05 May 2026
EMA/PRAC/89531/2026 Corr.1[1]
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 04-07 May 2026

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

04 May 2026, 13:00 – 19:30, room 2C

05 May 2026, 08:30 – 19:30, room 2C

06 May 2026, 08:30 – 19:30, room 2C

07 May 2026, 08:30 – 16:00, room 2C

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also change during the course of the review. Additional details on some of these procedures will be published in the PRAC meeting highlights once the procedures are finalised.

Of note, this agenda is a working document primarily designed for PRAC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006 Rev.1).

[1] Title of topic 4.1.1 updated to include clorazepate (NAP) and triazolam (NAP).

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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 04-07 May 2026. See April month 2026 PRAC minutes (to be published post June 2026 PRAC meeting).

1.2. Agenda of the meeting on 04-07 May 2026

Action: For adoption

1.3. Minutes of the previous meeting on 07-10 April 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[2]

None

3.5. Others

None

4. Signals assessment and prioritisation[3]

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

4.1.1. Alprazolam (NAP); amitriptyline hydrochloride / medazepam (NAP); amitriptyline / chlordiazepoxide (NAP); bromazepam (NAP); bromazepam / propantheline bromide (NAP); brotizolam (NAP); chlordiazepoxide (NAP); chlordiazepoxide / clidinium bromide (NAP); cinolazepam (NAP); clidinium bromide / diazepam (NAP); clobazam (NAP); cyclobarbital calcium / diazepam (NAP);clonazepam (NAP); clorazepate (NAP); clotiazepam (NAP); cloxazolam (NAP); delorazepam (NAP); diazepam (NAP); diazepam / gamma-amino-beta-hydroxybutyric acid (NAP); diazepam / isopropamide iodide (NAP); diazepam / octatropine methylbromide (NAP); diazepam / otilonium bromide (NAP); diazepam / sulpiride (NAP); diazepam / sulpiride / pyridoxine hydrochloride (NAP); estazolam (NAP); ethyl loflazepate (NAP); etizolam (NAP); flunitrazepam (NAP); flurazepam (NAP); ketazolam (NAP); loprazolam (NAP); lorazepam (NAP); lormetazepam (NAP); medazepam (NAP); mexazolam (NAP); midazolam - BUCCOLAM (CAP), NAP; nitrazepam (NAP); nordazepam (NAP); oxazepam (NAP); pinazepam (NAP); prazepam (NAP); remimazolam – BYFAVO (CAP), NAP; temazepam (NAP); tofisopam (NAP); triazolam (NAP); trimebutine maleate / medazepam (NAP)

Applicant(s): Neuraxpharm Pharmaceuticals S.L. (Buccolam), Paion Pharma GmbH (Byfavo), various

PRAC Rapporteur: To be appointed

Scope: Signal on miscarriage associated with in utero exposure to benzodiazepines (including fixed-dose combinations)

Action: For adoption of PRAC recommendation

EPITT 20272 – New signal

Lead Member State(s): DK, PL, SI, NL, FR, FI, ES, BE, IT, HU, MT, AT, DE, PT, SK, IE, EE

[2] Re-examination of PRAC recommendation under Article 32 of Directive 2001/83/EC
[3] 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. Amoxicillin (NAP); amoxicillin/clavulanic acid (NAP)

Applicants: various

PRAC Rapporteur: To be appointed

Scope: Signal of encephalopathy

Action: For adoption of PRAC recommendation

EPITT 20264 – New signal

Lead Member States: AT, DE

4.1.3. Dapagliflozin – EDISTRIDE (CAP); DAPAGLIFLOZIN VIATRIS (CAP); FORXIGA (CAP), NAP; dapagliflozin / metformin – EBYMECT (CAP), XIGDUO (CAP), NAP; dapagliflozin / saxagliptin – QTERN (CAP); dapagliflozin/sitagliptin (NAP)

Applicants: AstraZeneca AB (Ebymect, Edistride, Forxiga, Qtern, Xigduo), Viatris Limited (Dapagliflozin Viatris), various

PRAC Rapporteur: To be appointed

Scope: Signal of lichen sclerosus

Action: For adoption of PRAC recommendation

EPITT 20259 – New signal

Lead Member State(s): SE

4.1.4. Exenatide – BYDUREON (CAP), BYETTA (CAP); insulin icodec / semaglutide - KYINSU (CAP); semaglutide – KAYSHILD (CAP), OZEMPIC (CAP), RYBELSUS (CAP), WEGOVY (CAP), WEGOVY FLEXTOUCH (CAP)

Applicant: AstraZeneca AB (Bydureon, Byetta), Novo Nordisk A/S (Ozempic, Kayshild, Kyinsu, Rybelsus, Wegovy, Wegovy flextouch)

PRAC Rapporteur: To be appointed

Scope: Signal of of peripheral neuropathies

Action: For adoption of PRAC recommendation

EPITT 20270 – New signal

Lead Member State(s): SE

4.1.5. Ixekizumab - TALTZ (CAP)

Applicants: Eli Lilly and Co (Ireland) Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Signal of Behcet’s syndrome

Action: For adoption of PRAC recommendation

EPITT 20269 – New signal

Lead Member State(s): DE

4.1.6. Semaglutide – OZEMPIC (CAP), RYBELSUS (CAP), WEGOVY (CAP), WEGOVY FLEX TOUCH (CAP), KAYSHILD (CAP); insulin icodec / semaglutide - KYINSU (CAP)

Applicant: Novo Nordisk A/S

PRAC Rapporteur: To be appointed

Scope: Signal of gastrointestinal volvulus

Action: For adoption of PRAC recommendation

EPITT 20260 – New signal

Lead Member State(s): SE

4.1.7. Tocilizumab – AVTOZMA (CAP); RoACTEMRA (CAP); TOCILIZUMAB STADA (CAP); TUYORY(CAP); TYENNE (CAP)

Applicants: Celltrion Healthcare Hungary Kft. (Avtozma), Fresenius Kabi Deutschland GmbH (Tyenne), Gedeon Richter (Tuyory), Roche Registration GmbH (RoActemra), STADA Arzneimittel AG (Tocilizumab STADA)

