29 September 2025
EMA/PRAC/291018/2025
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 29 September – 02 October 2025

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

29 September 2025, 13:00 – 19:30, room 1C

30 September 2025, 08:30 – 19:30, room 1C

01 October 2025, 08:30 – 19:30, room 1C

02 October 2025, 08:30 – 16:00, room 1C

Organisational, regulatory and methodological matters (ORGAM)

16 October 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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Table of contents

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 29 September – 02 October 2025. See October 2025 PRAC minutes (to be published post November 2025 PRAC meeting).

1.2. Agenda of the meeting on 29 September – 02 October 2025

Action: For adoption

1.3. Minutes of the previous meeting on 01 – 04 September 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

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination procedures[1]

None

3.5. Others

None

4. Signals assessment and prioritisation[2]

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

4.1.1. Tirzepatide – MOUNJARO (CAP)

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

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

Action: For adoption of PRAC recommendation

EPITT 20198 – New signal

Lead Member State(s): NL

4.1.2. Pancreatin (NAP)

Applicant: various

PRAC Rapporteur: To be appointed

Scope: Signal of infection due to viral transmission

Action: For adoption of PRAC recommendation

EPITT 20205 – New signal

Lead Member State(s): DE

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

4.2. Signals follow-up and prioritisation

None

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. Aficamten - (CAP MAA) - EMEA/H/C/006228

Scope (pre D-180 phase): Treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) in adult patients

Action: For adoption

5.1.2. Depemokimab - (CAP MAA) - EMEA/H/C/006446

Scope (pre D-180 phase): As an add-on maintenance treatment of asthma, and as an add-on treatment of inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)

Action: For adoption

5.1.3. Etanercept - (CAP MAA) - EMEA/H/C/006738

Scope : Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis, paediatric plaque psoriasis

Action: For adoption

5.1.4. Golimumab - (CAP MAA) - EMEA/H/C/006621

Scope (pre D-180 phase): Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis.

Action: For adoption

5.1.5. Lutetium (^{177}Lu) chloride - (CAP MAA) - EMEA/H/C/006596

Scope (pre D-180 phase): Used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with Lutetium (177Lu) chloride

Action: For adoption

5.1.6. Nogapendekin alfa inbakicept - (CAP MAA) - EMEA/H/C/006622

Scope (pre D-180 phase): Treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours

Action: For adoption

5.1.7. Ranibizumab - (CAP MAA) - EMEA/H/C/006502

Scope (pre D-180 phase): Treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment and other retinopathies

Action: For adoption

5.1.8. Tolebrutinib - (CAP MAA) - EMEA/H/C/006386

Scope (pre D-180 phase): Treatment of non-relapsing secondary progressive multiple sclerosis (nrSPMS) in adults

Action: For adoption

5.1.9. Trofinetide - (CAP MAA) - EMEA/H/C/006482, Orphan

Applicant: Comharsa Life Sciences Limited

Scope (pre D-180 phase): Treatment of Rett syndrome in adults and paediatric patients 2 years of age and older

Action: For adoption

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

5.2.1. Emtricitabine / Rilpivirine / Tenofovir disoproxil – EVIPLERA (CAP) – EMA/VR/0000287296

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of two variations:

C.I.11.b: Submission of an updated RMP version 16.1 in order to propose the removal of 'Missing information' (Safety in pregnancy) and the removal of a Category 3 Additional Pharmacovigilance Activity (Antiretroviral Pregnancy Registry [APR]).

C.I.11.b: Submission of an updated RMP version 16.1 in order to propose the removal of Specific Adverse Reaction Follow-up Questionnaires related to bone and renal risks.

Action: For adoption

5.2.2. Mavacamten – CAMZYOS (CAP) – EMA/VR/0000275832

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Submission of an updated RMP version 6.0 in order to introduce a change in the time of assessment of the primary objective from 52-week to 48-week of the ODYSSEY-HCM study (CV027031), listed as a category 3 study in the RMP. Additionally, the opportunity is taken to include a change to the submission due date of the ODYSSEY-HCM final clinical study report from July 2025 to June 2026.

