5 May 2025
EMA/PRAC/125561/2025
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 05-08 May 2025

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

05 May 2025, 10:30 – 19:30, via teleconference

06 May 2025, 08:30 – 19:30, via teleconference

07 May 2025, 08:30 – 19:30, via teleconference

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

Organisational, regulatory and methodological matters (ORGAM)

22 May 2025, 09:00 – 12:00, via teleconference

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).

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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 05-08 May 2025. See May 2025 PRAC minutes (to be published post June 2025 PRAC meeting).

1.2. Agenda of the meeting on 05-08 May 2025

Action: For adoption

1.3. Minutes of the previous meeting on 07-10 April 2025

Action: For adoption

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

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

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

3.1. Newly triggered procedures

3.1.1. Chikungunya virus (CHIKV) Δ5nsP3 strain (live, attenuated) – IXCHIQ (CAP) - EMEA/H/A-20/1540/C/005797

Applicant: Valneva Austria GmbH

PRAC Rapporteur: To be appointed; PRAC Co-rapporteur: To be appointed

Scope: Review of the benefit-risk balance following notification by the European Commission (EC) of a referral under Article 20 of Regulation (EC) No 726/2004, based on pharmacovigilance data

Action: For adoption of a list of questions (LoQ)

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

3.3.1. Dutasteride (NAP); dutasteride, tamsulosin (NAP); finasteride (NAP); finasteride, tadalafil (NAP); finasteride, tamsulosin (NAP) – EMEA/H/A-31/1539

Applicant(s): various

PRAC Rapporteur: Jana Lukačišinová; PRAC Co-rapporteur: Martin Huber

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

Action: For adoption of a recommendation to CMDh

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. Adalimumab – AMGEVITA, AMSPARITY, HEFIYA, HUMIRA, HUKYNDRA, HULIO, HYRIMOZ, IDACIO, IMRALDI, LIBMYRIS, YUFLYMA (CAP)

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

[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

(Hukyndra, Libmyris)

PRAC Rapporteur: Karin Bolin

Scope: Signal of morphoea

Action: For adoption of PRAC recommendation

EPITT 20166 – New signal

Lead Member State(s): SE

4.1.2. Chikungunya virus (CHIKV) Δ5nsP3 strain (live, attenuated) – IXCHIQ (CAP)

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Signal of adverse events (AEs) requiring hospitalisation in elderly patients

Action: For adoption of PRAC recommendation

EPITT 20178 – New signal

Lead Member State(s): DE

4.1.3. Dabigatran – PRADAXA (CAP); NAP

Applicant(s): Boehringer Ingelheim International, various

PRAC Rapporteur: To be appointed

Scope: Signal of splenic rupture

Action: For adoption of PRAC recommendation

EPITT 20164 – New signal

Lead Member State(s): DK

4.1.4. Desogestrel (NAP), etonogestrel (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of meningioma

Action: For adoption of PRAC recommendation

EPITT 20167 – New signal

Lead Member State(s): SE

4.1.5. Dinutuximab beta – QARZIBA (CAP)

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Signal of atypical haemolytic uraemic syndrome

Action: For adoption of PRAC recommendation

EPITT 20169 – New signal

Lead Member State(s): DE

4.1.6. Osimertinib – TAGRISSO (CAP)

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Signal of hepatitis B reactivation

Action: For adoption of PRAC recommendation

EPITT 20172 – New signal

Lead Member State(s): NL

4.1.7. Polatuzumab vedotin - POLIVY (CAP)

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Signal of infusion site extravasation

Action: For adoption of PRAC recommendation

EPITT 20171 – New signal

Lead Member State(s): SE

4.1.8. Somatrogon - NGENLA (CAP)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Signal of lipoatrophy

Action: For adoption of PRAC recommendation

EPITT 20173 – New signal

Lead Member State(s): NL

4.2. Signals follow-up and prioritisation

4.2.1. Adalimumab - AMGEVITA (CAP); AMSPARITY (CAP); HEFIYA (CAP); HUKYNDRA (CAP); HULIO (CAP); HUMIRA (CAP) - EMEA/H/C/000481/SDA/127; HYRIMOZ (CAP); IDACIO (CAP); IMRALDI (CAP); LIBMYRIS (CAP); YUFLYMA (CAP)

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

(Hukyndra, Libmyris)

PRAC Rapporteur: Karin Bolin

Scope: Signal of paradoxical hidradenitis

Action: For adoption of PRAC recommendation

EPITT 20126 – Follow-up to December 2024

4.2.2. Sertraline (NAP)

Applicant(s): various

PRAC Rapporteur: Liana Martirosyan

Scope: Signal of multiple acyl-coenzyme A dehydrogenase deficiency (MADD)

Action: For adoption of PRAC recommendation

EPITT 20125 – Follow-up to January 2025

4.2.3. Sulfamethoxazole, trimethoprim (co-trimoxazole) (NAP)

Applicant: various

PRAC Rapporteur: Barbara Kovačić Bytyqi

Scope: Signal of circulatory shock

Action: For adoption of PRAC recommendation

EPITT 20135 – Follow-up to January 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. Bifikafusp alfa, onfekafusp alfa (CAP MAA) - EMEA/H/C/005651

Scope (pre D-180 phase): Neoadjuvant treatment of adult patients with locally advanced fully resectable melanoma.

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.2. Denosumab (CAP MAA) - EMEA/H/C/006507

Scope (pre D-46 phase): Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures; treatment of bone loss associated with hormone ablation in

men with prostate cancer at increased risk of fractures; treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.3. Lenacapavir (CAP MAA) - EMEA/H/C/006658

Scope (pre D-90 phase, accelerated assessment): Pre-exposure prophylaxis to prevent HIV-1

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.4. Lenacapavir EMEA/H/W/006659

Scope (pre D-90 phase, accelerated assessment): Pre-exposure prophylaxis to prevent HIV-1

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.5. Lifileucel (CAP MAA) - EMEA/H/C/004741

ATMP

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

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CAT and CHMP

5.1.6. Olezarsen (CAP MAA) - EMEA/H/C/006477, Orphan

Applicant: Ionis Ireland Limited

Scope (pre D-180 phase): Treatment of familial chylomicronaemia syndrome

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.7. Pridopidine (CAP MAA) - EMEA/H/C/006261, Orphan

Applicant: Prilenia Therapeutics B.V.