PRAC Rapporteur: Dirk Mentzer

Scope: Signal of cutaneous vasculitis

Action: For adoption of PRAC recommendation

EPITT 20261 – New signal

Lead Member State(s): DE

4.2. Signals follow-up and prioritisation

4.2.1. Pancreatin (NAP)

Applicant: various

PRAC Rapporteur: Dennis Lex

Scope: Signal of infection due to viral transmission

Action: For adoption of PRAC recommendation

EPITT 20205 – Follow-up to October 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. Arimoclomol - (CAP MAA) - EMEA/H/C/006736, Orphan

Scope (pre D-180 phase): Treatment of Niemann-Pick disease type C (NPC) in patients aged 6 months and older in combination with miglustat

Action: For adoption

5.1.2. Azacitidine - (CAP MAA) - EMEA/H/C/006695

Scope (pre D-180 phase): Treatment of myelodysplastic syndromes (MDS), chronic myelomonocytic leukemia (CMML) and acute myeloid leukemia (AML)

Action: For adoption

5.1.3. Cefepime / Zidebactam - (CAP MAA) - EMEA/H/C/006799

Scope (pre D-90 phase, accelerated assessment): Treatment of a number of infections in adults

Action: For adoption

5.1.4. Icotrokinra hydrochloride - (CAP MAA) - EMEA/H/C/006730

Scope (pre D-180 phase): Treatment of plaque psoriasis in adults and adolescents 12 years or older

Action: For adoption

5.1.5. Obicetrapib - (CAP MAA) - EMEA/H/C/006516

Scope (pre D-180 phase): Treatment of primary hypercholesterolaemia or mixed dyslipidaemia

Action: For adoption

5.1.6. Obicetrapib / Ezetimibe - (CAP MAA) - EMEA/H/C/006517

Scope (pre D-180 phase): Treatment of primary hypercholesterolaemia or mixed dyslipidaemia

Action: For adoption

5.1.7. Ranibizumab - (CAP MAA) - EMEA/H/C/006527

Scope (pre D-180 phase): Treatment of neovascular (wet) age-related macular

degeneration (AMD)

Action: For adoption

5.1.8. Ranibizumab - (CAP MAA) - EMEA/H/C/006926

Scope (pre 60phase): Treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to diabetic macular oedema (DME), proliferative diabetic retinopathy (PDR), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to choroidal neovascularisation (CNV)**Action:** For adoption

5.1.9. Ruxolitinib hemifumarate - (CAP MAA) - EMEA/H/C/006618

Scope (pre D-180 phase): Treatment of myelofibrosis (MF), polycythaemia vera (PV) and Graft versus host disease (GvHD)

Action: For adoption

5.1.10. Senaparib - (CAP MAA) - EMEA/H/C/006708

Scope (pre D-180 phase): Maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer

Action: For adoption

5.1.11. Sufentanil / Ketamine - (CAP MAA) - EMEA/H/C/006395, PUMA

Scope (pre D-180 phase): Treatment of acute pain in children aged 1 to less than 18 years.

Action: For adoption

5.1.12. Tafamidis - (CAP MAA) - EMEA/H/C/006711

Scope (pre D-180 phase): Treatment of hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).

Action: For adoption

5.1.13. Trilaciclib - (CAP MAA) - EMEA/H/C/006709

Scope (pre D-180 phase): Prevention of chemotherapy-induced myelosuppression when administered prior to platinum/etoposide- or topotecan-containing regimens for extensive-stage small cell lung cancer (ES-SCLC)

Action: For adoption

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

5.2.1. 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

5.2.2. 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. Pegcetacoplan – ASPAVELI (CAP) – EMA/VR/0000333829

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: Submission of an updated RMP (version 5.1) in order to revise the patient number in the category 3 post-authorization safety study (PASS) Sobi.PEGCET-301 and the milestone date for the clinical study report for the Category 3 study APL2-307.

Action: For adoption

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

5.3.1. 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

5.3.2. Adalimumab – IMRALDI (CAP) – EMA/X/0000321285

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Karin Bolin

Scope: Extension application to add a new strength of 80 mg solution for injection in a single dose 0.8 ml pre-filled pen (PFP). This is a grouped line extension application including four quality variations

Action: For adoption

5.3.3. Alemtuzumab – LEMTRADA (CAP) – EMA/VR/0000335041

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: A grouped application consisting of:

C.4: Update of section 4.4 of the SmPC in order to add a new warning on vasculitis following request from Saudi Arabia and based on data from clinical studies and post-authorisation data sources. The RMP version 14.0 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI.

C.4: Update of section 5.1 in order to update information on paediatrics based on final results from study EFC13429 (LemKids) listed as a category 3 study in the RMP; this is a phase 3 multi-center, open-label, single-arm, before and after switch study to evaluate the efficacy, safety and tolerability of alemtuzumab in paediatric patients with relapsing remitting multiple sclerosis (RRMS) with disease activity on prior disease modifying therapy. The RMP version 14.0 has also been submitted.

Action: For adoption

5.3.4. Apixaban – ELIQUIS (CAP) – EMA/VR/0000327005

Applicant: Bristol-Myers Squibb Pfizer EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include neonates in the currently approved indication treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age for ELIQUIS, based on final results from

pivotal study CV185325. This is an open-label, multi-centre, randomized, active controlled trial to provide PK data and data on anti-Xa activity to support the extrapolation of efficacy to children, to evaluate safety and efficacy of apixaban in children (full term neonates to less than 18 years of age) who require anticoagulation for venous thromboembolism, and Study 2, modelling and simulation study to derive dosing of apixaban for use in neonates for treatment of venous thromboembolism; As a consequence, section 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 24.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the The Patient Card to mention Eliquis only once on the title page and refer to apixaban throughout the rest of the card.

Action: For adoption

5.3.5. Atidarsagene autotemcel – LIBMELDY (CAP) – EMA/VR/0000334917

Applicant: Orchard Therapeutics (Netherlands) B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: A grouped application consisting of:

C.12: Submission of the final report from study 201222 listed as a category 3 study in the RMP. This is a Phase I/II clinical trial of haematopoietic stem cell gene therapy for the treatment of metachromatic leukodystrophy (MLD).

C.12: Submission of the final report from study CUP 207394 listed as a category 3 study in the RMP. This is a gene therapy protocol using autologous haematopoietic stem cells for a patient with metachromatic leukodystrophy (MLD).

