7 April 2026
EMA/PRAC/68437/2026
Human Medicines Division

# Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 07-10 April 2026

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

07 April 2026, 09:30 – 19:30, via teleconference

08 April 2026, 08:30 – 19:30, via teleconference

09 April 2026, 08:30 – 19:30, via teleconference

10 April 2026, 08:30 – 16:00, via teleconference

**Disclaimers**

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

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

**Note on access to documents**

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

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# 1. Introduction

## 1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PRAC plenary session to be held 07-10 April 2026. See April month 2026 PRAC minutes (to be published post May 2026 PRAC meeting).

## 1.2. Agenda of the meeting on 07-10 April 2026

**Action:** For adoption

## 1.3. Minutes of the previous meeting on 09-12 March 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. Binimetinib - MEKTOVI (CAP); Encorafenib – BRAFTOVI (CAP)

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: To be appointed

Scope: Signal of neutropenia, febrile neutropenia

**Action:** For adoption of PRAC recommendation

EPITT 20255 – New signal

Lead Member State(s): LT, PT

## 4.2. Signals follow-up and prioritisation

### 4.2.1. Axicabtagene ciloleucel – YESCARTA (CAP) - EMEA/H/C/002695/SDA/019; lisocabtagene maraleucel – BREYANZI (CAP) - EMEA/H/C/002695/SDA/025

Applicants: Bristol-Myers Squibb Pharma EEIG (Breyanzi), Kite Pharma EU B.V. (Yescarta), ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Signal of increased risk of brain oedema in primary mediastinal large B-cell lymphoma (PMBCL) patients

**Action:** For adoption of PRAC recommendation

EPITT 20224 – Follow-up to December 2025

[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

### 4.2.2. Ponatinib - ICLUSIG (CAP) - EMEA/H/C/002695/SDA/019

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Signal of congenital megacolon, maternal exposure during pregnancy

**Action:** For adoption of PRAC recommendation

EPITT 20231 – Follow-up to December 2025

### 4.2.3. Tirzepatide - MOUNJARO (CAP); MOUNJARO KWIKPEN (CAP) - EMEA/H/C/005620/SDA/007

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Signal of drug interaction with warfarin and other coumarin derivatives leading to international normalised ratio decreased

**Action:** For adoption of PRAC recommendation

EPITT 20198 – 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. Catequentinib (CAP MAA) - EMEA/H/C/006317, Orphan

Scope (pre D-180 phase): Treatment of synovial sarcoma or leiomyosarcoma

**Action:** For adoption

### 5.1.2. Denosumab (CAP MAA) - EMEA/H/C/006626

Scope (pre D-180 phase): Prevention of skeletal related events and treatment of giant cell tumour of bone

**Action:** For adoption

### 5.1.3. Ensitrelvir (CAP MAA) - EMEA/H/C/006063

Scope (pre D-180 phase): Treatment of coronavirus disease 2019 (COVID-19)

**Action:** For adoption

### 5.1.4. Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated (CAP MAA) - EMEA/H/C/006692

Scope (pre D-180 phase): Prophylaxis of influenza

**Action:** For adoption

### 5.1.5. Insulin efsitora alfa (CAP MAA) - EMEA/H/C/006388

Scope (pre D-180 phase): Treatment of type 2 diabetes mellitus

**Action:** For adoption

### 5.1.6. Leriglitazone (CAP MAA) - EMEA/H/C/006693, Orphan

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

**Action:** For adoption

### 5.1.7. Levodopa / Carbidopa (CAP MAA) - EMEA/H/C/006629

Scope (pre D-180 phase): Treatment of adult patients with Parkinson’s disease

**Action:** For adoption

### 5.1.8. Narsoplimab (CAP MAA) - EMEA/H/C/005247, Orphan

Scope (pre D-180 phase): Treatment of patients with haemopoietic stem cell transplant-associated thrombotic microangiopathy.

**Action:** For adoption

### 5.1.9. Norucholic acid (CAP MAA) - EMEA/H/C/006515, Orphan

Scope (pre D-180 phase): Treatment of primary sclerosing cholangitis (PSC) in adults.

**Action:** For adoption

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

### 5.2.1. Bosentan – STAYVEER (CAP); TRACLEER (CAP) – EMA/VR/0000316336

Applicant: Janssen Cilag International

PRAC Rapporteur: Zoubida Amimour

Scope: Submission of an updated RMP version 12 for TRACLEER and STAYVEER to remove the Liver Safety Update Report (LSUR) as a routine pharmacovigilance activity for the important identified risk of hepatotoxicity. The Annex II is updated accordingly. In addition, the MAH is updating the list of safety concerns in line with requests from the PRAC in their assessment report for procedure PSUSA/00000425/202411.

**Action**: For adoption

### 5.2.2. Carfilzomib – KYPROLIS (CAP) – EMA/VR/0000325402

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Submission of an updated RMP version 13.0 in order to remove important identify risks from the list of safety concerns following PSUSA procedure EMEA/H/C/PSUSA/00010448/202207.

**Action**: For adoption

### 5.2.3. Ocrelizumab – OCREVUS (CAP) – EMA/VR/0000291534

Applicant: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

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

**Action**: For adoption

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

### 5.3.1. Afamelanotide – SCENESSE (CAP) – EMA/VR/0000325360

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Dennis Lex

Scope: Submission of the final report from study CUV052 listed as a category 3 study in the RMP. This is a phase II study to evaluate the pharmacokinetics of afamelanotide in patients with erythropoietic protoporphyria. The RMP version 11 has also been submitted.