Scope (pre D-180 phase): Treatment of Huntington's disease

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.8. Sebetralstat (CAP MAA) - EMEA/H/C/006211, Orphan

Applicant: Kalvista Pharmaceuticals (Ireland) Limited

Scope (pre D-180 phase): Treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.9. Zuranolone (CAP MAA) - EMEA/H/C/006488

Scope (pre D-180 phase): Treatment of postpartum depression (PPD) in adults

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

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

5.2.1. Agalsidase beta – FABRAZYME (CAP) - EMA/VR/0000254249

Applicant: Sanofi B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of an updated RMP version 3.0 in order to remove the PASS category 3 study "Fabrazyme home infusion educational materials effectiveness evaluation" from the pharmacovigilance plan in the RMP and to consider the routine pharmacovigilance monitoring with submission of safety assessment in PSURs to cover this commitment instead. In addition, the MAH introduced RMP updates agreed in previous procedures

Action: For adoption of PRAC Assessment Report

5.2.2. Brexucabtagene autoleucel - TECARTUS (CAP) - EMEA/H/C/005102/WS2771/0054; Axicabtagene ciloleucel - YESCARTA (CAP) - EMEA/H/C/004480/WS2771/0084

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Submission of an updated RMP version 4.3 for Tecartus and version 11.1 for Yescarta following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040), and of a PASS protocol for a framework for the sampling and testing of secondary malignancies of T-cell origin

Action: For adoption of PRAC Assessment Report

5.2.3. Fezolinetant – VEOZA (CAP) - EMA/VR/0000255134

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of an updated RMP version 4.0 in order to include Drug-Induced Liver Injury (DILI) as an important identified risk following PSUR procedure EMEA/H/C/PSUSA/00000231/202405 (EMA/PRAC/544509/2024)

Action: For adoption of PRAC Assessment Report

5.2.4. Rituximab - RIXATHON (CAP); RIXIMYO (CAP) - EMA/VR/0000249103

Applicant: Sandoz GmbH

PRAC Rapporteur: Karin Erneholm

Scope: To align the RMP with that of the reference product by updating the ATC code,

removing the important identified risks `Hepatitis B (HBV) reactivation (all indications)', `Hypogammaglobulinemia (non-oncology indications)' and missing information `Long-term use in Granulomatosis with polyangiitis (GPA)/ microscopic polyangiitis (MPA) patients (GPA/MPA)' `Relapses' (for GPA/MPA) from the list of safety concerns. To remove the targeted follow-up questionnaire (TFUQ) details and the additional risk minimization measures HCP educational leaflet and Patient educational leaflet

Action: For adoption of PRAC Assessment Report

5.2.5. Zoledronic acid - ZOMETA (CAP) - EMEA/H/C/000336/II/0104

Applicant: Phoenix Labs Unlimited Company

PRAC Rapporteur: Karin Erneholm

Scope: Submission of an updated RMP version 12.1 in order to update the list of safety concerns and missing information as per the guidance provided in the GVP V–Rev.2 and PSUSA/3149/202308

Action: For adoption of PRAC Assessment Report

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

5.3.1. Afamelanotide - SCENESSE (CAP) - EMEA/H/C/002548/II/0052

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

Scope: Update of section 4.2 of the SmPC in order to update the posology recommendations by removing the current recommendation of a maximum of four implants per year, based on a literature review and analysis of safety data. The Package Leaflet is updated accordingly. The RMP version 9.8 has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial change to the Product Information

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.2. Aflibercept – YESAFILI (CAP) - EMA/VR/0000245097

Applicant: Biosimilar Collaborations Ireland Limited

PRAC Rapporteur: Zoubida Amimour

Scope: Quality variations

An updated Product Information (PI) and revised Risk Management Plan (RMP version 1.1) are being submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.3. Anakinra – KINERET (CAP) - EMA/VR/0000249038

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Karin Erneholm

Scope: Update of sections 4.4, and 4.8 of the SmPC in order to include updated information on Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) following post-marketing safety surveillance; the Package Leaflet is updated accordingly. The RMP version 6.3 has also been submitted. In addition, the MAH took the opportunity to correct an editorial errors, and to include wording regarding excipient polysorbate 80 in accordance with the updated annex to the European Commission guideline in the PI

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.4. Anifrolumab - SAPHNELO (CAP) - EMEA/H/C/004975/X/0023

Applicant: AstraZeneca AB

PRAC Rapporteur: Liana Martirosyan

Scope: Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new route of administration (subcutaneous use) and a new strength (120 mg)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.5. Azacitidine - AZACITIDINE ACCORD (CAP) - EMEA/H/C/005147/X/0021

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Bianca Mulder

Scope: Extension application to introduce a new pharmaceutical form (film-coated tablet) associated with new strengths (200 and 300 mg) and new route of administration (oral use). The RMP (version 2.0) is updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.6. Bedaquiline – SIRTURO (CAP) - EMA/VR/0000249065

Applicant: Janssen Cilag International

PRAC Rapporteur: Karin Bolin

Scope: Extension of indication to include treatment of paediatric patients (2 years to less than 5 years of age and weighing at least 7 kg) with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to at least rifampicin and isoniazid, for SIRTURO, based on the Week 24 primary analysis from Cohort 3 (⩾2 to <5 years of age) of Study TMC207-C211; this is an open-label, multicentre, single-arm study to evaluate pharmacokinetics, safety/tolerability, antimycobacterial activity and dose selection of bedaquiline in children (birth to <18 years) with multidrug-resistant-TB (MDR-TB). Long-term follow-up to Week 120 in participants of Cohort 1 (⩾12 to <18 years of age) and Cohort 2 (⩾5 to <12 years of age) have also been submitted. 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 11.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and introduce minor changes to the PI

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.7. Bempedoic acid - NILEMDO (CAP) - EMEA/H/C/004958/WS2798/0045; Bempedoic acid, ezetimibe - NUSTENDI (CAP) - EMEA/H/C/004959/WS2798/0050

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Kimmo Jaakkola

Scope: Update of sections 4.2, 4.4, and 5.2 of the SmPC in order to amend information concerning renal impairment based on the final results from Study 1002-071 listed as a category 3 study in the RMP; this is a phase 1, open-label, single-dose study to evaluate the pharmacokinetics of bempedoic acid in healthy subjects with normal renal function and subjects with end-stage renal disease receiving HD; the Package Leaflet is updated accordingly. The RMP version 7.0 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.8. Daratumumab - DARZALEX (CAP) - EMEA/H/C/004077/II/0077, Orphan

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include daratumumab for the treatment of adult patients with smouldering multiple myeloma (SMM) at high risk of developing multiple myeloma based on results from studies 54767414SMM3001 (AQUILA) and 54767414SMM2001 (CENTAURUS). SMM3001 (AQUILA) is a Phase 3 Randomized, Multicentre Study of Subcutaneous Daratumumab Versus Active Monitoring in Subjects with High-risk Smoldering Multiple Myelom. SMM2001 (CENTAURUS) is a Randomized Phase 2 Trial to Evaluate Three Daratumumab Dose Schedules in Smoldering Multiple Myeloma.
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 update the PI in accordance with the latest EMA excipients guideline

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.9. Darolutamide - NUBEQA (CAP) - EMEA/H/C/004790/II/0024

Applicant: Bayer AG

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include in combination with androgen deprivation therapy (ADT) the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) for NUBEQA, based on final results from study 21140 (ARANOTE); this is a randomised, double-blind, placebo-controlled Phase 3 study of darolutamide to demonstrate the superiority of darolutamide in addition to ADT over placebo plus ADT in patients with mHSPC. 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 5.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and update the Package Leaflet to more patient friendly

wording based on patient council feedback

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.10. Dupilumab – DUPIXENT (CAP) - EMA/VR/0000248778

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of adults with bullous pemphigoid (BP) for DUPIXENT, based on final results from study R668-BP-1902 (LIBERTY-BP ADEPT); this is a phase 2/3, multicentre, randomised, double blind, placebo-controlled, parallel group study to assess the efficacy and safety of dupilumab in adult patients with bullous pemphigoid; As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 12.0 of the RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.11. Durvalumab - IMFINZI (CAP) - EMEA/H/C/004771/II/0073