C.12: Submission of the final report from studies CUP 206258 and HE 205029 listed as category 3 studies in the RMP. These are Expanded Access Programs (EAP) for hematopoietic stem cell gene therapy OTL-200 in subjects with early-onset metachromatic leukodystrophy (MLD).

The RMP version 4.1 has also been submitted.

Action: For adoption

5.3.6. 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

5.3.7. Belzutifan – WELIREG (CAP); Pembrolizumab – KEYTRUDA (CAP) – EMA/VR/0000313634

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Dennis Lex

Scope: Worksharing variation to extend the indication for KEYTRUDA, in combination with belzutifan, and for WELIREG, in combination with pembrolizumab, for the adjuvant treatment of adult patients with clear cell renal cell carcinoma at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions, based on results from study MK-6482-022 (LITESPARK-022). This is a multicenter, double-blind, randomized phase 3 study to compare the efficacy and safety of belzutifan plus pembrolizumab versus placebo plus pembrolizumab, in the adjuvant treatment of clear cell renal cell carcinoma (ccRCC) post nephrectomy. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC for KEYTRUDA and sections 4.1, 4.2, 4.8 and 5.1 of the SmPC for WELIREG are updated. The Package Leaflet for WELIREG is updated in accordance. The RMP version 53.1 for KEYTRUDA and version 2.1 for WELIREG have also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI for KEYTRUDA and WELIREG.

Action: For adoption

5.3.8. Belzutifan – WELIREG (CAP) – EMA/VR/0000326853

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include in combination with lenvatinib, treatment of adult patients with advanced clear cell renal cell carcinoma that progressed following a PD-1 or PD-L1 inhibitor for WELIREG, based on interim results from study P011V01MK6482 (LITESPARK-011); this is an open-label, randomized, Phase 3 study of belzutifan in combination with lenvatinib vs cabozantinib for treatment in participants with advanced renal cell carcinoma (RCC) who have progressed after prior anti-PD-1/L1 Therapy. As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.

Action: For adoption

5.3.9. Cabotegravir – VOCABRIA (CAP) – EMA/VR/0000332087

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Update of sections 4.4, 4.6 and 5.2 of the SmPC in order to update information on pregnancy based on interim results from study HPTN 084/084-01; this is phase 3 double blind safety and efficacy study of long-acting injectable cabotegravir compared to daily oral TDF/FTC for pre-exposure prophylaxis in HIV-uninfected women – Pregnancy Safety and PK Interim Analysis; the Package Leaflet is updated accordingly. The RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template and to make typographical edits.

Action: For adoption

5.3.10. Cabotegravir – APRETUDE (CAP) – EMA/VR/0000331993

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Update of sections 4.6 and 5.2 of the SmPC in order to update information and recommendations on pregnancy, based on interim results from the open label extension (OLE) phase of the Phase 3 study HPTN 084 (study 201739) on the use of cabotegravir (CAB) for HIV-1 pre-exposure prophylaxis (PrEP) during pregnancy. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce updates to the information on excipients in alignment with the excipient guideline and to introduce minor editorial and formatting changes to the PI.

Action: For adoption

5.3.11. Cetuximab – ERBITUX (CAP) – EMA/VR/0000326978

Applicant: Merck Europe B.V.

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include in combination with encorafenib treatment of with metastatic colorectal cancer (mCRC) with a BRAF V600E mutation, who have received prior systemic therapy for ERBITUX, based on final results from study ARRAY-818-302 (BEACON-CRC); this is a randomized, open label, 3-arm Phase 3 design that investigated the BRAF inhibitor, encorafenib in combination with cetuximab with or without the mitogen-activated protein kinase (MEK) inhibitor, binimetinib, in patients with BRAF V600E-mutated mCRC whose disease has progressed after 1 or 2 prior regimens in the metastatic setting. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 21.1 of the RMP has also been submitted.

Action: For adoption

5.3.12. Cetuximab – ERBITUX (CAP) – EMA/VR/0000327014

Applicant: Merck Europe B.V.

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include in combination with encorafenib and mFOLFOX6 treatment of metastatic colorectal cancer with a BRAF V600E mutation for ERBITUX, based on interim results from study C4221015 (BREAKWATER); this is an open-label, multicenter, 3-arm, randomized phase 3 study of EC alone or in combination with mFOLFOX6 versus standard-of-care chemotherapy in first-line participants with BRAF V600E-mutant mCR . 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 21.1 of the RMP has also been submitted.

Action: For adoption

5.3.13. COVID-19 mRNA vaccine – SPIKEVAX (CAP) – EMA/VR/0000335829

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Update of sections 4.2, 4.8 and 5.1 of the SmPC to update the posology recommendation for the 2 years through 4 years age group, based on final results from the study mRNA-1273-P306 listed as a category 3 study in the RMP; this is an Open-Label, Phase 3 Study to Evaluate the Safety and Immunogenicity of the mRNA Vaccines for SARS-CoV-2 Variants in Participants Aged 6 Months to <6 Years; the Package Leaflet is updated accordingly. The RMP version 14.0 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

5.3.14. Damoctocog alfa pegol – JIVI (CAP) – EMA/VR/0000326847

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

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

C.6.a: Extension of indication to include treatment and prophylaxis of bleeding in previously untreated patients ≥7 years of age with haemophilia A for JIVI, following the guideline for clinical investigation of recombinant and human plasma-derived factor VIII products (EMA/CHMP/BPWP/144552/2009 rev 2). As a consequence, sections 4.1, 4.2, 4.4 and 4.8 of the SmPC are updated. The Package Leaflet is updated accordingly.

C.4: Update of section 4.2 of the SmPC in order to update posology recommendations for patients 7 to <12 years of age, based on integrated analysis results from Part B of the Alfa-PROTECT study (21824) and PROTECT Kids extension study (15912). Alfa-PROTECT is a Phase 3, single-group treatment, open-label study to evaluate the safety of BAY 94-9027 infusions for prophylaxis and treatment of bleeding in previously treated children aged 7 to <12 years with severe hemophilia A. The PROTECT Kids study was a Phase 3, open-label, uncontrolled, multicenter study in previously treated children <12 years of age with severe hemophilia A (>50 prior EDs).

Version 4.1 of the RMP has also been submitted.