**Action**: For adoption

### 5.3.2. Alpelisib – PIQRAY (CAP) – EMA/VR/0000317159

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication for PIQRAY in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following an endocrine-based regimen; based on the primary analysis (DCO 15-Oct-2024) from the Phase III Study CBYL719C2303 (C2303, EPIK-B5). This is a Phase III, randomized, double-blind, placebo-controlled study of alpelisib (BYL719) in combination with fulvestrant for men and postmenopausal women with HR-positive, HER2-negative advanced breast cancer with PIK3CA mutation, who progressed on or after aromatase inhibitor and a CDK4/6 inhibitor. As a consequence, sections 4.2, 4.4, 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.

**Action**: For adoption

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

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

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

Type II (C.I.6): Extension of indication to include acute treatment of migraine with or without aura in adults, based on interim results from study M24-305; this is a 24-week, global, Phase 3, multicenter, randomized, double blind, placebo-controlled, multiple-migraine attack study with an open label period to evaluate the safety and efficacy of atogepant in adult participants for the acute treatment of migraine (ECLIPSE). As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.2 of the RMP has also been submitted.

**Action**: For adoption

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

Applicant: Kite Pharma EU B.V.

PRAC Rapporteur: Karin Erneholm

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

**Action**: For adoption

### 5.3.5. Berotralstat – ORLADEYO (CAP) – EMA/X/0000268892

Applicant: Biocryst Ireland Limited

PRAC Rapporteur: Julia Pallos

Scope: Extension application to introduce a new pharmaceutical form associated with new strengths (78 mg, 96 mg, 108 and 132 film - coated granules). The new presentations are indicated to include treatment for paediatric patients aged 2 to less than 12 years. The extension application is grouped with a type II clinical variation (C.I.4). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2.1 of the RMP has also been submitted.

**Action**: For adoption

### 5.3.6. Capivasertib – TRUQAP (CAP) – EMA/VR/0000293735

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Extension of indication to include Truqap in combination with abiraterone for the treatment of metastatic castration-sensitive prostate cancer characterized by PTEN deficient tumours based on non-clinical and clinical dataset, including interim results from the pivotal study D361BC00001 (CAPItello-281); this is a Phase III double-blind, randomised, placebo-controlled study assessing the efficacy and safety of capivasertib + abiraterone versus placebo + abiraterone as treatment for patients with de novo metastatic hormone-sensitive prostate cancer (mHSPC) characterised by PTEN deficiency; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 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

### 5.3.7. Ceftolozane / Tazobactam – ZERBAXA (CAP) – EMA/VR/0000320716

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Adam Przybylkowski

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

C.I.6: Extension of indication to include treatment of hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP), in paediatric patients from birth to less than 18 years of age for ZERBAXA, based on the final results from study MK-7625A-036. This is a Phase 1, open-label, non-comparative, multicentre clinical study to evaluate the safety, tolerability, and pharmacokinetics of ceftolozane/tazobactam in paediatric participants with nosocomial pneumonia. 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 accordingly.

C.I.4: Update of sections 4.2 and 5.2 of the SmPC in order to include dosing recommendations for paediatric patients with impaired renal function, for the indications of complicated Intra-Abdominal Infections (cIAI), Acute pyelonephritis (AP) and complicated Urinary Tract Infections (cUTI), based on an M&S analysis integrating adult and pediatric

data sources as described in M&S report "Population pharmacokinetic and probability of target attainment analyses of MK-7625A (ZERBAXA) in pediatric patients in support of nosocomial pneumonia"

Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, section 5.1 "Susceptibility testing breakpoints" in the SmPC has been brought in line with the Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections.

**Action**: For adoption

### 5.3.8. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/VR/0000320534

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

C.I.6.a. To modify the approved therapeutic indication by extending from COMIRNATY concentrate for dispersion for injection formulation to Comirnaty dispersion for injection formulation as well as the overall change of posology from 3mcg to 10mcg and dosing regimen simplification (i.e. from 3-dose to a 2-dose primary course for 6 months to <2 years of age and to a single dose for 2 years to <5 years of age) for the active immunization to prevent COVID-19 caused by SARS-CoV-2 in infants and children from 6 months to <5 years without history of completion of COVID-19 primary series based on sub-study A (SSA) phase 2/3 Groups 1-5 of study C4591048 as well as to support the approved 10mcg single dose simplified posology in vaccine-naïve children from 5 to 11 years of age based on substudy E (SSE) of study C4591048, listed as a category 3 study in the RMP. As consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 6.5, 6.6 and 8 of the SmPC and sections 1, 2, 3, 4 and 6 of the PL are updated accordingly. Study C4591048 is a master phase 1/2/3 protocol to investigate the safety, tolerability, and immunogenicity of variant adapted BNT162b2 RNA – based vaccine candidate(s) in healthy children. The updated RMP version 15.2 has also been submitted. In addition, the MAH took the opportunity to implement minor editorial changes in the PI.

C.I.7.b. To delete the 3mcg strength from the Comirnaty Marketing authorisation (EU/1/20/1528/035-036, EU/1/20/1528/042, EU/1/20/1528/050).

**Action**: For adoption

### 5.3.9. Dapivirine – DAPIVIRINE VAGINAL RING 25 MG (CAP) – EMA/X/0000314697

Applicant: International Partnership For Microbicides

PRAC Rapporteur: Jan Neuhauser

Scope: Extension application to add a new strength of 100 mg for dapivirine vaginal delivery system, for vaginal use grouped with a type IA variation (A.2.a) to change the (invented) name of the medicinal product from 'Dapivirine Vaginal Ring 25 mg' to 'Dapivirine Vaginal Ring'. The RMP (version 2.1) is updated in accordance.