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Extension of indication to include IMFINZI in combination with cisplatin-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, for the treatment of adults with muscle invasive bladder cancer (MIBC), based on an ongoing pivotal study D933RC00001 (NIAGARA); this is a phase 3, randomised, open-label, multi-centre, global study to determine the efficacy and safety of durvalumab in combination with gemcitabine+cisplatin for neoadjuvant treatment followed by durvalumab alone for adjuvant treatment in patients 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 accordingly. The RMP version 13 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and update the PI according to the Excipients Guideline

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.12. Entrectinib - ROZLYTREK (CAP) - EMEA/H/C/004936/II/0025

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Submission of the final integrated analysis report for bone biomarkers based on GO40782 [STARTRK-2], CO40778 [STARTRK-NG], and BO41932 [TAPISTRY] studies (PAESs). The RMP version 6 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.13. Etrasimod – VELSIPITY (CAP) - EMA/VR/0000249630

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Bolin

Scope: Update of sections 4.4, and 4.6 of the SmPC in order to amend an existing warning and information on pregnancy regarding reduced the contraceptive washout period from 14 to 7 days based on the results of recently completed DDI studies; the Package Leaflet is updated accordingly. 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 and to introduce editorial changes in the PI

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.14. Faricimab - VABYSMO (CAP) - EMEA/H/C/005642/II/0016

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Update of section 5.1 of the SmPC to reflect the long-term safety profile of faricimab in patients with diabetic macular edema (DME) based on the final results from study GR41987 (Rhone-X) listed as a category 3 study of the RMP. Rhone-X was a phase III interventional, multicentre, open-label extension study to evaluate the long-term safety and tolerability of faricimab in patients with diabetic macular oedema. The RMP version 7.0 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.15. Formoterol, glycopyrronium bromide, budesonide - RILTRAVA AEROSPHERE (CAP) - EMEA/H/C/005311/WS2780/0017; Formoterol, glycopyrronium bromide, budesonide - TRIXEO AEROSPHERE (CAP) - EMEA/H/C/004983/WS2780/0024

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Quality variations

The RMP version 2 has also been submitted.

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.16. Guselkumab – TREMFYA (CAP) - EMA/VR/0000257669

Applicant: Janssen Cilag International

PRAC Rapporteur: Gabriele Maurer

Scope: Quality variations

The changes result in amendments to the Annex A, SmPC, Labeling and Package Leaflet. An updated EU RMP (Version 11.1) is also included

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.17. Guselkumab – TREMFYA (CAP) - EMA/VR/0000257541

Applicant: Janssen Cilag International

PRAC Rapporteur: Gabriele Maurer

Scope: Update of sections 4.2, 4.5, 4.8, 5.1, and 5.2 of the SmPC in order to add subcutaneous induction dosing for the ulcerative colitis (UC) indication based on interim results from study CNTO1959UCO3004 listed as a category 3 study in the RMP; this is a phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicentre study to evaluate the efficacy and safety of guselkumab subcutaneous induction therapy in participants with moderately to severely active UC; the Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted. In addition, the MAH took the opportunity to bring editorial changes to the PI

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.18. Herpes zoster vaccine (recombinant, adjuvanted) – SHINGRIX (CAP) - EMA/X/0000243671

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Sonja Hrabcik

Scope: Extension application to introduce a new pharmaceutical form (suspension for injection in pre-filled syringe)

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.19. Lebrikizumab – EBGLYSS (CAP) - EMA/VR/0000249804

Applicant: Almirall S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

C.I.4: Update of sections 4.8, and 5.1 of the SmPC in order to update information on clinical efficacy and the long-term safety based on final results from study J2T-DM-KGAA (ADjoin) listed as a category 3 study in the RMP; this is a long-term study to assess the long-term safety and efficacy of lebrikizumab in patients with moderate-to-severe atopic dermatitis over 100 weeks, which was ongoing at the time of the MAA submission; The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to introduce the changes following PEI linguistic review and editorial changes to the PI.

C.I.4: Update of section 5.1 of the SmPC in order to update information on clinical efficacy based on final results from study J2T-AP-KGBQ (Advantage); this is a randomised, double-blind, placebo-controlled phase 3 clinical trial to assess the efficacy and safety of lebrikizumab in combination with topical corticosteroids up to 52 weeks in patients with moderate to-severe atopic dermatitis who were not adequately controlled with ciclosporin or non-eligible for cyclosporine

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.20. Lenacapavir - SUNLENCA (CAP) - EMEA/H/C/005638/II/0022/G

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Grouping of two type II variations:
- Update of section 5.1 of the SmPC to include efficacy and resistance data based on week 156 interim data from Study GS-US-200-4625; a phase 2/3 study to evaluate the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with an optimised background regimen in heavily treatment experienced people living with HIV-1 infection with multidrug resistance (category 3 study in the RMP). Additionally, upon request by the CHMP following the assessment of II/0013, the MAH proposes to update section 4.8 of the SmPC to include information related to injection site nodules and induration that were non-resolved at the end of follow-up.
- Provision of the final study report of Study GS-US-200-4334: a phase 2 randomised, open label, active controlled study evaluating the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with other antiretroviral agents in people living with HIV (category 3 study in the RMP).
An updated RMP version 2.1 was included as part of the application

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.21. Mavacamten – CAMZYOS (CAP) - EMA/VR/0000249369

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Submission of the final report from long-term follow-up study MYK-461-017/CV027006 listed as a category 3 study in the RMP. This is a phase 3, randomised, double-blind, placebo-controlled study to evaluate mavacamten in adults with symptomatic obstructive hypertrophic cardiomyopathy who are eligible for septal reduction therapy (VALOR-HCM). The RMP version 5.0 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.22. Natalizumab - TYSABRI (CAP) - EMEA/H/C/000603/II/0150

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Update of sections 4.2 and 4.4 of the SmPC in order to modify administration instructions to add the option for self-administration or administration by a caregiver and to update educational guidance, based on supportive data including final results from study 101MS330; this is a Single-Arm, Open-Label, Phase 3 Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Multiple Doses of Natalizumab Administered to Japanese Participants With Relapsing-Remitting Multiple Sclerosis via a Subcutaneous Route of Administration. The Annex II, Labelling and Package Leaflet are updated accordingly. The RMP version 32.1 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.23. Nonacog beta pegol – REFIXIA (CAP) - EMA/VR/0000249232

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Gabriele Maurer

Scope: Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on the latest data obtained from the completed clinical studies, including results from studies NN7999-3774 and NN7999-3895. The RMP version 6.0 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.24. Pegcetacoplan - ASPAVELI (CAP) - EMEA/H/C/005553/II/0028, Orphan

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: Update of section 4.8 of the SmPC in order to add urticaria/hives to the list of adverse drug reactions (ADRs) with frequency "common" and to add anaphylactic reaction and anaphylactic shock to the list of ADRs with frequency "uncommon", based on post-marketing data and literature; the Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.25. Pegcetacoplan – ASPAVELI (CAP) - EMA/VR/0000248937

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of adults and adolescents aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulopathy (IC-MPGN) for ASPAVELI, based on interim results from study APL2-C3G-310; this is a randomized, placebo-controlled, double-blinded, multicenter study to evaluate the safety and efficacy of twice-weekly s.c. infusions of pegcetacoplan in patients diagnosed with C3G or primary IC-MPGN and results from Phase 2 study APL2-C3G-204, an open-label, randomized, controlled study to evaluate the efficacy and safety of pegcetacoplan in posttransplant recurrence of C3G or primary IC-MPGN. 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 3.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, the PI is brought in line with the latest QRD template version 10.4

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.26. Pyronaridine, artesunate - PYRAMAX (Art 58[3]) - EMEA/H/W/002319/II/0036

Applicant: Shin Poong Pharmaceutical Co., Ltd.