Action: For adoption

5.3.15. Deferasirox – EXJADE (CAP) – EMA/VR/0000333352

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of sections 4.3 and 4.5 of the SmPC in order to remove the existing contraindication for the combination of deferasirox with other iron chelator therapies, based on a cumulative review of the available data. The Package Leaflet is updated accordingly. The RMP version 24.0 has also been submitted.

Action: For adoption

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

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

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

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

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

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

Action: For adoption

5.3.17. 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

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

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include PADCEV, in combination with pembrolizumab, for use as neoadjuvant treatment and continued as adjuvant treatment following radical cystectomy, is indicated for the treatment of adult patients with muscle-invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy, based on interim

results from study EV-303/KN-905; this is a randomized phase 3 study evaluating cystectomy with perioperative pembrolizumab and cystectomy with perioperative enfortumab, vedotin and pembrolizumab versus cystectomy alone in participants who are cisplatin-ineligible or decline cisplatin with muscle-invasive bladder cancer. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, and to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

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

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Extension of indication to include in combination with rituximab and lenalidomide treatment of patients with relapsed/refractory follicular lymphoma (FL) for Tepkinly, based on interim results from study M20-638; this is a Phase 3, open-label study to evaluate safety and efficacy of epcoritamab in combination with rituximab and lenalidomide (R2) compared to R2 in subjects with relapsed or refractory follicular lymphoma (EPCORE FL-1). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.20. Filgotinib – JYSELECA (CAP) – EMA/VR/0000325892

Applicant: Alfasigma S.p.A.

PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include treatment of axial spondyloarthritis in adult patients with active radiographic axial spondyloarthritis (r-axSpA) and with active non-radiographic axial spondyloarthritis (nr-axSpA) for JYSELECA, based on interim results from study LPG0634-CL-336 (OLINGUITO); this is a Phase 3 randomized, placebo-controlled, double-blind, parallel-group program to evaluate efficacy and safety of filgotinib in adult subjects with active axial spondyloarthritis which provide evidence of the efficacy and safety of filgotinib up to Week 52. 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 7.1 of the RMP has also been submitted.

Action: For adoption

5.3.21. Florbetapir (18F) – AMYVID (CAP) – EMA/VR/0000333287

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Dennis Lex

Scope: Update of section 4.8 of the SmPC in order to revise the frequency category of ADRs and include additional adverse reaction terms related to injection site reactions based on a pooled safety analysis incorporating cumulative florbetapir (18F) exposure data from 26 979 subjects from 48 clinical trials; the Package Leaflet is updated accordingly. The RMP version 6.1 has also been submitted. In addition, the MAH took the opportunity update Annex II.D of the SmPC to align with proposed RMP changes.

Action: For adoption

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

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

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

Action: For adoption

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

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

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

Action: For adoption

5.3.24. 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

5.3.25. Glofitamab – COLUMVI (CAP) – EMA/VR/0000327100

Applicant: Roche Registration GmbH

PRAC Rapporteur: Veronika Macurova

Scope: Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add a new warning on 'haemophagocytic lymphohistiocytosis' and to add it to the list of adverse drug reactions (ADRs) with frequency not known, based on a drug safety report. The Package Leaflet is updated accordingly. The RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and administrative changes to the PI.

Action: For adoption

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

Applicant: Proveca Pharma Limited

PRAC Rapporteur: Zane Neikena

Scope: Extension application to introduce a new pharmaceutical form associated with two new strengths (0.68 mg and 1.36 mg orodispersible tablets).

Action: For adoption

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

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Kimmo Jaakkola

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

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

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

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

Action: For adoption

5.3.28. 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

5.3.29. Lacosamide – LACOSAMIDE UCB (CAP); VIMPAT (CAP) – EMA/VR/0000321459

Applicant: UCB Pharma

PRAC Rapporteur: Karin Bolin

Scope: Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update clinical information based on final results from study SP0968 and study EP0223. SP0968 was a phase 2/3, multicenter, open-label, randomized, active comparator study that evaluated the PK, efficacy, safety, and tolerability of lacosamide in neonatal study participants with repeated electroencephalographic neonatal seizures compared with an Active Comparator chosen based on standard of care per the local practice and treatment guidelines. EP0223 is a comparative study on long-term neurodevelopmental outcomes in neonates treated with lacosamide versus other antiseizure medications for neonatal seizures. The RMP version 18.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to implement corrections in some local languages in both Vimpat and Lacosamide UCB Product Information.

Action: For adoption

5.3.30. Obinutuzumab – GAZYVARO (CAP) – EMA/VR/0000327013

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

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

C.6.a: Extension of indication to include treatment of adult patients with active systemic lupus erythematosus (SLE) who are receiving standard therapy, for GAZYVARO, based on the results from study CA42750 (ALLEGORY); this is a Phase III, randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy and safety of obinutuzumab in patients with SLE treated with standard-of-care therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 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 SmPC with minor edits. Version 12 of the RMP has also been submitted.

C.4: Update of section 4.2 of the SmPC to introduce short duration infusion (SDI) as method of administration for SLE patients, supported by previously submitted data in patients with Follicular Lymphoma and by simulations conducted using an integrated population PK model to estimate exposures following administration as an SDI to SLE patients.

Action: For adoption

5.3.31. Octreotide – OCZYESA (CAP) – EMA/VR/0000333073

Applicant: Camurus AB

PRAC Rapporteur: Eamon O Murchu

Scope: Submission of the final report from study HS-19-647, listed as a category 3 study in the RMP. This is a Phase 3, open-label, single-arm, multi-center trial to assess the long-term safety of octreotide subcutaneous depot (CAM2029) in patients with acromegaly. The RMP version 1.1 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. 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

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

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

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

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength (5 mg hard capsule) grouped with an Extension of Indication to include treatment of paediatric patients aged 6 years and older with chronic phase chronic myeloid leukaemia (CP-CML) who are resistant or intolerant to at least one tyrosine kinase inhibitor for ICLUSIG, based on interim results from study INCB 84344-102 and a final results from early-terminated study Ponatinib-1501; the first is an ongoing open-label, single-arm, Phase 1/2 study evaluating the safety and efficacy of ponatinib MONOTHERAPY for the treatment of R/R leukemias, lymphomas, or solid tumors in pediatric participants. The second is a Phase 1/2, single-arm, open-label, multicenter study designed to evaluate the safety, tolerability, PK, and efficacy of ponatinib when administered IN COMBINATION WITH multiagent CHEMOTHERAPY in pediatric patients with Ph+ ALL, Ph+ MPAL, or Ph-like ALL who had a relapse, were resistant or intolerant to at least 1 prior BCR-ABL1 TKI therapy, or had the T315I mutation. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1 and 6.5 of

the SmPC are updated. Package Leaflet is updated accordingly. The RMP version 23.4 has also been submitted.