**Action**: For adoption

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

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy for INAQOVI in combination with venetoclax, based on interim results from study ASTX727-07; this is a single-arm, open-label pharmacokinetic, safety, and efficacy study of ASTX727 in combination with venetoclax in adult patients with acute myeloid leukemia; As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and bring editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

**Action**: For adoption

## 5.3.11. Deucravacitinib – SOTYKTU (CAP) – EMA/VR/0000309456

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

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

**Action**: For adoption

## 5.3.12. Evolocumab – REPATHA (CAP) – EMA/VR/0000322435

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to extend the indication for REPATHA to include adults at high risk for a first cardiovascular event, based on the final results from study 20170625 (VESALIUS); this is a Phase 3, double-blind, randomized, placebo-controlled, multicenter study to evaluate the impact of evolocumab on major cardiovascular events in patients at high cardiovascular risk without prior myocardial infarction or stroke. 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 9.0 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. Furthermore, some typographical errors were corrected, and the PI is brought in line with the latest QRD template version.

**Action**: For adoption

### 5.3.13. Fedratinib – INREBIC (CAP) – EMA/VR/0000324950

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Sonja Radowan

Scope: A grouped application consisting of:

C.4. Update of sections 4.4, 4.8, and 5.1 of the SmPC in order to update clinical pharmacology, efficacy and safety information based on final results from study FEDR MF 002 listed as a category 3 study in the RMP; this is a phase 3, multicenter, open-label, randomized study to evaluate the efficacy and safety of fedratinib compared to best available therapy in subjects with DIPSS-intermediate or high-risk primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis and previously treated with ruxolitinib; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted.

C.3. Update of section 4.8 of the SmPC in order to add subdural hematoma to the list of adverse drug reactions (ADRs) following recommendation of PSUSA PSUSA/00010909/202508.

**Action**: For adoption

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

Applicant: CSL Behring GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: A grouped application consisting of:

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

**Action**: For adoption

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

Applicant: AstraZeneca AB

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.2 and 4.4 of the SmPC in order to introduce self-administration instructions based on postmarketing data and literature. The Package Leaflet and Labelling updated accordingly. The RMP version 13.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.

**Action**: For adoption

### 5.3.16. Insulin icodec / Semaglutide – KYINSU (CAP) – EMA/VR/0000322527

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise for KYINSU, based on results from the Phase 3b study NN1535-4988 (COMBINE 4); this is a 40-week study comparing the efficacy and safety of once weekly IcoSema and daily insulin glargine 100 units/mL in participants with type 2 diabetes inadequately controlled on oral anti-diabetic drugs. 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 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.

**Action**: For adoption

### 5.3.17. Lisocabtagene maraleucel / Lisocabtagene maraleucel – BREYANZI (CAP) – EMA/VR/0000327431

Applicant: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of the final report from study CA082-1105 listed as a Specific Obligation in the Annex II of the Product Information. This is a non-interventional study submitted to summarize the consistency of Breyanzi product batch quality data measured at the time of release and clinical outcomes in patients treated with Breyanzi in the post-marketing setting for R/R LBCL within the approved indications and dose range per the EU PI. The Annex II and the RMP version 10.0 are updated accordingly. In addition, the MAH took the opportunity to make a minor editorial update by removing some grey shading from Annex III.

**Action**: For adoption

### 5.3.18. Mavacamten – CAMZYOS (CAP) – EMA/VR/0000294573

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: A grouped application consisting of:

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

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

**Action**: For adoption

### 5.3.19. Naloxone – NYXOID (CAP) – EMA/VR/0000325329

Applicant: Mundipharma Corporation (Ireland) Limited

PRAC Rapporteur: Liana Martirosyan

Scope: Change in the legal status of Nyxoid from 'medicinal product subject to medical prescription' to 'medicinal products not subject to medical prescription'.

**Action**: For adoption

### 5.3.20. Nivolumab – OPDIVO (CAP) – EMA/VR/0000304938

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include OPDIVO for the treatment of adults and adolescents 12 years of age and older with previously untreated Stage III or IV classical Hodgkin Lymphoma (cHL), based on results from the pivotal study CA2098UT (SWOG 1826), a Phase 3, randomized, open-label study of nivolumab (Opdivo) + AVD (N-AVD) versus brentuximab vedotin (Adcetris) + AVD (Bv-AVD) in patients (age ≥12 years) with newly diagnosed, advanced stage cHL. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 51.0 of the RMP has also been submitted.

**Action**: For adoption

### 5.3.21. Pandemic influenza vaccine (H5N1) (live attenuated, nasal) – PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) – EMA/VR/0000321324

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Extension of indication to remove the upper age limit from the indication for Pandemic influenza vaccine (H5N1) (live, nasal), based on efficacy and safety data previously submitted in the Marketing Authorisation Application (MAA). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, and 5.3 of the SmPC are updated. The Annex II and the Package Leaflet are updated in accordance. Version 2.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes throughout the PI and update the list of local representatives in the Package Leaflet.

**Action**: For adoption

### 5.3.22. Risankizumab – SKYRIZI (CAP) – EMA/X/0000296763

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Extension application to introduce a new strength of 55 mg solution for injection grouped with a type II variation C.I.6.a to include treatment of paediatric plaque psoriasis (6 to < 18 years) for Skyrizi, based on final results from study M19-977 and interim results

from study M19-973. M19-977 is a randomized, active-controlled, efficacy assessor-blinded study to evaluate pharmacokinetics, safety, and efficacy of risankizumab in patients from 6 to less than 18 years of age with moderate to severe plaque psoriasis; M19-973 is a phase 3 multicenter, single-arm, open-label extension study to assess the safety, tolerability, and efficacy of risankizumab in subjects with moderate to severe plaque psoriasis who have completed participation in study M19-977. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.4, 6.5, 6.6, and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.0 of the RMP has also been submitted.

**Action**: For adoption

### 5.3.23. Sacituzumab govitecan – TRODELVY (CAP) – EMA/VR/0000320818

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include Trodelvy, in combination with pembrolizumab, for the treatment of adult patients with unresectable locally advanced or metastatic TNBC who have not received prior systemic therapy for metastatic disease and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10, based on results from study GS-US-592-6173 (ASCENT-04), which is a phase 3 study of sacituzumab govitecan (IMMU-132) and Pembrolizumab versus treatment of physician's choice and Pembrolizumab in patients with previously untreated, locally advanced inoperable or metastatic triple-negative breast cancer, whose tumors express PD-L1. 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 4.2 of the RMP has also been submitted.