Action: For adoption

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

5.3.1. Aflibercept – EYLEA (CAP) – EMA/VR/0000264981

Applicant: Bayer AG

PRAC Rapporteur: Zoubida Amimour

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

C.I.6: Extension of indication to include the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch, central and hemiretinal RVO) for EYLEA, based on results from study 22153 (QUASAR); this is a randomized, double-masked, active-controlled Phase 3 study of the efficacy and safety of aflibercept 8 mg in macular edema secondary to retinal vein occlusion. 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 accordingly. The RMP version 36.1 has also been submitted.

C.I.4: Update of section 4.2 of the SmPC in order to change posology recommendations of the approved indications neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME) based on the results from study 22153 (QUASAR) and post-hoc analysis of the pivotal studies 20968 (PULSAR), 21091 (PHOTON) and Phase II study 21086 (CANDELA).

Action: For adoption

5.3.2. Asciminib – SCEMBLIX (CAP) – EMA/VR/0000265010

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Eva Jirsová

Scope: A grouped application consisting of:

C.I.6.a: Extension of indication to include treatment of adult patients with newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) for SCEMBLIX, based on primary and key secondary analysis results from study CABL001J12301 (ASC4FIRST, J12301); this is an ongoing Phase III, multi-center, open-label, randomized study of oral asciminib (80 mg once daily, q.d.) versus Investigator selected tyrosine kinase inhibitor (TKI) in patients with newly diagnosed Ph+ CML-CP, with

the primary and key secondary objectives to compare the major molecular response (MMR) rates at Week 48 and Week 96, respectively. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. RMP version 4.0 has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.

C.I.4: Update of sections 4.2, 4.5, 5.1, 5.2 and 5.3 of the SmPC in order to introduce a new posology regimen based on results from studies CABL001J12301 and CABL001A2302 (ASC4OPT, A2302). CABL001A2302 is an ongoing Phase IIIb, multi-center, open-label, treatment optimization study of oral asciminib (80 mg daily, randomized to 40 mg b.i.d. or 80 mg q.d.) in patients with Ph+ CML-CP previously treated with two or more TKIs, with the primary objective to estimate the MMR rate at Week 48 of all the patients (40 mg b.i.d. and 80 mg q.d.) with no evidence of MMR at baseline. The Package Leaflet is updated accordingly. RMP version 4.0 has also been submitted.

Action: For adoption

5.3.3. Bempedoic acid – NILEMDO (CAP); NUSTENDI (CAP) – EMA/VR/0000284929

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Kimmo Jaakkola

Scope: Update of section 4.6 of the SmPC in order to update information on breastfeeding and lactation, based on final results from study 1002FDC-075. This is an open-label, phase 4, postmarketing milk-only lactation study to evaluate the concentration of bempedoic acid and bempedoic acid and ezetimibe in the breast milk of healthy lactating women administered therapeutic doses of bempedoic acid or bempedoic acid/ezetimibe fixed combination drug product (FCDP). The Package Leaflet is updated accordingly. The updated RMP version 8.1 has also been submitted.

Action: For adoption

5.3.4. Blinatumomab – BLINCYTO (CAP) – EMA/VR/0000286935

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Veronika Macurova

Scope: Update of sections 4.4, 4.8 of the SmPC in order to add a new warning on Haemophagocytic lymphohistiocytosis (HLH)/Immune effector-cell-associated haemophagocytic lymphohistiocytosis-like syndrome (IEC-HS) following the evolving understanding of cytokine release syndrome and HLH/IEC-HS; the Package Leaflet is updated accordingly. The RMP version 20.0 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI.