Action: For adoption

5.3.36. Rucaparib – RUBRACA (CAP) – EMA/VR/0000332297

Applicant: pharmaand GmbH

PRAC Rapporteur: Mari Thorn

Scope: Submission of the updated RMP version 9.0 in order to revise the originally anticipated overall survival (OS) maturity threshold for the ATHENA MONO study.

Action: For adoption

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

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication for treatment of adult patients with PD-L1-negative metastatic triple- negative breast cancer or PD-L1-positive metastatic triple-negative breast cancer previously treated with an anti-PD-(L)1 agent in the curative setting for Trodelvy, based on results from study GS-US-592-6238 (ASCENT-03), which is a phase 3 study of sacituzumab govitecan (IMMU-132) versus treatment of physician's choice (TPC) in Patients With Previously Untreated, Locally Advanced, Inoperable or Metastatic Triple-Negative Breast Cancer Whose Tumors Do Not Express PD-L1 or in Patients Previously Treated With Anti-PD-(L)1 Agents in the Early Setting Whose Tumors Do Express PD-L1. As a consequence, sections 4.1, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted

Action: For adoption

5.3.38. Secukinumab – COSENTYX (CAP) – EMA/VR/0000326984

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Extension of indication to include treatment of polymyalgia rheumatica in adults who have had an inadequate response to glucocorticoids or who experience a relapse during glucocorticoid taper for COSENTYX, based on the week 52 primary analysis results from study CAIN457C22301 as well as supportive safety data from the Phase 3 study CAIN457R12301 (GCAptAIN) in giant cell arteritis (GCA) patients. Study CAIN457C22301 is a randomized, parallel-group, double-blind, placebo-controlled, multicenter Phase 3 trial to evaluate efficacy and safety of secukinumab administered subcutaneously versus placebo, in combination with a glucocorticoid taper regimen, in patients with polymyalgia rheumatica (PMR). 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 13.0 of the RMP has also been submitted. In addition, the MAH is taking this opportunity to implement updates regarding polysorbate

80 in the PI following the guidance on excipients, and to introduce minor editorial changes to the PI.

Action: For adoption

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

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

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

Action: For adoption

5.3.40. 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

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

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Zoubida Amimour

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

Action: For adoption

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

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

5.3.43. Trastuzumab – ZERCEPAC (CAP) – EMA/X/0000321364

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Dirk Mentzer

Scope: Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (600 mg) and a new route of administration (subcutaneous use).

Action: For adoption

5.3.44. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/VR/0000326482

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include treatment of adult patients with HER2-positive breast cancer (IHC3+ or ISH+) who have residual invasive disease after neoadjuvant HER2

targeted treatment for ENHERTU, based on interim results from study DS8201-A-U305 (DESTINY-Breast05); this is a phase 3, multicenter, randomized, open-label, active-controlled study of trastuzumab deruxtecan (T-DXd) versus trastuzumab emtansine (T-DM1) in subjects with high-risk HER2-positive primary breast cancer who have residual invasive disease in breast or axillary lymph nodes following neoadjuvant therapy. 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 10.2 of the RMP has also been submitted.

Action: For adoption

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

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

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

Action: For adoption

5.3.46. Upadacitinib – RINVOQ (CAP) – EMA/VR/0000325958

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include the treatment of non-segmental vitiligo in adults and adolescents 12 years and older who are candidates for systemic therapy, for RINVOQ, based on results from the two replicate Phase 3 studies M19-044: study 1 (R&D/25/1342) and study 2 (R&D/25/1343), as well as from integrated long-term safety data. Study 1 and study 2 are Phase 3, global, randomized, double-blind, placebo-controlled multi-center studies that evaluate the safety and efficacy of upadacitinib in adult and adolescent patients with non-segmental vitiligo. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet has been updated in accordance. Version 19.0 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. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.47. Ustekinumab – USRENTY (CAP) – EMA/VR/0000325350

Applicant: Biosimilar Collaborations Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: C.2.a (Type IB): To update sections 4.1, 4.5, 4.8 and 5.2 of the SmPC to reflect the removal of the wording "or have medical contraindications to such therapies" from the therapeutic indication for Crohn's disease, the brief update of interaction data, the update of safety data, and the addition of CYP450 interaction information, following assessment of the same changes for the reference product Stelara;

Q.IV.2.a (Type II): To add 45 mg solution for injection in pre-filled pen (EU/1/25/1973/00x) and 90 mg solution for injection in pre-filled pen (EU/1/25/1973/00x);

Version 1.1 of RMP (dated 21-Jan-2026) for which data lock point is 31-Oct-2025 has been included.

Action: For adoption

5.3.48. 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. Alemtuzumab – LEMTRADA (CAP) – EMA/PSUR/0000321520

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00010055/202509)

Action: For adoption

6.1.2. Amikacin – ARIKAYCE LIPOSOMAL (CAP) – EMA/PSUR/0000321506

Applicant: Insmed Netherlands B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010882/202509)

Action: For adoption

6.1.3. Atogepant – AQUIPTA (CAP) – EMA/PSUR/0000321517

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00000100/202509)

Action: For adoption

6.1.4. Brolucizumab – BEOVU (CAP) – EMA/PSUR/0000321518

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010829/202510)

Action: For adoption

6.1.5. Chenodeoxycholic acid – CHENODEOXYCHOLIC ACID LEADIANT (CAP) – EMA/PSUR/0000321503

Applicant: Leadiant GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010590/202510)

Action: For adoption

6.1.6. Chikungunya vaccine (live) – IXCHIQ (CAP) – EMA/PSUR/0000327923

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011058/202511)

Action: For discussion

6.1.7. Concizumab – ALHEMO (CAP) – EMA/PSUR/0000321510

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011105/202509)