**Action**: For adoption

### 5.3.24. Semaglutide – WEGOVY (CAP) – EMA/X/0000296344

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

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

**Action**: For adoption

### 5.3.25. Semaglutide – WEGOVY (CAP) – EMA/VR/0000327359

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Update of sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to reflect clinical results related to adults with overweight/obesity and metabolic dysfunction-associated steatohepatitis (MASH) based on interim results from phase 3a clinical study NN9931-4553 (ESSENCE) as well as three additional clinical trials NN9931-4381, NN9931-4296 and NN9931-4492 in adults with metabolic dysfunction-associated steatotic liver

disease and/or MASH; supportive non-clinical results have also been submitted. The Package Leaflet is updated accordingly. The RMP version 10.2 has also been submitted.

**Action**: For adoption

## 5.3.26. Teclistamab – TECVAYLI (CAP) – EMA/VR/0000322279

Applicant: Janssen Cilag International

PRAC Rapporteur: Veronika Macurova

Scope: Extension of indication to include in combination with daratumumab treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy for TECVAYLI, based on interim analysis data from the pivotal study MajesTEC-3 (64007957MMY3001). This is an on-going multicentre, randomised, open-label, Phase 3 study to determine whether adding teclistamab to daratumumab (Tec-Dara) is more efficacious than adding pomalidomide/dexamethasone (DPd) or bortezomib/dexamethasone (DVd) to daratumumab in participants with multiple myeloma who previously received 1 to 3 prior line(s) of therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.7, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated accordingly. References to the conditional MA have been removed throughout the document. Additionally, the MAH took the opportunity to update the latest renewal date in section 9 of the SmPC, the list of local representatives in the Package Leaflet and made editorial changes throughout. And updated RMP version 6.1 has been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

**Action**: For adoption

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

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Maria del Pilar Rayon

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

**Action**: For adoption

## 5.3.28. Tezepelumab – TEZSPIRE (CAP) – EMA/VR/0000321455

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

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

C.I.13: Submission of the report from study D5180C00024 (SUNRISE) listed as a category 3 study in the RMP. This is a randomised, double-blind, parallel-group, placebo-controlled 28-week phase 3 efficacy and safety study of tezepelumab in reducing oral corticosteroid use in

adults with oral corticosteroid dependent asthma. The RMP version 7 has also been updated accordingly.

C.I.11: Submission of an updated RMP version 7 in order to add study D5241C00006 (EMBARK) and study D5241C00007 (JOURNEY) as additional pharmacovigilance activities to further characterize the important potential risks: "Serious infections" and "Malignancies".

**Action**: For adoption

### 5.3.29. Tolvaptan – JINARC (CAP) – EMA/VR/0000246866

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Update of sections 4.2 and 5.1 of the SmPC in order to update information based on final results from study 156-12-299 listed as a category 1 study in the RMP. This is a 7.5-year, Multicentre, Non-interventional, Post-authorisation Safety Study for Patients Prescribed JINARC for Autosomal Dominant Polycystic Kidney Disease. This study was intended to explore the safety profile and usage of Jinarc when used in the real-world setting in Europe, particularly with relation to the risk of liver injury. The Package Leaflet is updated accordingly. The RMP version 15.1 has also been submitted. In addition, the MAH took the opportunity to update Annex II section D, to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4.

**Action**: For adoption

### 5.3.30. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/VR/0000322236

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include the indication first-line treatment of adult patients with unresectable or metastatic HER2-positive breast cancer for Enhertu (trastuzumab deruxtecan) in combination with pertuzumab is based on results from the phase 3 DESTINY-Breast09 study. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 of SmPC are updated and the Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted.

**Action**: For adoption

### 5.3.31. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/VR/0000293327

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumours who have received prior treatment and who have no satisfactory alternative treatment options for Enhertu, based on pooled pop-PK analysis and interim results from study D967VC00001 (DESTINY-PanTumor02); this is a Phase II, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of Trastuzumab

Deruxtecan (T-DXd, DS-8201a) for the Treatment of Selected HER2-expressing Tumors; 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 9.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI.

**Action**: For adoption

## 5.3.32. Vamorolone – AGAMREE (CAP) – EMA/VR/0000293535

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of 2 to <4 year olds for AGAMREE, based on final results from study VBP15-006; this is a phase II open-label, multiple dose study to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and exploratory efficacy of vamorolone in boys ages 2 to <4 years and 7 to <18 years with Duchenne Muscular Dystrophy (DMD) and an updated paediatric extrapolation report referencing 4 to <7-year-old subjects with DMD from Study VBP15-004, compared to the 2 to <4-year-old population from Study VBP15-006. 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 2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to make some editorial corrections to SmPC.

**Action**: For adoption

## 5.3.33. Venetoclax – VENCLYXTO (CAP) – EMA/VR/0000322237

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include, in combination with ibrutinib, the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) for VENCLYXTO based on the results of the phase 3 study 54179060CLL3011 (GLOW) and phase 2 study PCYC-1142-CA (CAPTIVATE). GLOW is a randomized, open-label, phase 3 study of the combination of ibrutinib plus venetoclax versus chlorambucil plus obinutuzumab for the first-line treatment of subjects with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL). CAPTIVATE study is a phase 2, multicenter, international, efficacy and safety study assessing treatment with venetoclax plus ibrutinib in subjects with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL). 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 11.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet.