[3] 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)

PRAC Rapporteur: Zoubida Amimour

Scope: Update of sections 4.4 and 4.6 of the SmPC with revised recommendations for treatment during pregnancy. The Package Leaflet has been updated accordingly. An updated RMP version 18 was provided as part of the application

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.27. Olipudase alfa - XENPOZYME (CAP) - EMEA/H/C/004850/II/0012/G, Orphan

Applicant: Sanofi B.V.

PRAC Rapporteur: Martin Huber

Scope: A grouped application consisting of:
C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study DFI12712 ASCEND, listed as a category 3 study in the RMP; this is a Phase 2/3, multicentre, randomised, double-blinded, placebo-controlled, repeat-dose study to evaluate the efficacy, safety, pharmacodynamics and pharmacokinetics of olipudase alfa in patients with AMSD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the SmPC.
C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study LTS13632 listed as a category 3 study in the RMP; this is a long-term study the ongoing safety and efficacy of olipudase alfa in patients with ASMD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.28. rADAMTS13 – ADZYNMA (CAP) - EMA/VR/0000255553

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Maia Uusküla

Scope: Submission of the final report from study 281102 listed as a Specific Obligation in the Annex II of the Product Information. This is a phase 3, prospective, randomised, controlled, open-label, multicentre study evaluating the safety and efficacy of TAK-755 (rADAMTS13) in the prophylactic and on-demand treatment of subjects with cTTP. In addition, results from the second interim analysis for Study 3002, which is a Phase 3b, prospective, open-label, multicentre, single treatment arm, continuation study of study 281102 was also submitted. The Annex II and the RMP version 1.1 are updated accordingly

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.29. Respiratory syncytial virus mRNA vaccine (nucleoside modified) – MRESVIA (CAP) - EMA/VR/0000248175

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

Scope: To modify the approved therapeutic indication to include active immunisation for the

prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV for mRESVIA, based on results from Study mRNA-1345-P303 (Part A) - A Phase 3 Study to Evaluate the Immunogenicity and Safety of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus, in High-risk Adults. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC and the corresponding sections of the Package Leaflet are updated accordingly. The updated RMP Version 1.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI. As part of the application, the MAH also requests an extension of the market protection by one additional year

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.30. Respiratory syncytial virus vaccine (bivalent, recombinant) – ABRYSVO (CAP) - EMA/VR/0000254927

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update clinical efficacy and safety information on the use of Abrysvo in immunocompromised individuals, based on final results from Study C3671023 (substudy B); this is a phase 3 clinical study designed to evaluate the safety, tolerability, and immunogenicity of Abrysvo in adults at high risk of severe RSV disease. Substudy B was conducted in approximately 200 immunocompromised participants who were 18 years of age and older and received 2 doses of RSVpreF 120 µg, with an interval of 1 month. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce a minor change to the PI

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.31. Retifanlimab – ZYNYZ (CAP) - EMA/VR/0000247788

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include in combination with carboplatin and paclitaxel treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC) for ZYNYZ, based on interim results from study INCMGA 0012-303 (POD1UM-303/InterAACT-2); this is a phase 3 global, multicentre, double-blind randomised study of carboplatin-paclitaxel with retifanlimab or placebo in participants with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal not previously treated with systemic chemotherapy; 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 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce 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 of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.32. Solriamfetol - SUNOSI (CAP) - EMEA/H/C/004893/II/0026

Applicant: Atnahs Pharma Netherlands B.V.

PRAC Rapporteur: Julia Pallos

Scope: Update of sections 4.6 and 5.2 of the SmPC in order to update information on lactation and breast-feeding based on results from the post-marketing lactation study JZP110-401 listed as a category 3 study in the RMP. This was a Phase 4, open-label, single-dose study to evaluate the PK of solriamfetol in the breast milk and plasma of healthy postpartum women following oral administration of a 150 mg solriamfetol tablet. The Package Leaflet is updated accordingly. The RMP version 1.3 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.33. Spesolimab – SPEVIGO (CAP) - EMA/VR/0000249137

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Zoubida Amimour

Scope: Update of sections 4.4, and 4.8 of the SmPC in order to add a new warning on hypersensitivity and add hypersensitivity to the list of adverse drug reactions (ADRs) with frequency 'not known' based on data from clinical trials and post-marketing data sources; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

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

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of symptomatic chronic heart failure with preserved ejection fraction (HFpEF) in adults with obesity for MOUNJARO, based on results from the phase 3 trial I8F-MC-GPID (SUMMIT). SUMMIT was a randomised, multicentre, international, placebo-controlled, double-blind, parallel-arm study in participants with HFpEF and obesity. The study was designed to evaluate the effect of tirzepatide compared with placebo on both clinical and symptomatic or functional outcomes. As a consequence, sections 4.1, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.35. Tislelizumab - TEVIMBRA (CAP) - EMEA/H/C/005919/II/0017

Applicant: Beigene Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include, in combination with gemcitabine and cisplatin, the first-line treatment of adult patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) for TEVIMBRA based on final results from study BGB-A317-309 (study 309). Study 309 was a phase 3 randomised, double-blind, placebo-controlled, Asia-only study that

compared the efficacy and safety of tislelizumab combined with gemcitabine plus cisplatin (GC) versus placebo combined with GC as first line treatment for recurrent or metastatic NPC. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.6 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial and administrative changes to the PI as well as to update the PI in line with the Excipients Guideline

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.36. Tralokinumab – ADTRALZA (CAP) - EMA/VR/0000254976

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Kimmo Jaakkola

Scope: Update of sections 4.8 and 5.1 of the SmPC in order to update clinical efficacy and safety information based on the final clinical trial report of the open-label extension PASS study LP0162-1337 (ECZTEND), listed as a category 3 study in the RMP. This is a phase 3 open-label, single-arm, multi-centre, long-term extension trial to evaluate the safety and efficacy of tralokinumab in subjects with moderate-to-severe atopic dermatitis who participated in previous tralokinumab clinical trials. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to update the PI according to the updated EU Excipient guideline to include a warning regarding polysorbate as well as to include minor editorial changes and to update the list of local representatives in the Package Leaflet

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.37. Ustekinumab - PYZCHIVA (CAP) - EMEA/H/C/006183/X/0006

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension application to introduce a new strength (45 mg solution for injection in a vial) for partial use in paediatric patients.

