upadacitinib – RINVOQ (CAP) – EMA/PAM/0000320090

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Progress report for Study P24-343: Long-Term Safety Study of Upadacitinib Use in Ulcerative Colitis and Crohn's Patients in Europe.

Action: For adoption

7.5.24. Vimseltinib – ROMVIMZA (CAP) – EMA/PAM/0000321470

Applicant: Deciphera Pharmaceuticals (Netherlands) B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Feasibility report PASS DCC-3014-04-002 Long-term safety and tolerability of vimseltinib and further characterise the safety concerns of arterial hypertension, drug-induced livery injury (DILI), muscle injury/rhabdomyolysis, nephrotoxicity, cognitive disorders/CNS adverse events, and malignancies

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. Defibrotide – DEFITELIO (CAP) – EMA/S/0000316340

Applicant: Gentium S.r.l.

PRAC Rapporteur: Mari Thorn

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

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

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Amelia Cupelli

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. 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

8.2. Conditional renewals of the marketing authorisation

8.2.1. Entrectinib – ROZLYTREK (CAP) – EMA/R/0000319073

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.2. Futibatinib – LYTGOBI (CAP) – EMA/R/0000317381

Applicant: Taiho Pharma Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.3. Givinostat – DUVYZAT (CAP) – EMA/R/0000316670

Applicant: Italfarmaco S.p.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.4. Mirdametinib – EZMEKLY (CAP) – EMA/R/0000323237

Applicant: Springworks Therapeutics Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.5. Obecabtagene autoleucel – AUCATZYL (CAP) – EMA/R/0000319964

Applicant: Autolus GmbH

PRAC Rapporteur: Karin Erneholm

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Cabozantinib – COMETRIQ (CAP) – EMA/R/0000316559

Applicant: Ipsen Pharma

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.2. Fingolimod – FINGOLIMOD MYLAN (CAP) – EMA/R/0000314834

Applicant: Mylan Pharmaceuticals Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.3. Vosoritide – VOXZOGO (CAP) – EMA/R/0000314604

Applicant: Biomarin International Limited

PRAC Rapporteur: Zane Neikena

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. Ocrelizumab – OCREVUS (CAP) – EMA/VR/0000313041

Applicant: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Liver Injury' and to add it to the list of adverse drug reactions (ADRs) with frequency 'rare', based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to submit a DHPC Letter and to introduce minor changes to the PI, including the Labelling section.

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. PRAC working group - Best Practice Guide (BPG) implementation goals and statistics - update

PRAC lead: Ulla Wandel Liminga

Action: For adoption

12.1.3. Nominated 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

12.4.1. European Network Training Centre (EU NTC) – Pharmacogenomics – New training curriculum

Action: For information

12.5. Cooperation with International Regulators

None

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

None

12.7. PRAC work plan

None

12.8. Planning and reporting

None

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

PRAC lead: Petar Mas

Action: For discussion

12.10.3. PSURs repository

None

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

PRAC lead: Ulla Wändel Liminga

Action: For discussion

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

Action: For adoption

12.11. Signal management

12.11.1. Reflection paper on particulars for signal detection for (traditional) herbal medicinal products.

PRAC lead: Julia Pallos

Action: For discussion

12.11.2. Signals and safety analytics project – update and change management plan for the National Competent Authorities (NCAs) rollout

PRAC lead: To be appointed

Action: For discussion

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.13.2. EudraVigilance annual report 2025

Action: For discussion

12.13.3. EudraVigilance – Expert Working Group (EV-EWG) - nomination of PRAC representative

Action: For discussion

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. CHMP assessment report (AR) template – Revamp Project - report on the completed pilot

Action: For discussion

12.21.2. PRAC Assessors trainings - update

PRAC Lead(s): Liana Martirosyan, Ulla Wändel Liminga

Action: For information

12.21.3. Draft Questions and Answers (Q&A) on EMA Guidance on the use of Real-World Data

PRAC Lead: Carla Torre

Action: For discussion

12.21.4. Guidance on how to best involve PRAC's members nominated by the European Commission in PRAC activities - update

Action: For information

12.21.5. Real World Evidence (RWE) project related to Alzheimer's disease and Duchenne muscular dystrophy – update

PRAC Lead(s): Carla Torre, Patricia McGettigan, Ulla Wändel Liminga

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)