Action: For adoption

6.1.8. Dibotermin alfa – INDUCTOS (CAP) – EMA/PSUR/0000321514

Applicant: Medtronic Biopharma B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001034/202509)

Action: For adoption

6.1.9. Etrasimod – VELSIPITY (CAP) – EMA/PSUR/0000321519

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00000273/202510)

Action: For adoption

6.1.10. Futibatinib – LYTGOBI (CAP) – EMA/PSUR/0000321515

Applicant: Taiho Pharma Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00000068/202509)

Action: For adoption

6.1.11. Herpes zoster vaccine (recombinant, adjuvanted) – SHINGRIX (CAP) – EMA/PSUR/0000321507

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010678/202510)

Action: For adoption

6.1.12. Histamine dihydrochloride – CEPLENE (CAP) – EMA/PSUR/0000321522

Applicant: Laboratoires Delbert

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00001610/202510)

Action: For adoption

6.1.13. Inavolisib – ITOVEBI (CAP) – EMA/PSUR/0000321509

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011164/202510)

Action: For adoption

6.1.14. Lasmiditan – RAYVOW (CAP) – EMA/PSUR/0000321508

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Jana Pecherova

Scope: Evaluation of a PSUSA procedure (PSUSA/00011011/202510)

Action: For adoption

6.1.15. Macitentan / Tadalafil – YUVANCI (CAP) – EMA/PSUR/0000321504

Applicant: Janssen Cilag International

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00011090/202510)

Action: For adoption

6.1.16. Maralixibat – LIVMARLI (CAP) – EMA/PSUR/0000321513

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011032/202509)

Action: For adoption

6.1.17. Marstacimab – HYMPAVZI (CAP) – EMA/PSUR/0000321516

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011101/202510)

Action: For adoption

6.1.18. Mirikizumab – OMVOH (CAP) – EMA/PSUR/0000321511

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000049/202509)

Action: For adoption

6.1.19. Nemolizumab – NEMLUVIO (CAP) – EMA/PSUR/0000321530

Applicant: Galderma International

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011111/202509)

Action: For adoption

6.1.20. Olipudase alfa – XENPOZYME (CAP) – EMA/PSUR/0000321501

Applicant: Sanofi B.V.

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011003/202509)

Action: For adoption

6.1.21. Selumetinib – KOSELUGO (CAP) – EMA/PSUR/0000321505

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010936/202510)

Action: For adoption

6.1.22. Tobramycin – VANTOBRA (CAP) – EMA/PSUR/0000321512

Applicant: Pari Pharma GmbH

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010370/202509)

Action: For adoption

6.1.23. Trabectedin – YONDELIS (CAP) – EMA/PSUR/0000321523

Applicant: Pharma Mar S.A.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00003001/202509)

Action: For adoption

6.1.24. Vilobelimab – GOHIBIC (CAP) – EMA/PSUR/0000321533

Applicant: InflaRx GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011103/202510)

Action: For adoption

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

6.2.1. Choriogonadotropin alfa – OVITRELLE (CAP), NAP; Chorionic gonadotrophin (NAP); Human chorionic gonadotropin (NAP) – EMA/PSUR/0000321521

Applicants: Merck Europe B.V., various

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000736/202509)

Action: For adoption

6.2.2. Midazolam – BUCCOLAM (CAP); NAP – EMA/PSUR/0000321529

Applicants: Neuraxpharm Pharmaceuticals S.L., various

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010118/202509)

Action: For adoption

6.2.3. Sodium oxybate – XYREM (CAP); NAP – EMA/PSUR/0000321502

Applicants: UCB Pharma, various

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010612/202510)

Action: For adoption

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

6.3.1. Allergen for therapy: dermatophagoides pteronyssinus / dermatophagoides farina (oromucosal use, products authorised via mutually recognition procedure and decentralised procedure) – EMA/PSUR/0000321532

Applicants: various

PRAC Lead: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010582/202509)

Action: For adoption

6.3.2. Bivalirudin – EMA/PSUR/0000321527

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00000421/202509)

Action: For adoption

6.3.3. Lactitol – EMA/PSUR/0000321534

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00001819/202509)

Action: For adoption

6.3.4. Lisinopril, lisinopril / hydrochlorothiazide – EMA/PSUR/0000321531

Applicants: various

PRAC Lead: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010532/202509)

Action: For adoption

6.3.5. Progesterone – EMA/PSUR/0000321526

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00002540/202509)

Action: For adoption

6.3.6. Silver sulfadiazine – EMA/PSUR/0000321525

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00002702/202509)

Action: For adoption

6.3.7. Terizidone – EMA/PSUR/0000321528

Applicants: various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00002904/202509)

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

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

Applicant: Eisai GmbH

PRAC Rapporteur: Eva Jirsová

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

Action: For adoption

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

Applicant: Autolus GmbH

[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

PRAC Rapporteur: Karin Erneholm

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

Action: For adoption

7.1.3. Volanesorsen – WAYLIVRA (CAP) – EMA/PASS/0000334506

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: PASS amendment (PASS 107o): PASS and Product Registry to further characterise the safety and effectiveness of WAYLIVRA in patients with Familial Chylomicronaemia Syndrome (FCS) under real-world conditions

Action: For adoption

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

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)

Action: For adoption

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

Applicant: CSL Behring GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

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

Action: For adoption

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

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

[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

Scope: Xeljanz Submission of A3921321 study interim report (RMP category 3 study; MEA) and protocol amendment (version 8.0) "A Post-Authorisation Safety Study of the Utilisation and Prescribing Patterns of Xeljanz (tofacitinib) in the European Union Using Secondary Data Sources"

Action: For adoption

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

None

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

7.4.1. Conestat alfa – RUCONEST (CAP) – EMA/VR/0000326016

Applicant: Pharming Group N.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Submission of the final report from study PHARM/EU/aRMM/01 listed as a category 3 study in the RMP. This is a non-imposed non-interventional PASS concerning additional risk minimization measures for Ruconest – European survey of educational materials. The RMP version 22.0 has also been submitted.

Action: For adoption

7.4.2. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/VR/0000332196

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final report from study C4591009 listed as a category 3 study in the RMP. This is an observational PASS designed to assess safety events of interest (including myocarditis and pericarditis) among recipients of original monovalent Pfizer-BioNTech COVID-19 Vaccine, using data from administrative claims and electronic health records from data research partners participating in the Sentinel System.