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.38. Vedolizumab – ENTYVIO (CAP) - EMA/VR/0000255408

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Adam Przybylkowski

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

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

6. Periodic safety update reports (PSURs)

6.1. PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) only

6.1.1. Abemaciclib - VERZENIOS (CAP) - PSUSA/00010724/202409

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.2. Alglucosidase alfa - MYOZYME (CAP) - PSUSA/00000086/202409

Applicant: Sanofi B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.3. Aliskiren - RASILEZ (CAP); aliskiren, hydrochlorothiazide - RASILEZ HCT[4] - PSUSA/00000089/202409

Applicant: Noden Pharma DAC

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.4. Amikacin[5] - ARIKAYCE LIPOSOMAL (CAP) - PSUSA/00010882/202409

Applicant: Insmed Netherlands B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[4] European Commission (EC) decision on the marketing authorisation (MA) withdrawal for Rasilez HCT dated 20 December 2021

[5] Centrally authorised product(s) only

6.1.5. Atogepant - AQUIPTA (CAP) - PSUSA/00000100/202409

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.6. Axicabtagene ciloleucel - YESCARTA (CAP) - PSUSA/00010703/202410

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.7. Aztreonam, avibactam - EMBLAVEO (CAP) - PSUSA/00011055/202410

Applicant: Pfizer Europe Ma EEIG

PRAC Rapporteur: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.8. Brolucizumab - BEOVU (CAP) - PSUSA/00010829/202410

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.9. Cemiplimab - LIBTAYO (CAP) - PSUSA/00010780/202409

Applicant: Regeneron Ireland Designated Activity Company

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.10. Chenodeoxycholic acid[6] [7] - CHENODEOXYCHOLIC ACID LEADIANT (CAP) - PSUSA/00010590/202410

Applicant: Leadiant GmbH

[6] Indicated for the treatment of inborn errors of primary bile acid synthesis due to sterol 27 hydroxylase deficiency (presenting as cerebrotendinous xanthomatosis (CTX))
[7] Centrally authorised product(s) only

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.11. COVID-19 Vaccine (recombinant, adjuvanted) - BIMERVAX (CAP) - PSUSA/00011045/202409

Applicant: Hipra Human Health S.L.

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.12. COVID-19 vaccine (Ad26.COV2-S [recombinant]) - JCOVDEN (CAP)[8] - PSUSA/00010916/202402

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For discussion

6.1.13. Dacomitinib - VIZIMPRO (CAP) - PSUSA/00010757/202409

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.14. Dapagliflozin - EDISTRIDE (CAP); FORXIGA (CAP) - PSUSA/00010029/202410

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.15. Daptomycin - CUBICIN (CAP) - PSUSA/00000931/202409

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Pernille Harg

[8] European Commission decision for withdrawal of marketing authorisation for Jcovden (COVID-19 Vaccine Janssen (Ad26.COV2.S)) in the European Union (EU) is dated 26 July 2024. The withdrawal was at the request of the marketing authorisation holder, Janssen-Cilag International N.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.16. Darunavir, cobicistat, emtricitabine, tenofovir alafenamide - SYMTUZA (CAP) - PSUSA/00010646/202409

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.17. Denosumab[9] - JUBBONTI (CAP); PROLIA (CAP) - PSUSA/00000954/202409

Applicant: Sandoz GmbH (Jubbonti), Amgen Europe B.V. (Prolia)

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.18. Dulaglutide - TRULICITY (CAP) - PSUSA/00010311/202409

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.19. Eltrombopag - REVOLADE (CAP) - PSUSA/00001205/202409

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. Erdafitinib - BALVERSA (CAP) - PSUSA/00011072/202410

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[9] Indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer

6.1.21. Etrasimod - VELSIPITY (CAP) - PSUSA/00000273/202410

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.22. Futibatinib - LYTGOBI (CAP) - PSUSA/00000068/202409

Applicant: Taiho Pharma Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.23. Hepatitis A (inactivated), hepatitis B (rDNA[10]) vaccines (adsorbed) - AMBIRIX (CAP); TWINRIX ADULT (CAP); TWINRIX PAEDIATRIC (CAP) - PSUSA/00001593/202409

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.24. Herpes zoster vaccine (recombinant, adjuvanted) - SHINGRIX (CAP) - PSUSA/00010678/202410

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.25. Histamine[11] - CEPLENE (CAP) - PSUSA/00001610/202410

Applicant: Laboratoires Delbert

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[10] Ribosomal deoxyribonucleic acid
[11] Indicated for acute myeloid leukaemia

6.1.26. Ivacaftor, tezacaftor, elexacaftor - KAFTRIO (CAP) - PSUSA/00010868/202410

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.27. Lasmiditan - RAYVOW (CAP) - PSUSA/00011011/202410

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Anna Mareková

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.28. Loncastuximab tesirine - ZYNLONTA (CAP) - PSUSA/00011027/202410

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.29. Lopinavir, ritonavir - ALUVIA (Art 58[12]) - EMEA/H/W/000764/PSUV/0121

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUR procedure

Action: For adoption of recommendation to CHMP

6.1.30. Lopinavir, ritonavir - KALETRA (CAP) - PSUSA/00001905/202409

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.31. Macitentan, tadalafil - YUVANCI (CAP) - PSUSA/00011090/202410

Applicant: Janssen - Cilag International

[12] 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)

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.32. Maralixibat - LIVMARLI (CAP) - PSUSA/00011032/202409

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.33. Mirikizumab - OMVOH (CAP) - PSUSA/00000049/202409

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. Nintedanib[13] - OFEV (CAP) - PSUSA/00010319/202410

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.35. Niraparib, abiraterone acetate - AKEEGA (CAP) - PSUSA/00011051/202410

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.36. Olipudase alfa - XENPOZYME (CAP) - PSUSA/00011003/202409

Applicant: Sanofi B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[13] Respiratory indication only

6.1.37. Oseltamivir - TAMIFLU (CAP) - PSUSA/00002225/202409

Applicant: Roche Registration GmbH

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.38. Pandemic influenza vaccine (H5N1)[14] - FOCLIVIA (CAP); zoonotic influenza vaccine (H5N1) AFLUNOV (CAP); zoonotic influenza vaccine (H5N8)[15] - ZOONOTIC INFLUENZA VACCINE SEQIRUS (CAP) - PSUSA/00010008/202410

Applicant: Seqirus S.r.l (Aflunov, Foclivia), Seqirus S.r.l. (Zoonotic Influenza Vaccine Seqirus)

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. Parathyroid hormone - NATPAR (CAP) - PSUSA/00010591/202410

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.40. Pemigatinib - PEMAZYRE (CAP) - PSUSA/00010923/202410

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. Pitolisant - OZAWADE (CAP); WAKIX (CAP) - PSUSA/00010490/202409

Applicant: Bioprojet Pharma

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[14] Surface antigen, inactivated, adjuvanted
[15] Surface antigen, inactivated, adjuvanted

6.1.42. Riociguat - ADEMPAS (CAP) - PSUSA/00010174/202409

Applicant: Bayer AG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.43. Selumetinib - KOSELUGO (CAP) - PSUSA/00010936/202410

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Talazoparib - TALZENNA (CAP) - PSUSA/00010781/202410

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Tofersen - QALSODY (CAP) - PSUSA/00011064/202410

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Trastuzumab - HERCEPTIN (CAP); HERWENDA (CAP); HERZUMA (CAP); KANJINTI (CAP); OGIVRI (CAP); ONTRUZANT (CAP); TRAZIMERA (CAP); TUZNUE (CAP); ZERCEPAC (CAP) - PSUSA/00003010/202409

Applicant: Roche Registration GmbH (Herceptin), Sandoz GmbH (Herwenda), Celltrion Healthcare Hungary Kft. (Herzuma), Amgen Europe B.V., BREDA (Kanjinti), Biosimilar Collaborations Ireland Limited (Ogivri), Samsung Bioepis NL B.V. (Ontruzant), Pfizer Europe MA EEIG (Trazimera), Prestige Biopharma Belgium (Tuznue), Accord Healthcare S.L.U. (Zercepac)