Action: For adoption

5.3.5. Cemiplimab – LIBTAYO (CAP) – EMA/VR/0000264999

Applicant: Regeneron Ireland Designated Activity Company

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of adjuvant treatment of adult patients with Cutaneous Squamous Cell Carcinoma (CSCC) at high risk of recurrence after surgery and radiation for LIBTAYO, based on interim results from study R2810-ONC-1788; this is a phase 3, randomized, placebo-controlled, double-blind study of adjuvant cemiplimab versus placebo after surgery and radiation therapy in patients with high risk CSCC; As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the warnings for the excipients proline and polysorbate to reflect EU guidance (Section 4.4), and also updated Annex IID of the PI in line with the updates made to the RMPv4.2 to consolidate the aRMMs.

Action: For adoption

5.3.6. COVID-19 mRNA vaccine – KOSTAIVE (CAP) – EMA/VR/0000284897

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Update of sections 4.5, 4.8 and 5.1 of the SmPC in order to add information based on final results from study ARCT-2303-01 listed as a category 3 study in the RMP; this is a Phase 3 observer-blind, randomized controlled study to evaluate the immunogenicity, reactogenicity, and safety of Kostaive administered concomitantly with quadrivalent influenza vaccines in adults. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH is taking the opportunity to implement editorial changes to the PI.

Action: For adoption

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

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

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

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of moderate to severe chronic spontaneous urticaria (CSU) in children aged 2 to 11 years whose disease is inadequately controlled by H1 antihistamines and who are naive to anti-IgE therapy for CSU for DUPIXENT, based on the results from study PKM16982; this is a multi-center, single-arm study to investigate the pharmacokinetics and safety of dupilumab in male and female participants ≥2 years to <12 years of age with uncontrolled chronic spontaneous urticaria (CSU). Consequently, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template.

Action: For adoption

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

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

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

Action: For adoption

5.3.10. Golimumab - SIMPONI (CAP) - EMEA/H/C/000992/II/0121

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Karin Bolin

Scope: Extension of indication to include treatment of paediatric ulcerative colitis for SIMPONI, based on results from study CNTO148UCO3003; this is a Phase 3 Randomized, Open-label Study to Assess the Efficacy, Safety, and Pharmacokinetics of Golimumab Treatment, a Human anti-TNFα Monoclonal Antibody, Administered Subcutaneously in Paediatric Participants with Moderately to Severely Active Ulcerative Colitis. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. Version 28.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.

Furthermore, the PI is updated in accordance with the latest EMA excipients guideline and aligned with the latest QRD template version 10.4.

Action: For adoption

5.3.11. Guselkumab – TREMFYA (CAP) – EMA/X/0000248626

Applicant: Janssen Cilag International

PRAC Rapporteur: Gabriele Maurer

Scope:

Extension application to add a new strength of 45 mg (100 mg/ml) in a pre-filled syringe (glass) in pre-filled pen (VarioJect) grouped with an extension of indication (C.I.6.a) to include treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years who are candidates for systemic therapy based on results from study CNTO1959PSO3011. This is a Phase 3, Multicenter, Randomized, Placebo- and Active Comparator-Controlled Study Evaluating the Efficacy, Safety, and Pharmacokinetics of Subcutaneously Administered Guselkumab for the Treatment of Chronic Plaque Psoriasis in Pediatric Participants (≥6 To <18 Years of Age). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 10.3 of the RMP has also been submitted.

Action: For adoption

5.3.12. Inebilizumab – UPLIZNA (CAP) – EMA/VR/0000257358

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: A grouped application consisting of:

C.I.6 (Extension of indication): Extension of indication to include add-on to standard therapy for the treatment of adult patients with generalised myasthenia gravis (gMG) for Uplizna, based on primary analysis results from Study MINT (VIB0551.P3.S1); this is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adults subjects with myasthenia gravis. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1, 5.2, and 7 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

A.6: Update of the ATC code of inebilizumab to L04AG10 in line with the 2024 ATC INDEX.