Action: For adoption

7.4.3. 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

[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

study (PASS) relying on data collected as part of the PedNet Registry. The RMP version 6.0 has also been submitted.

Action: For adoption

7.4.4. Enfortumab vedotin – PADCEV (CAP) – EMA/VR/0000333033

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Submission of the final report from study ISN: 7465-PV-0002 listed as a category 3 study in the RMP. This is a non-interventional PASS to assess patients', or their caregivers', awareness and understanding of the content of the Padcev Patient Card (PC) related to the risk of skin reactions and reported behaviours to minimise the risk. The RMP version 5.2 has also been submitted.

Action: For adoption

7.4.5. Eslicarbazepine acetate – ZEBINIX (CAP) – EMA/VR/0000332409

Applicant: Bial Portela & Ca S.A.

PRAC Rapporteur: Dennis Lex

Scope: Submission of the final report from the post authorisations safety study EURAP (BIA-2093-402) listed as a category 3 study in the RMP. This is an international, prospective observational registry designed to assess the risks associated with antiepileptic drug exposure during pregnancy. The updated RMP version 23.0 has also been submitted. Risk information has been updated based on clinical evidence, including clinical trials and post-marketing data, together with a comprehensive review of the published literature.

Action: For adoption

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

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Dennis Lex

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

Action: For adoption

7.4.7. Ofatumumab – KESIMPTA (CAP) – EMA/VR/0000315689

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Update of section 4.6 'pregnancy' of the SmPC based on the final reports from Kesimpta Pregnancy Registry and the PRegnancy outcomes Intensive Monitoring (PRIM) study.

Action: For adoption

7.4.8. Ropeginterferon alfa-2b – BESREMI (CAP) – EMA/VR/0000332690

Applicant: Aop Orphan Pharmaceuticals GmbH

PRAC Rapporteur: Carla Torre

Scope: Submission of the final report from the post-authorisation safety study (PASS) EUPAS29462, listed as a category 3 study in the RMP. This is a multicenter, non-interventional, observational and non-imposed post-authorisation safety study of ropeginterferon alfa-2b in polycythaemia vera patients. The RMP version 4.0 has also been submitted.

Action: For adoption

7.4.9. Tacrolimus – ADVAGRAF (CAP); MODIGRAF (CAP); NAP – EMA/VR/0000315125

Applicants: Astellas Pharma Europe B.V., various

PRAC Rapporteur: Eamon O Murchu

Scope: Submission of the final report from noninterventional post-authorization safety study (NIPASS) listed as a category 3 study in the RMP. This is a feasibility assessment of conducting a NIPASS of outcomes associated with the use of tacrolimus around conception, or during pregnancy or lactation using data from available secondary use data sources to replicate the Transplant Pregnancy Registry International (TPRI) study. The RMP version 6.0 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. Abatacept – ORENCIA (CAP) – EMA/PAM/0000334018

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Interim study results for Study IM101240: Observational Registry of Abatacept in Patients with Juvenile Idiopathic Arthritis.

Action: For adoption

7.5.2. Abrocitinib – CIBINQO (CAP) – EMA/PAM/0000333269

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: Submission of the first progress report for the PASS B7451120, a prospective active surveillance study to monitor growth, development, and maturation among adolescents with atopic dermatitis exposed to abrocitinib.

Action: For adoption

7.5.3. Atogepant – AQUIPTA (CAP) – EMA/PAM/0000334196

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: Submission of the third interim report for Study P22-392: Atogepant pregnancy exposure registry

Action: For adoption

7.5.4. Atogepant – AQUIPTA (CAP) – EMA/PAM/0000334182

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: Third Interim report and Updated Protocol Submission - Study P22-419 Category 3 PASS: Observational study to assess pregnancy outcomes following exposure to atogepant

Action: For adoption

7.5.5. Diroximel fumarate – VUMERITY (CAP) – EMA/PAM/0000334226

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Dennis Lex

Scope: Third annual interim report for cat. 3 PASS 272MS401 (A prospective observational pregnancy exposure registry to characterise how DRF may affect pregnancy and infant outcomes).

Action: For adoption

7.5.6. Etuvetidigene autotemcel – WASKYRA (CAP) – EMA/PAM/0000334844

Applicant: Fondazione Telethon Ets, ATMP

PRAC Rapporteur: Jo Robays

Scope: Submission of an updated PASS protocol (version 3.0) for the imposed interventional Post-Approval Safety Study (PASS) WAS-TLT003-01, a Category 1- Required additional

pharmacovigilance activity. The protocol is submitted within three months of the EC Decision as defined in the approved RMP (version 0.6)

Action: For adoption

7.5.7. Fenfluramine – FINTEPLA (CAP) – EMA/PAM/0000323622

Applicant: UCB Pharma

PRAC Rapporteur: Dennis Lex

Scope: P46 EP0241 Final Clinical Study Report for non-interventional retrospective cohort study using national pharmacy database to evaluate the real-world use of fenfluramine (Fintepla) for Dravet syndrome, Lennox-Gastaut syndrome, and other epilepsies in the United States.

Action: For adoption

7.5.8. Fenfluramine – FINTEPLA (CAP) – EMA/PAM/0000326084

Applicant: UCB Pharma

PRAC Rapporteur: Dennis Lex

Scope: P46 RWE1609 Final Clinical Study Report of non-interventional retrospective cohort study using US claims and fact-of-death to evaluate mortality rates and associated risk factors among patients diagnosed with Dravet Syndrome and Lennox-Gastaut Syndrome.

Action: For adoption

7.5.9. Fenfluramine – FINTEPLA (CAP) – EMA/PAM/0000327550

Applicant: UCB Pharma

PRAC Rapporteur: Dennis Lex

Scope: P46 Study RWE1608: non-interventional retrospective cohort analysis using US Komodo claims data to evaluate the impact of Fintepla initiation among LGS patients.

Action: For adoption

7.5.10. Inotersen – TEGSEDI (CAP) – EMA/PAM/0000326086

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Fourth annual report on A Prospective, Non-Interventional, Long-Term, Multinational Cohort Safety Study of Patients with Hereditary Transthyretin Amyloidosis with Polyneuropathy (hATTR-PN) .