**Action**: For adoption

## 5.3.34. Venetoclax – VENCLYXTO (CAP) – EMA/VR/0000322240

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include, in combination with acalabrutinib with or without obinutuzumab, the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) for VENCLYXTO based on the results from the pivotal study ACE-CL-311/D8221C00001 (AMPLIFY); this is a randomized, multicenter, open-label, Phase 3 study to compare the efficacy and safety of acalabrutinib (ACP-196) in combination with venetoclax with and without obinutuzumab compared to investigator's choice of chemoimmunotherapy in subjects with previously untreated chronic lymphocytic leukemia without del(17p) or TP53 mutation. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 11.1 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. Abrocitinib – CIBINQO (CAP) – EMA/PSUR/0000317674

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010976/202509)

**Action**: For adoption

### 6.1.2. Aprocitentan – JERAYGO (CAP) – EMA/PSUR/0000317689

Applicant: Idorsia Pharmaceuticals Deutschland GmbH

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00011067/202509)

**Action**: For adoption

### 6.1.3. Asenapine – SYCREST (CAP) – EMA/PSUR/0000317636

Applicant: Organon N.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00000256/202508)

**Action**: For adoption

### 6.1.4. Bedaquiline – SIRTURO (CAP) – EMA/PSUR/0000317651

Applicant: Janssen Cilag International

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010074/202509)

**Action**: For adoption

### 6.1.5. Brentuximab vedotin – ADCETRIS (CAP) – EMA/PSUR/0000317688

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010039/202508)

**Action**: For adoption

### 6.1.6. Caplacizumab – CABLIVI (CAP) – EMA/PSUR/0000317662

Applicant: Ablynx

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010713/202508)

**Action**: For adoption

### 6.1.7. Cenobamate – ONTOZRY (CAP) – EMA/PSUR/0000317671

Applicant: Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00010921/202509)

**Action**: For adoption

### 6.1.8. Crizotinib – XALKORI (CAP) – EMA/PSUR/0000317663

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00010042/202508)

**Action**: For adoption

### 6.1.9. Damoctocog alfa pegol – JIVI (CAP) – EMA/PSUR/0000317669

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010732/202508)

**Action**: For adoption

### 6.1.10. Dasiglucagon – ZEGALOGUE (SRD[3]) – EMA/PSUR/0000317683

Applicant: Zealand Pharma A/S

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00011078/202508)

**Action**: For discussion

### 6.1.11. Deucravacitinib – SOTYKTU (CAP) – EMA/PSUR/0000317694

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011046/202509)

**Action**: For adoption

### 6.1.12. Doravirine – PIFELTRO (CAP) – EMA/PSUR/0000317664

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010729/202508)

**Action**: For adoption

### 6.1.13. Doravirine / Lamivudine / Tenofovir disoproxil – DELSTRIGO (CAP) – EMA/PSUR/0000317666

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010731/202508)

**Action**: For adoption

### 6.1.14. Duvelisib – COPIKTRA (SRD[4]) – EMA/PSUR/0000317672

Applicant: Secura Bio Limited

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010939/202509)

[3] European Commission (EC) decision on the withdrawal of the marketing authorisation for ZEGALOGUE dated 23 February 2026

[4] European Commission (EC) decision on the withdrawal of the marketing authorisation for COPIKTRA dated 16 February 2026

**Action**: For discussion

### 6.1.15. Ebola vaccine (Ad26.ZEBOV-GP [recombinant]) – ZABDENO (CAP); Ebola vaccine (MVA-BN-Filo [recombinant]) – MVABEA (CAP) – EMA/PSUR/0000317690

Applicant: Janssen Cilag International

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010857/202509)

**Action**: For adoption

### 6.1.16. Epcoritamab – TEPKINLY (CAP) – EMA/PSUR/0000317637

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00000107/202509)

**Action**: For adoption

### 6.1.17. Filgotinib – JYSELECA (CAP) – EMA/PSUR/0000317681

Applicant: Alfasigma S.p.A.

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010879/202509)

**Action**: For adoption

### 6.1.18. Fruquintinib – FRUZAQLA (CAP) – EMA/PSUR/0000317678

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011069/202509)

**Action**: For adoption

### 6.1.19. Ganaxolone – ZTALMY (CAP) – EMA/PSUR/0000317639

Applicant: Immedica Pharma AB

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000093/202509)

**Action**: For adoption

### 6.1.20. Infliximab – FLIXABI (CAP); INFLECTRA (CAP); REMICADE (CAP); REMSIMA (CAP); ZESSLY (CAP) – EMA/PSUR/0000317670

Applicants: Janssen Cilag International, Celltrion Healthcare Hungary Kft., Pfizer Europe MA EEIG, Samsung Bioepis NL B.V., Sandoz GmbH

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010759/202508)

**Action**: For adoption

### 6.1.21. Insulin icodec – AWIQLI (CAP) – EMA/PSUR/0000317726

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011053/202508)

**Action**: For adoption

### 6.1.22. Lebrikizumab – EBGLYSS (CAP) – EMA/PSUR/0000317693

Applicant: Almirall S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000175/202509)

**Action**: For adoption

### 6.1.23. Linaclotide – CONSTELLA (CAP) – EMA/PSUR/0000317653

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010025/202508)

**Action**: For adoption

### 6.1.24. Lorlatinib – LORVIQUA (CAP) – EMA/PSUR/0000317668

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00010760/202509)

**Action**: For adoption

### 6.1.25. Influenza vaccine (live, nasal) – FLUENZ (CAP) – EMA/PSUR/0000317656

Applicant: AstraZeneca AB

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00001742/202508)

**Action**: For adoption

### 6.1.26. Mecasermin – INCRELEX (CAP) – EMA/PSUR/0000317644

Applicant: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001942/202508)

**Action**: For adoption

### 6.1.27. Mepolizumab – NUCALA (CAP) – EMA/PSUR/0000317655

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010456/202509)