Action: For adoption

5.3.13. Insulin aspart – KIRSTY (CAP) – EMA/VR/0000285173

Applicant: Biosimilar Collaborations Ireland Limited

PRAC Rapporteur: Mari Thorn

Scope: Quality

Action: For adoption

5.3.14. Insulin icodec – AWIQLI (CAP) – EMA/VR/0000268356

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Sonja Radowan

Scope: Update of sections 4.4, and 5.1 of the SmPC in order to update information related to medication errors based on post-marketing data and data from clinical trials; the Package Leaflet (PL) is updated accordingly. The RMP version 2.0 has also been submitted in order to add new identified risk of "Medication errors with accidental overdose, due to erroneous transfer of dosing habits from other once-weekly injectable antidiabetic medicines". In addition, "ankle swelling" was reworded to "swelling around ankles" in the PL.

Action: For adoption

5.3.15. 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

5.3.16. Lisocabtagene maraleucel / Lisocabtagene maraleucel – BREYANZI (CAP) – EMA/VR/0000272242

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Update of sections 4.2, 4.4, 4.7 and 4.8 of the SmPC in order to update the post-treatment safety monitoring information based on clinical trials and real-world data. The

Package leaflet section is updated in accordance. Version 8.0 of the RMP has also been submitted. In addition, the MAH the opportunity to update Annex II.

Action: For adoption

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

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Jean-Michel Dogné

Scope: Extension of indication for MENQUADFI to include the active immunisation of patients from 6 weeks of age based on final results from study MET58 and additional supportive clinical studies. Study MET58 is a Phase 3, immunogenicity and Safety Study of an Investigational Quadrivalent Meningococcal Conjugate Vaccine when Administered Concomitantly with Routine Pediatric Vaccines in Healthy Infants and Toddlers in Europe. As a consequence, sections 4.1, 4.2, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. An updated Risk Management Plan (RMP) version 4.0 is also included.

Action: For adoption

5.3.18. Methylthioninium chloride – METHYLTHIONINIUM CHLORIDE PROVEBLUE (CAP) – EMA/VR/0000265559

Applicant: Provepharm

PRAC Rapporteur: Karin Bolin

Scope: Submission of the final report from study PVP-2016005; this is an Open-label, Parallel group, Population-matched, Single-Dose Study to Investigate the Influence of Hepatic Impairment on the Pharmacokinetics and safety of ProvayBlue (methylene blue). The RMP version 3.4 has also been submitted.

Action: For adoption

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

Applicant: Janssen Cilag International

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include AKEEGA with prednisone or prednisolone for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and HRR-mutations (germline and/or somatic, based on interim results from study 67652000PCR3002 (AMPLITUDE); this is a phase 3 randomized, placebo-controlled, double-blind study of niraparib in combination with abiraterone acetate and prednisone versus abiraterone acetate and prednisone for the treatment of participants with deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-sensitive Prostate cancer (mCSPC). As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH)

took the opportunity to update the list of local representatives in the Package Leaflet. In addition, the MAH is requesting an additional year of market protection for a new indication.

Action: For adoption

5.3.20. Nirmatrelvir / Ritonavir - PAXLOVID (CAP) - EMEA/H/C/005973/II/0061/G

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: A grouped application comprised of a Type II Variation and a Type IB Variation, as follows:

Type II (C.I.6.a): Extension of indication to include treatment of coronavirus disease 2019 (COVID-19) in paediatric patients 6 years of age and older weighing at least 20 kg for PAXLOVID, based on the final analysis of Cohorts 1 and 2 from pivotal Study C4671026; this is a Phase 2/3, Interventional Safety, Pharmacokinetics, and Efficacy, Open-Label, Multi-Center, Single-Arm Study to Investigate Orally Administered PF 07321332 (Nirmatrelvir)/Ritonavir in Nonhospitalized Symptomatic Pediatric Participants With COVID-19 Who Are at Risk of Progression to Severe Disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

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

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

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

Action: For adoption

5.3.22. Obinutuzumab – GAZYVARO (CAP) – EMA/VR/0000244907

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of adult patients with active lupus nephritis who are receiving standard therapy for GAZYVARO, based on results from study Regency (CA41705). This is an ongoing, Phase III, randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy and safety of obinutuzumab administered at standard infusion rates in patients with ISN/RPS 2003 Class III or IV lupus nephritis treated with standard-of-care therapy.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11 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.