Action: For adoption

7.5.11. Iptacopan – FABHALTA (CAP) – EMA/PAM/0000331969

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Lina Seibokiene

Scope: PAM [MEA] - First Interim report of Post-authorization safety study of iptacopan in adult patients with paroxysmal nocturnal hemoglobinuria (PNH) using data from the non-interventional IPIG PNH Registry

Action: For adoption

7.5.12. Iptacopan – FABHALTA (CAP) – EMA/PAM/0000331978

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Lina Seibokiene

Scope: PAM [MEA] -2nd Interim report of safety and eGFR data from all patients with recurrent complement 3 glomerulopathy (C3G) enrolled in the C3G EAP/MAP

Action: For adoption

7.5.13. Lasmiditan – RAYVOW (CAP) – EMA/PAM/0000332938

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Jana Pecherova

Scope: Interim study results for Observational Cohort Study of Lasmiditan Exposure and Motor Vehicle Accidents in the United States

Action: For adoption

7.5.14. Naldemedine – RIZMOIC (CAP) – EMA/PAM/0000320323

Applicant: Shionogi B.V.

PRAC Rapporteur: Eamon O Murchu

Scope: 4th Annual Progress Report with interim report with study results for Naldemedine: An Observational Post-Authorisation Safety Study (PASS) of Patients with Chronic Opioid Use for Non-Cancer Pain and Cancer Pain who have Opioid-Induced Constipation (OIC)

Action: For adoption

7.5.15. 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

7.5.16. Risdiplam – EVRYSDI (CAP) – EMA/PAM/0000310307

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: 4th annual progress report for Evrysdi non-interventional pregnancy surveillance Study BN42833

Action: For adoption

7.5.17. Rurioctocog alfa pegol – ADYNOVI (CAP) – EMA/PAM/0000326983

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Bianca Mulder

Scope: 5th Interim report of study PASS TAK-660-403: Evaluation of long-term safety of Adynovi/Adynovate (Antihaemophilic Factor [Recombinant] PEGylated, rurioctocog alfa pegol) in patients with haemophilia A

Action: For adoption

7.5.18. 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. Glucarpidase – VORAXAZE (CAP) – EMA/S/0000322329

Applicant: Serb

PRAC Rapporteur: Dennis Lex

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.2. Pegzilarginase – LOARGYS (CAP) – EMA/S/0000326830

Applicant: Immedica Pharma AB

PRAC Rapporteur: Dennis Lex

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. Susoctocog alfa – OBIZUR (CAP) – EMA/S/0000324538

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.4. Tabelecleucel – EBVALLO (CAP) – EMA/S/0000326533

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Amelia Cupelli

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

8.2.1. Avapritinib – AYVAKYT (CAP) – EMA/R/0000335342

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.2. Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded – ZEMCELPRO (CAP) – EMA/R/0000333327

Applicant: Cordex Biologics International Limited

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.3. Elafibranor – IQIRVO (CAP) – EMA/R/0000335590

Applicant: Ipsen Pharma

PRAC Rapporteur: Rugile Pilviniene

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.4. Epcoritamab – TEPKINLY (CAP) – EMA/R/0000334812

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.5. Larotrectinib – VITRAKVI (CAP) – EMA/R/0000335017

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.6. Odronextamab – ORDSPONO (CAP) – EMA/R/0000333139

Applicant: Regeneron Ireland Designated Activity Company

PRAC Rapporteur: Veronika Macurova

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.7. Tafasitamab – MINJUVI (CAP) – EMA/R/0000334308

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Adalimumab – LIBMYRIS (CAP) – EMA/R/0000326540

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.2. Adalimumab – HUKYNDRA (CAP) – EMA/R/0000326487

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.3. Diroximel fumarate – VUMERITY (CAP) – EMA/R/0000327345

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Dennis Lex

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.4. Pegcetacoplan – ASPAVELI (CAP) – EMA/R/0000326756

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) – VAXNEUVANCE (CAP) – EMA/R/0000326976

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. Ripretinib – QINLOCK (CAP) – EMA/R/0000326982

Applicant: Deciphera Pharmaceuticals (Netherlands) B.V.

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.7. Rivaroxaban – RIVAROXABAN VIATRIS (CAP) – EMA/R/0000327079

Applicant: Viatris Limited

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.8. Sacituzumab govitecan – TRODELVY (CAP) – EMA/R/0000326788

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.9. Sugammadex – SUGAMMADEX MYLAN (CAP) – EMA/R/0000327067

Applicant: Mylan Pharmaceuticals Limited

PRAC Rapporteur: Terhi Lehtinen

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.10. Zanubrutinib – BRUKINSA (CAP) – EMA/R/0000326587

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspections

Disclosure of information on results of pharmacovigilance inspections could undermine the protection of the purpose of these inspections, investigations and audits. Therefore such information is not reported in the agenda.

9.3. Others

None

10. Other safety issues for discussion requested by the Member States, CHMP or the EMA

None

11. Scientific advice procedures

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

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC membership

Action: For information

12.1.2. 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. PRAC strategic review and learning meeting (SRLM) under the Cyprus presidency of the European Union (EU) Council – Pafos, Cyprus, 12 – 13 May 2026 - update

PRAC lead: Panagiotis Psaras

Action: For discussion

12.5. Cooperation with International Regulators

12.5.1. International Conference on Harmonisation (ICH) E23 guideline - update

PRAC lead: Carla Torre

Action: For information

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

None

12.7. PRAC work plan

None

12.8. Planning and reporting

12.8.1. Marketing authorisation applications (MAA) and technology forecast: April 2026 – December 2028

Action: For information

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

PRAC lead: Petar Mas

Action: For discussion

12.10.3. PSURs repository

None

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

Action: For adoption

12.11. Signal management

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

PRAC lead: Dennis Lex

Action: For discussion

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

12.14.2. Tools, educational materials and effectiveness measurement of risk minimisations

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

12.15.2. Post-authorisation Safety Studies – non-imposed PASS

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

12.20.1. Study on the implementation of controlled access to and distribution of medicinal products in EU Member States (SC02/EMA/2020/46/TDA/L4.02) - regulatory follow-up

PRAC lead: Liana Martirosyan

Action: For discussion

12.21. Others

None

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).