**Action**: For adoption

### 6.1.28. Momelotinib – OMJJARA (CAP) – EMA/PSUR/0000317675

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00000263/202509)

**Action**: For adoption

### 6.1.29. Naltrexone hydrochloride / Bupropion hydrochloride – MYSIMBA (CAP) – EMA/PSUR/0000317654

Applicant: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010366/202509)

**Action**: For adoption

### 6.1.30. Ofatumumab – KESIMPTA (CAP) – EMA/PSUR/0000317682

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010927/202509)

**Action**: For adoption

### 6.1.31. Retifanlimab – ZYNYZ (CAP) – EMA/PSUR/0000317673

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011059/202509)

**Action**: For adoption

### 6.1.32. Rezafungin – REZZAYO (CAP) – EMA/PSUR/0000317633

Applicant: Mundipharma GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000221/202509)

**Action**: For adoption

### 6.1.33. Ritonavir – NORVIR (CAP) – EMA/PSUR/0000317692

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00002651/202508)

**Action**: For adoption

### 6.1.34. Ruxolitinib – OPZELURA (CAP) – EMA/PSUR/0000317686

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011052/202509)

**Action**: For adoption

### 6.1.35. Serplulimab – HETRONIFLY (CAP) – EMA/PSUR/0000317684

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011112/202509)

**Action**: For adoption

### 6.1.36. Sotatercept – WINREVAIR (CAP) – EMA/PSUR/0000317685

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00011076/202509)

**Action**: For adoption

### 6.1.37. Spesolimab – SPEVIGO (CAP) – EMA/PSUR/0000317676

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00011033/202509)

**Action**: For adoption

### 6.1.38. Tasonermin – BEROMUN (CAP) – EMA/PSUR/0000317660

Applicant: Belpharma S.A.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00002850/202508)

**Action**: For adoption

### 6.1.39. Tenecteplase – METALYSE (CAP) – EMA/PSUR/0000317658

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00002888/202508)

**Action**: For adoption

### 6.1.40. Tisotumab vedotin – TIVDAK (CAP) – EMA/PSUR/0000317687

Applicant: Genmab A/S

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00011127/202509)

**Action**: For adoption

### 6.1.41. Vemurafenib – ZELBORAF (CAP) – EMA/PSUR/0000317646

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00009329/202508)

**Action**: For adoption

### 6.1.42. Vernakalant – BRINAVESS (CAP) – EMA/PSUR/0000317649

Applicant: Advanz Pharma Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00003109/202508)

**Action**: For adoption

### 6.1.43. Vibegron – OBGEMSA (CAP) – EMA/PSUR/0000317679

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011068/202509)

**Action**: For adoption

### 6.1.44. Zilucoplan – ZILBRYSQ (CAP) – EMA/PSUR/0000317635

Applicant: UCB Pharma

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000169/202509)

**Action**: For adoption

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

### 6.2.1. Atropine sulfate – RYJUNEA (CAP); NAP – EMA/PSUR/0000317677

Applicants: Santen Oy, various

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011142/202508)

**Action**: For adoption

### 6.2.2. Budesonide / Formoterol – BIRESP SPIROMAX (CAP); DUORESP SPIROMAX (CAP); Budesonide / Formoterol fumarate dihydrate – GORESP DIGIHALER (CAP); NAP – EMA/PSUR/0000317659

Applicants: Teva Pharma B.V., various

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010585/202508)

**Action**: For adoption

### 6.2.3. Octocog alfa – ADVATE (CAP); KOVALTRY (CAP); NAP – EMA/PSUR/0000317640

Applicants: Takeda Manufacturing Austria AG, Bayer AG, various

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00002200/202508)

**Action**: For adoption

### 6.2.4. Trientine – CUFENCE (CAP); CUPRIOR (CAP); NAP – EMA/PSUR/0000317661

Applicants: Orphalan, Univar Solutions B.V., various

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010637/202509)

**Action**: For adoption

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

### 6.3.1. Biperiden – EMA/PSUR/0000317634

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000415/202508)

**Action**: For adoption

### 6.3.2. Clonidine – EMA/PSUR/0000317638

Applicants: various

PRAC Lead: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00000813/202508)

**Action**: For adoption

### 6.3.3. Drospirenone / ethinylestradiol – EMA/PSUR/0000317652

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010217/202509)

**Action**: For adoption

### 6.3.4. Finasteride – EMA/PSUR/0000317641

Applicants: various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00001392/202508)

**Action**: For adoption

### 6.3.5. Fluocinolone acetonide (intravitreal implant in applicator) – EMA/PSUR/0000317680

Applicants: various

PRAC Lead: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010224/202508)

**Action**: For adoption

### 6.3.6. Hexoprenaline sulfate – EMA/PSUR/0000317650

Applicants: various

PRAC Lead: Roxana Dondera

Scope: Evaluation of a PSUSA procedure (PSUSA/00003170/202508)

**Action**: For adoption

### 6.3.7. Losartan – EMA/PSUR/0000317642

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001912/202509)

**Action**: For adoption

### 6.3.8. Meclozine – EMA/PSUR/0000317667

Applicants: various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00001945/202508)

**Action**: For adoption

### 6.3.9. Metronidazole / neomycin / nystatin – EMA/PSUR/0000317665

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00010508/202509)

**Action**: For adoption

### 6.3.10. Nifedipine – EMA/PSUR/0000317647

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00002156/202508)

**Action**: For adoption

### 6.3.11. Poractant alfa – EMA/PSUR/0000317645

Applicants: various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00002478/202508)

**Action**: For adoption

### 6.3.12. Povidone, polyvinyl alcohol / povidone – EMA/PSUR/0000317643

Applicants: various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00002475/202509)

**Action**: For adoption

### 6.3.13. Raltitrexed – EMA/PSUR/0000317648

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00002605/202509)