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Tremelimumab - IMJUDO (CAP) - PSUSA/00011038/202410

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. Vortioxetine - BRINTELLIX (CAP) - PSUSA/00010052/202409

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

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

6.2.1. Filgrastim - ACCOFIL (CAP); FILGRASTIM HEXAL (CAP); GRASTOFIL[16]; NIVESTIM (CAP); RATIOGRASTIM (CAP); TEVAGRASTIM (CAP); ZARZIO (CAP); NAP - PSUSA/00001391/202409

Applicant(s): Accord Healthcare S.L.U. (Accofil, Grastofil), Hexal AG (Filgrastim Hexal), Pfizer Europe MA EEIG (Nivestim), ratiopharm GmbH (Ratiograstim), TEVA GmbH (Tevagrastim), Sandoz GmbH (Zarzio), various

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.2. Rivaroxaban - XARELTO (CAP); NAP - PSUSA/00002653/202409

Applicant(s): Bayer AG (Xarelto), various

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.3. Sodium oxybate[17] - XYREM (CAP); NAP - PSUSA/00010612/202410

Applicant(s): UCB Pharma S.A. (Xyrem), various

PRAC Rapporteur: Ana Sofia Diniz Martins

[16] European Commission (EC) decision on the marketing authorisation (MA) withdrawal for Grastofil, dated 13 January 2025
[17] For oral use only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.4. Teriparatide - FORSTEO (CAP); KAULIV (CAP); LIVOGIVA (CAP); MOVYMIA (CAP); SONDELBAY (CAP); TERIPARATIDE SUN (CAP); TERROSA (CAP); NAP - PSUSA/00002903/202409

Applicant(s): Accord Healthcare S.L.U. (Sondelbay), Eli Lilly Nederland B.V. (Forsteo), Strides Pharma (Cyprus) Limited (Kauliv), Sun Pharmaceutical Industries Europe B.V. (Teriparatide SUN), Gedeon Richter Plc. (Terrosa), Theramex Ireland Limited (Livogiva), STADA Arzneimittel AG (Movymia), various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

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

6.3.1. Alfentanil (NAP) - PSUSA/00000082/202409

Applicant(s): various

PRAC Lead: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.2. Atenolol, chlortalidone (NAP) - PSUSA/00000260/202409

Applicant(s): various

PRAC Lead: Anna Mareková

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Betamethasone, tetryzoline (NAP) - PSUSA/00010072/202409

Applicant(s): various

PRAC Lead: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.4. Carmustine[18] (NAP) - PSUSA/00010348/202409

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. Diclofenac[19] (NAP) - PSUSA/00001048/202409

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.6. Hexaminolevulinate hydrochloride (NAP) - PSUSA/00001606/202409

Applicant(s): various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.7. Levosimendan (NAP) - PSUSA/00001858/202409

Applicant(s): various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. Opium (NAP) - PSUSA/00010670/202409

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.9. Phloroglucinol (NAP); phloroglucinol, trimethylphloroglucinol (NAP); phloroglucinol, simeticone (NAP) - PSUSA/00010355/202409

Applicant(s): various

[18] Implant
[19] Systemic formulations only

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. Pramiracetam (NAP) - PSUSA/00002492/202409

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. Sodium oxybate[20] (NAP) - PSUSA/00010613/202410

Applicant(s): various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. Sumatriptan (NAP); Naproxen, sumatriptan (NAP) - PSUSA/00002832/202409

Applicant(s): various

PRAC Lead: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. Trifarotene (NAP) - PSUSA/00010929/202410

Applicant(s): various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.14. Zidovudine (NAP) - PSUSA/00003143/202409

Applicant(s): various

PRAC Lead: Jana Lukačišinová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

[20] For intravenous use only

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Ocrelizumab - OCREVUS (CAP) - EMA/PAM/0000255140

Applicant: Roche Registration GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: LEG to further clarify Febrile Neutropenia and agranulocytosis events following EMEA/H/C/PSUSA/00010662/202403: provision of a cumulative review of all cases from clinical trials, post-marketing and literature reporting the MedDRA PTs "Febrile neutropenia" and "Agranulocytosis" associated with ocrelizumab treatment. The MAH is welcome to include further PTs in its search, provided it is justified and reasonable. Possible pathophysiologic mechanisms and the need to revise the product information and/or the risk management plan should be discussed

Action: For adoption of advice to CHMP

6.4.2. Ocrelizumab - OCREVUS (CAP) - EMA/PAM/0000255181

Applicant: Roche Registration GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: LEG to further clarify alopecia events following EMEA/H/C/PSUSA/00010662/202403: provision of information on alopecia events from the controlled treatment periods of its pivotal clinical studies OPERA I/II and ORATORIO and report incidence rates per 100 per year in the ocrelizumab versus comparator arms (i.e., interferon beta-1a and placebo) and presentation in a tabular format , cases reporting alopecia which fulfilled established diagnostic criteria, are not confounded by other risk factors for alopecia, are not concomitantly treated with other drugs known to cause alopecia, and time to onset. Narratives of these cases should be presented

Action: For adoption of advice to CHMP

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Doravirine, lamivudine, tenofovir disoproxil - DELSTRIGO (CAP) - EMA/VR/0000247253

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Update of sections 4.4, and 4.8 of the SmPC in order amend an existing warning on bone effects and add 'bone mineral density decreased' to the list of adverse drug reactions (ADRs) with frequency 'common' following PRAC recommendation for Viread PSUSA 00002892-202303; the Package Leaflet (PL) is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the PL

Action: For adoption of PRAC Assessment Report

6.5.2. Human thrombin, human fibrinogen - TACHOSIL (CAP) - EMEA/H/C/000505/II/0131

Applicant: Corza Medical GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Update of section 4.2 of the SmPC to emphasise correct product handling and section 4.8 of the SmPC to reflect the fact that cases of product non-adhesion issues have been reported, upon request by PRAC following the outcome of the PSUR procedure EMEA/H/C/PSUSA/00010297/202306. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC.

Action: For adoption of PRAC Assessment Report

6.5.3. Ivacaftor, tezacaftor, elexacaftor - KAFTRIO (CAP) - EMEA/H/C/005269/II/0055, Orphan

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Martin Huber

Scope: Update of section 4.6 of the SmPC in order to amend the existing wording on exposure during pregnancy following PSUR procedure (EMEA/H/C/PSUSA/00010868/202310)

Action: For adoption of PRAC Assessment Report

6.5.4. Saxagliptin, metformin hydrochloride – EBYMECT (CAP); KOMBOGLYZE (CAP); XIGDUO (CAP) - EMA/VR/0000258017

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: C.I.3.z: To update section 4.4 of the SmPC to implement the signal recommendations from PSUR outcome for the metformin PSUSA/00002001/202404. Section 2 of the Package Leaflet was updated accordingly

Action: For adoption of PRAC Assessment Report

6.5.5. Sitagliptin, metformin hydrochloride - EFFICIB (CAP); JANUMET (CAP); RISTFOR (CAP); VELMETIA (CAP) - EMA/VR/0000253633

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: C.I.3.z: To update section 4.4 of the SmPC to implement the signal recommendations from PSUR outcome for the metformin PSUSA/00002001/202404. Section 2 of the Package Leaflet was updated accordingly.