**Action**: For adoption

## 6.4. Follow-up to PSUR/PSUSA procedures

None

## 6.5. Variation procedure(s) resulting from PSUSA evaluation

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

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

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

**Action**: For adoption

## 6.6. Expedited summary safety reviews[5]

None

# 7. Post-authorisation safety studies (PASS)

## 7.1. Protocols of PASS imposed in the marketing authorisation(s)[6]

### 7.1.1. Lisocabtagene maraleucel / Lisocabtagene maraleucel – BREYANZI (CAP) – EMA/PASS/0000328042

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: PASS amendment [107o]: Non-interventional PASS of patients treated with commercially available liso-cel (lisocabtagene maraleucel) for large B-cell lymphomas

**Action**: For adoption

### 7.1.2. Sodium valproate (NAP) – EMA/PASS/0000328174

Applicants: various

PRAC Rapporteur: Liana Martirosyan

Scope: PASS interim report: valproate [study protocol evaluated within procedure EMEA/H/N/PSP/J/0094]; AVALON: Assessment of VALproate in utero exposure On Neurodevelopment

**Action**: For adoption

[5] 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

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

## 7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[7]

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

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Liana Martirosyan

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

**Action**: For adoption

### 7.2.2. Inebilizumab – UPLIZNA (CAP) – EMA/PAM/0000325493

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Protocol amendment submission of PASS Cat.3 Study A real-world observational study of treatment patterns and outcomes for patients with neuromyelitis optica spectrum disorders (NMOSDs) and immunoglobulin G4-related disease (IgG4-RD) treated with inebilizumab (UPLIZNA) in Europe

**Action**: For adoption

### 7.2.3. Vamorolone – AGAMREE (CAP) – EMA/PAM/0000274869

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: PASS protocol for a non-interventional, post-authorisation safety study to evaluate the safety of vamorolone (AGAMREE®) in patients with Duchenne muscular dystrophy in a real world setting.

**Action**: For adoption

## 7.3. Results of PASS imposed in the marketing authorisation(s)[8]

None

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

## 7.4. Results of PASS imposed and non-imposed in the marketing authorisation(s)[9]

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

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

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

**Action**: For adoption

### 7.4.2. Elosulfase alfa – VIMIZIM (CAP) – EMA/VR/0000268096

Applicant: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Update of sections 4.6, 4.8 and 5.1 of the SmPC based on final results from Morquio A Registry Study (MARS, Study 110-504) listed as a category 1 study in the RMP; this is an observational registry study to evaluate long-term safety and effectiveness of elosulfase alfa. The RMP version 7.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II and to update the PI in accordance with the latest EMA excipients guideline.

**Action**: For adoption

### 7.4.3. Fenfluramine – FINTEPLA (CAP) – EMA/VR/0000296039

Applicant: UCB Pharma

PRAC Rapporteur: Dennis Lex

Scope: Submission of the final report for study EP0220 listed as a category 3 study in the RMP. This is a non-interventional study to assess the effectiveness of risk minimization measures in approved indications for fenfluramine hydrochloride. The RMP version 5.1 has been updated accordingly.

**Action**: For adoption

### 7.4.4. Linaclotide – CONSTELLA (CAP) – EMA/VR/0000281586

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Dennis Lex

[9] In accordance with Article 61a (6) of Regulation (EC) No 726/2004, in line with the revised variations regulation for any submission as of 4 August 2013

Scope: Submission of the 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

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

### 7.5.1. Clascoterone – WINLEVI (CAP) – EMA/PAM/0000325634

Applicant: Cassiopea S.p.A.

PRAC Rapporteur: Zane Neikena

Scope: Feasibility assessment for a post- authorisation safety study (PASS) to characterise the potential risk of HPA axis suppression with long-term use of Winlevi in adolescents

**Action**: For adoption

### 7.5.2. Damoctocog alfa pegol – JIVI (CAP) – EMA/PAM/0000324421

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: 17th annual report for Study 14149: EUHASS Registry (European Haemophilia Safety Surveillance)

**Action**: For adoption

### 7.5.3. Fenfluramine – FINTEPLA (CAP) – EMA/PAM/0000323622

Applicant: UCB Pharma

PRAC Rapporteur: Dennis Lex

Scope: 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

### 7.5.4. Infliximab – REMSIMA (CAP) – EMA/PAM/0000325710

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Kimmo Jaakkola

Scope: 3rd annual recruitment report for Study CT-P13 4.8, an observational, prospective cohort study to evaluate safety of Remsima SC (subcutaneous) in patients with Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis and Psoriasis; former MEA 020

**Action**: For adoption

### 7.5.5. Naltrexone hydrochloride / Bupropion hydrochloride – MYSIMBA (CAP) – EMA/PAM/0000292603

Applicant: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: Study NB-451: Interim report of Drug Utilisation and Safety Study (Study NB-451) for Mysimba/ Contrave in Europe and the United States.

**Action**: For adoption

### 7.5.6. Nirmatrelvir / Ritonavir – PAXLOVID (CAP) – EMA/PAM/0000324414

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Dennis Lex

Scope: The second interim report (31 December 2025) for PASS C4671047: Use and safety of Paxlovid among patients with moderate or severe hepatic impairment.

**Action**: For adoption

### 7.5.7. Nonacog beta pegol – REFIXIA (CAP) – EMA/PAM/0000323326

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Dirk Mentzer

Scope: 7th progress report of study NN7999-4031: A non-interventional post-authorisation safety study (PASS) in male haemophilia B patients receiving Nonacog Beta Pegol (N9-GP) prophylaxis treatment.

**Action**: For adoption

### 7.5.8. Rivaroxaban – XARELTO (CAP) – EMA/PAM/0000316572

Applicant: Bayer AG

PRAC Rapporteur: Mari Thorn

Scope: Third study progress report for the Paediatric VTE PASS Drug Utilization Study (XAPAEDUS): An observational, longitudinal, multi-source drug utilization safety study to evaluate the drug use patterns and safety of rivaroxaban oral suspension in children under two years with venous thromboembolism.

**Action**: For adoption

### 7.5.9. Sebelipase alfa – KANUMA (CAP) – EMA/PAM/0000320327

Applicant: Alexion Europe

PRAC Rapporteur: Mari Thorn

Scope: LAL-D registry 8th interim report of Study ALX-LALD-501, An observational disease and clinical outcomes registry of patients with lysosomal acid lipase (lal) deficiency dated 02 December 2025 (cut-off date: 28 August 2025)

**Action**: For adoption

### 7.5.10. Selexipag – UPTRAVI (CAP) – EMA/PAM/0000309454

Applicant: Janssen Cilag International

PRAC Rapporteur: Zoubida Amimour

Scope: Second interim Clinical study report of study AC-065A403 (EDUCATE), a category 3 PASS study (EMEA/H/C/003774/MEA/003) with a data cut-off date of 11 July 2025.

**Action**: For adoption

### 7.5.11. Vosoritide – VOXZOGO (CAP) – EMA/PAM/0000321452

Applicant: Biomarin International Limited

PRAC Rapporteur: Zane Neikena

Scope: Provision of 2nd Bi-annual safety report for PASS study 111-603 (former MEA 005.6).

**Action**: For adoption

### 7.5.12. Zanubrutinib – BRUKINSA (CAP) – EMA/PAM/0000319828

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Interim report of study BGB-3111-LTE1: an open-label, multicenter, long-term extension study of zanubrutinib (BGB-3111) regimens in patients with B-cell 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. Afamelanotide – SCENESSE (CAP) – EMA/S/0000322534

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Dennis Lex

Scope: Annual reassessment of the marketing authorisation

**Action**: For adoption

### 8.1.2. Glucarpidase – VORAXAZE (CAP) – EMA/S/0000322329

Applicant: Serb

PRAC Rapporteur: Dennis Lex

Scope: Annual reassessment of the marketing authorisation

**Action**: For adoption

### 8.1.3. Histamine dihydrochloride – CEPLENE (CAP) – EMA/S/0000319752

Applicant: Laboratoires Delbert

PRAC Rapporteur: Eamon O Murchu

Scope: Annual reassessment of the marketing authorisation

**Action**: For adoption

### 8.1.4. Maralixibat – LIVMARLI (CAP) – EMA/S/0000317715

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

**Action**: For adoption

### 8.1.5. Tagraxofusp – ELZONRIS (CAP) – EMA/S/0000320819

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Annual reassessment of the marketing authorisation

**Action**: For adoption

### 8.1.6. Vilobelimab – GOHIBIC (CAP) – EMA/S/0000319310

Applicant: InflaRx GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Annual reassessment of the marketing authorisation

**Action**: For adoption

## 8.2. Conditional renewals of the marketing authorisation

### 8.2.1. Imlifidase – IDEFIRIX (CAP) – EMA/R/0000327647

Applicant: Hansa Biopharma AB

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

**Action**: For adoption

### 8.2.2. Resmetirom – REZDIFFRA (CAP) – EMA/R/0000326759

Applicant: Madrigal Pharmaceuticals EU Limited

PRAC Rapporteur: Lina Seibokiene

Scope: Conditional renewal of the marketing authorisation

**Action**: For adoption

### 8.2.3. Talquetamab – TALVEY (CAP) – EMA/R/0000327092

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Conditional renewal of the marketing authorisation

**Action**: For adoption

### 8.2.4. Teclistamab – TECVAYLI (CAP) – EMA/R/0000327677

Applicant: Janssen Cilag International

PRAC Rapporteur: Veronika Macurova

Scope: Conditional renewal of the marketing authorisation

**Action**: For adoption

## 8.3. Renewals of the marketing authorisation

None

# 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. Anti-t lymphocyte immunoglobulin for human use, rabbit (NAP) – ES 2026/62650/II/0122, DE II-2601996-20251223-01, IE/H/xxxx/WS/395, SE/H/xxxx/WS/1162, FR/H/xxxx/WS/627, DK/H/xxxx/WS/495

Applicant(s): Sanofi B.V.

PRAC Lead: Maria Martinez Gonzalez

Scope: PRAC consultation on variation procedures (ES 2026/62650/II/0122 and DE II-2601996-20251223-01) and worksharing variations (IE/H/xxxx/WS/395, SE/H/xxxx/WS/1162, FR/H/xxxx/WS/627, DK/H/xxxx/WS/495) to update the product information of anti-t lymphocyte immunoglobulin for human use, rabbit-containing medicinal products, regarding thrombotic microangiopathy (TMA), at request of Spain.

**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. 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. Health threats and EMA Emergency Task Force (ETF) activities - update

**Action:** For discussion

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

PRAC lead: Panagiotis Psaras

**Action:** For discussion

## 12.5. Cooperation with International Regulators

None

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

None

## 12.7. PRAC work plan

None

## 12.8. Planning and reporting

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. PSURs repository

None

### 12.10.3. Union reference date list – consultation on the draft list

**Action:** For adoption

## 12.11. Signal management

None

## 12.12. Adverse drug reactions reporting and additional reporting

### 12.12.1. Management and reporting of adverse reactions to medicinal products

None

### 12.12.2. Additional monitoring

None

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

**Action:** For adoption

### 12.12.4. Good Pharmacovigilance Practice (GVP) module VI on Management and reporting of adverse reactions to medicinal products - revision

PRAC lead : Dennis Lex

**Action:** For information

## 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. Strategy on measuring the impact of pharmacovigilance – PRAC interest group (IG) Impact - Annual activity report 2025

PRAC Lead: Liana Martirosyan

**Action:** For adoption

## 12.21. Others

### 12.21.1. Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling

PRAC lead: 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)