In addition, the Product Information was brought in line with the latest QRD template (version 10.4).

Minor editorial corrections have also been implemented.

The MAH also took the opportunity to update the contact details of the local representatives

Action: For adoption of PRAC Assessment Report

6.5.6. Vildagliptin, metformin hydrochloride- EUCREAS (CAP); ICANDRA (CAP); ZOMARIST (CAP) - EMA/VR/0000261605

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: To update section 4.4 (Special warnings and precautions for use) of the SmPC and section 2 (Warnings and precautions) of the Package Leaflet of Eucreas, Icandra and Zomarist with MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD) following PRAC recommendation regarding signal assessment of MELAS Syndrome/MIDD.

The MAH took the opportunity to correct the EU numbers in section 8 of the SmPC for the Icandra and Zomarist Croatian (HR) annexes

Action: For adoption of PRAC Assessment Report

6.6. Expedited summary safety reviews[21]

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[22]

7.1.1. Ciltacabtagene autoleucel - CARVYKTI (CAP) - EMA/PASS/0000256848

Applicant: Janssen Cilag International; ATMP

PRAC Rapporteur: Jo Robays

Scope: PASS 107o [PASS protocol amendment]: Substantial amendment to a PASS Study 68284528MMY4009: A Post-authorization Safety Study to Evaluate the Safety of Multiple Myeloma Patients Treated with Ciltacabtagene Autoleucel

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.2. Pegzilarginase - LOARGYS (CAP) - EMA/PASS/0000258458

Applicant: Immedica Pharma AB

PRAC Rapporteur: Martin Huber

Scope: PASS 107n (protocol): MAH's response to PSP/0105.2 [A European, non-interventional, multicentre, registry-based post-authorisation safety study to evaluate the

[21] 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

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

long-term safety of Loargys treatment in arginase 1 deficiency patients in standard clinical care] as per the request for supplementary information (RSI) adopted in Jan 2025

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.3. Topiramate - EMEA/H/N/PSP/J/0106.2

Applicant: Janssen (on behalf of a consortium)

PRAC Rapporteur: Karin Bolin

Scope: MAH's response to PSP/0106.1 [DUS to evaluate the effectiveness of the implemented risk minimisation measures, particularly focusing on preventing pregnancies and further characterising the prescribing patterns for topiramate in the target populations for pregnancy prevention] as per the request for supplementary information (RSI) adopted in January 2025

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[23]

7.2.1. Bimekizumab - BIMZELX (CAP) - EMA/PAM/0000249072

Applicant: UCB Pharma

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of a PASS protocol version 2 amendment #4 for the Cohort Study PS0037 to Evaluate Foetal and Infant Outcomes following Maternal Exposure to bimekizumab during Pregnancy

Action: For adoption of advice to CHMP

7.2.2. Deucravacitinib - SOTYKTU (CAP) - EMA/PAM/0000263305

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Protocol for PASS IM011194: Long-term, observational cohort study of adults with plaque psoriasis, who are new users of deucravacitinib, non-TNFi (tumour necrosis factor inhibitor) biologics, TNFi biologics, or non-biologic systemic therapy in the real-world clinical setting to evaluate the long-term safety of deucravacitinib

Action: For adoption of advice to CHMP

7.2.3. Marstacimab - HYMPAVZI (CAP) - EMA/PAM/0000255006

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

[23] 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: Submission of a study protocol for a category 3 study B7841016: A Post-Authorisation Safety Study to Evaluate the Safety of Marstacimab Among Patients with Severe Haemophilia A or B using Real-World Data in European Haemophilia Registers

Action: For adoption of advice to CHMP

7.2.4. Risankizumab- SKYRIZI (CAP) - EMA/PAM/0000254975

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: PASS study protocol P23-653: Pregnancy Exposures and Outcomes in Women with Inflammatory Bowel Disease Treated with Risankizumab.

Action: For adoption of advice to CHMP

7.2.5. Risankizumab - SKYRIZI (CAP) - EMA/PAM/0000254982

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Protocol amendment PASS study P23-654: Comparative Cohort Study of Long-term Safety Outcomes of Risankizumab Compared to Biologic Treatments for Ulcerative Colitis and Crohn's Disease in a Real-world Setting in Sweden and Denmark

Action: For adoption of advice to CHMP

7.2.6. Selexipag - UPTRAVI (CAP) - EMA/PAM/0000256686

Applicant: Janssen Cilag International

PRAC Rapporteur: Zoubida Amimour

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

Action: For adoption of advice to CHMP

7.2.7. Spesolimab - SPEVIGO (CAP) - EMA/PAM/0000254921

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Zoubida Amimour

Scope: Response to MEA 003.2 RSI adopted in January 2025 - amended protocol of PASS 1368-0128 (Non-imposed/Non-interventional). A 5-year active surveillance, post-authorisation safety study to characterise the safety of spesolimab for flare treatment in patients with GPP

Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)[24]

None

7.4. Results of PASS non-imposed in the marketing authorisation(s)[25]

7.4.1. Deferasirox - EXJADE (CAP) - EMEA/H/C/000670/II/0090

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of section 4.2 of the SmPC in order to update information on posology based on the non-interventional study CICL670A2429 listed as a category 3 study in the RMP. This is a survey to assess physicians' knowledge of Exjade posology and biological monitoring recommendations as described in the Educational Materials (EMs)

Action: For adoption of PRAC Assessment Report

7.4.2. Filgrastim – ZARZIO (CAP); FILGRASTIM HEXAL (CAP) - EMA/VR/0000249070

Applicant: Sandoz GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Submission of the final report from study EP06-501 listed as a category 3 study in the RMP. This is a non-interventional, prospective, long-term observational PASS to assess the safety and effectiveness of Zarzio / Filgrastim HEXAL (EP2006) administered to healthy unrelated stem cell donors for peripheral blood progenitor cell mobilization. The RMP version 14.0 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.3. Human C1-esterase inhibitor - CINRYZE (CAP) - EMEA/H/C/001207/II/0104

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Gabriele Maurer

Scope: Update of sections 4.6, 5.1 and 5.3 of the SmPC based on final results from the Icatibant Outcome Survey (IOS), listed as an imposed PASS in the Annex II. This is a prospective, observational disease registry. The Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the product information in line with the latest QRD template version 10.4 and to update Annex II of the PI

Action: For adoption of PRAC Assessment Report

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

7.5. Interim results of imposed and non-imposed PASS submitted before the entry into force of the revised variation regulation

7.5.1. Avapritinib – AYVAKYT (CAP) - EMA/PAM/0000256424

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Submission of interim results from Study BLU-285-1406 [SOB 3]: In order to further confirm the safety and efficacy of avapritinib in the treatment of adult patients with unresectable or metastatic GIST harbouring the PDGFRA D842V mutation, the MAH should submit the results of an observational safety and efficacy study in patients with unresectable or metastatic PDGFRA D842V-mutant GIST

Action: For adoption of advice to CHMP

7.5.2. COVID-19 mRNA vaccine – SPIKEVAX (CAP) - EMA/PAM/0000248944

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Sixth Interim Update for study P910 – Natural history and clinical outcomes of vaccine associated myocarditis (EU) – Category 3 study – included in the Risk Management Plan for Spikevax and as per the request from procedure MEA065.5

Action: For adoption of advice to CHMP

7.5.3. Guselkumab – TREMFYA (CAP) - EMA/PAM/0000256444

Applicant: Janssen Cilag International

PRAC Rapporteur: Gabriele Maurer

Scope: Interim study results for PsoBest Registry - German Registry on the Treatment of Psoriasis with Biologics and Systemic Therapeutic

Action: For adoption of advice to CHMP

7.5.4. Venetoclax – VENCLYXTO (CAP) - EMA/PAM/0000255427

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: To provide targeted tumour lysis syndrome (TLS) assessment reports on a biannual basis through 2023, and annually from Q1 2024 onwards, as per the RMP v8.1, to ensure close monitoring of the important identified risk of TLS, and the evaluation of the impact of newly implemented risk minimisation measures for TLS, on adherence to both already existing and updated recommendation added to the SmPC, the impact of the DHPC distributed to haematologists, and the patient card

Action: For adoption of advice to CHMP

7.6. Others

7.6.1. Abatacept – ORENCIA (CAP) - EMA/PAM/0000256412

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Annual update of the Observational Registry of Abatacept in Patients with Juvenile Idiopathic Arthritis (Study IM101240)

Action: For adoption of advice to CHMP

7.6.2. Diroximel fumarate – VUMERITY (CAP) - EMA/PAM/0000256697

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of annual progress report number 2 for Study 272MS401: A prospective observational pregnancy exposure registry to characterise how DRF may affect pregnancy and infant outcomes

Action: For adoption of advice to CHMP

7.7. New Scientific Advice

7.8. Ongoing Scientific Advice

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

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Afamelanotide – SCENESSE (CAP) - EMA/S/0000245110

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.2. Glucarpidase – VORAXAZE (CAP) - EMA/S/0000245171

Applicant: Serb

PRAC Rapporteur: Martin Huber

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.3. Pegzilarginase – LOARGYS (CAP) - EMA/S/0000247405

Applicant: Immedica Pharma AB

PRAC Rapporteur: Martin Huber

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.4. Tabelecleucel – EBVALLO (CAP) - EMA/S/0000249324

Applicant: Pierre Fabre Medicament; ATMP

PRAC Rapporteur: Amelia Cupelli

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CAT and CHMP

8.1.5. Tagraxofusp – ELZONRIS (CAP) - EMA/S/0000244851

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.6. Tecovirimat – TECOVIRIMAT SIGA (CAP) - EMA/S/0000248804

Applicant: Siga Technologies Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.2. Conditional renewals of the marketing authorisation

8.2.1. Avapritinib – AYVAKYT (CAP) - EMA/R/0000257352

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.2. Elafibranor – IQIRVO (CAP) - EMA/R/0000257350

Applicant: Ipsen Pharma

PRAC Rapporteur: Rugile Pilviniene

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.3. Epcoritamab – TEPKINLY (CAP) - EMA/R/0000257200

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Monica Martinez Redondo

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.4. Larotrectinib – VITRAKVI (CAP) - EMA/R/0000257511

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.5. Odronextamab – ORDSPONO (CAP) - EMA/R/0000254850

Applicant: Regeneron Ireland Designated Activity Company

PRAC Rapporteur: Jana Lukacisinova

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.6. Tafasitamab – MINJUVI (CAP) - EMA/R/0000256675

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.7. Valoctocogene roxaparvovec – ROCTAVIAN (CAP) - EMA/R/0000250212

Applicant: Biomarin International Limited; ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CAT and CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Acalabrutinib – CALQUENCE (CAP) - EMA/R/0000247050

Applicant: AstraZeneca AB

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.2. Arsenic trioxide - ARSENIC TRIOXIDE MEDAC (CAP) - EMEA/H/C/005218/R/0006 (without RMP)

Applicant: medac Gesellschaft fur klinische Spezialpraparate mbH

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Bupivacaine – EXPAREL LIPOSOMAL (CAP) - EMA/R/0000248989

Applicant: Pacira Ireland Limited

PRAC Rapporteur: Eamon O'Murchu

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Inclisiran – LEQVIO (CAP) - EMA/R/0000247528

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Kimmo Jaakkola

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.5. Lumacaftor, ivacaftor – ORKAMBI (CAP) - EMA/R/0000249341

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Eamon O'Murchu

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.6. Lumasiran – OXLUMO (CAP) - EMA/R/0000245133

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.7. Pegfilgrastim – NYVEPRIA (CAP) - EMA/R/0000249250

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.8. Quadrivalent influenza vaccine (recombinant, prepared in cell culture) – SUPEMTEK TETRA (CAP) - EMA/R/0000249010

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Zoubida Amimour

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.9. Susoctocog alfa – OBIZUR (CAP) - EMA/R/0000248614

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspections

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

9.3. Others

None

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

10.1. Safety related variations of the marketing authorisation

None

10.2. Timing and message content in relation to Member States' safety announcements

None

10.3. Other requests

None

10.4. Scientific Advice

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

11. Other safety issues for discussion requested by the Member States

11.1. Safety related variations of the marketing authorisation

11.1.1. Levofloxacin[26] (NAP) - DE/H/5119/001-003/II/113

Applicant(s): Sanofi-Aventis Deutschland GmbH

PRAC Lead: Martin Huber

Scope: PRAC consultation on a variation procedure (DE/H/5119/001-003/II/113) to update the product information based on submitted cumulative data including causality assessment of all cases of acute generalised exanthematous pustulosis (AGEP) associated with levofloxacin, following the conclusion of the PSUSA procedure on levofloxacin (PSUSA/00010767/202310) in May 2024, at request of Germany

Action: For adoption of advice to Member States

[26] For intravenous and oral use only

11.1.2. Mycophenolate mofetil (NAP); mycophenolic acid (NAP) - DE/H/xxxx/WS/1997

Applicant: Hexal Aktiengesellschaft, 1 A Pharma GmbH

PRAC Lead: Martin Huber

Scope: PRAC consultation on a worksharing variation procedure (DE/H/xxxx/WS/1997) regarding the need to align RMP requirements for reporting on long term safety of generic products containing mycophenolate mofetil or mycophenolic acid with the originator, and the need to reconsider whether long term safety is still considered as missing information in the RMP, at request of Germany

Action: For adoption of advice to Member States

11.2. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC membership

Action: For information

12.1.2. PRAC working group - Best practice guide on using PRAC plenary time efficiently and effectively – update on the implementation of quantitative goals – Q1 2025

Action: For information

12.1.3. Vote by proxy

Action: For information

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

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

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

12.5. Cooperation with International Regulators

12.5.1. International Conference on Harmonisation (ICH) E2D(R1) - Guideline

Action: For discussion

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

12.8.1. Medicinal Products and Technology Pipeline: 3-Year Outlook Report

Action: For discussion

12.8.2. PRAC workload statistics – Q1 2025

Action: For discussion

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

PRAC lead: Jana Lukačišinová

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

None

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

12.20.1. Strategy on measuring the impact of pharmacovigilance – PRAC interest group (IG) Impact - review of feasibility assessment outcomes of RMM effectiveness and impact research

Action: For discussion

12.21. Others

12.21.1. Good Pharmacovigilance Practices (GVP) module XVI – Addendum on pregnancy - update

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.21.2. Onboarding/offboarding experience of Committee/CMD members and alternates

Action: For information

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/