Action: For adoption

5.3.23. Pegunigalsidase alfa - ELFABRIO (CAP) - EMEA/H/C/005618/II/0007

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC in order to introduce an alternative posology regimen based on results from study PB-102-F50 (BRIGHT) and interim results from its extension study CLI-06657AA1-03 (formerly presented as PB-102-F51), as well as results of the observational patient reporting outcome study CLI-06657AA1-05. CLI-06657AA1-03 is an Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Pegunigalsidase Alfa (PRX-102)2 mg/kg Administered by Intravenous Infusion Every 4 Weeks in Patients with Fabry Disease. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

5.3.24. Respiratory syncytial virus mRNA vaccine (nucleoside modified) – MRESVIA (CAP) – EMA/VR/0000263124

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

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

C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information of co-administration of mRESVIA (mRNA-1345) dispersion for injection, in its all-registered presentations, with a Standard dose, Seasonal Influenza Vaccine, based on data forthcoming from mRNA-1345-P302 part A clinical study. It is a Phase 3 study to evaluate safety and immunogenicity of mRNA-1345 for respiratory syncytial virus (RSV) when given alone or co-administered with a Seasonal Influenza vaccine or COVID-19 vaccine. The package leaflet is updated accordingly. The RMP version 2.0 has also been submitted.

C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information of co-administration of mRESVIA (mRNA-1345) dispersion for injection, in its all-registered presentations, with COVID-19 Vaccine, based on data forthcoming from mRNA-1345-P302 part B clinical study. It is a Phase 3 study to evaluate safety and immunogenicity of mRNA-

1345 for RSV when given alone or co-administered with a Seasonal Influenza vaccine or COVID-19 vaccine. The package leaflet is updated accordingly. The RMP version 2.0 has also been submitted.

C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information of co-administration of mRESVIA (mRNA 1345) dispersion for injection, in its all-registered presentations, with a High-dose, Quadrivalent Seasonal Influenza vaccine in Adults ≥65 Years of Age, based on data forthcoming from mRNA-1345-P304 clinical study. It is a Phase 3 Study to evaluate the safety and immune response of mRNA-1345, when co-administered with a High-dose, Quadrivalent Seasonal Influenza vaccine. The package leaflet is updated accordingly. The RMP version 2.0 has also been submitted.

Action: For adoption

5.3.25. Rurioctocog alfa pegol – ADYNOVI (CAP) – EMA/VR/0000268348

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Update of sections 4.2, 4.4, 4.8, 5.1, and 5.2 of the SmPC in order to update clinical pharmacokinetic, efficacy, and safety information based on final results from study 261203, listed as a category 3 study in the RMP; this is a phase 3, prospective, multi-center, open label study to investigate safety, immunogenicity, and hemostatic efficacy of PEGylated Factor VIII (BAX 855) in previously untreated patients (PUPs); the Package Leaflet is updated accordingly. The RMP version 5.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to introduce editorial changes, and to bring the PI in line with the latest QRD template.

Action: For adoption

5.3.26. Secukinumab – COSENTYX (CAP) – EMA/VR/0000267996

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Submission of the final report from study CAIN457F2304E1, listed as a category 3 study in the RMP. This is a phase 3, long-term, open-label, efficacy, safety and tolerability in JPsA and ERA subtypes of JIA up to 4 years in patients with active JPsA and ERA subtypes of JIA and who completed the Phase III study CAIN457F2304. The RMP version 12.0 has also been submitted.

Action: For adoption

5.3.27. Seladelpar lysine dihydrate – LYVDELZI (CAP) – EMA/VR/0000282041

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Amelia Cupelli

Scope: Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on final results from study CB8025-21838 listed as a category 3 study in the RMP. This

is an open-label study following oral dosing of seladelpar to subjects with primary biliary cholangitis (PBC) and hepatic impairment. In addition, the MAH took the opportunity to introduce additional administrative changes and corrections to the PI. The RMP version 1.1 has also been submitted.

Action: For adoption

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

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope:

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

Action: For adoption

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

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include HETRONIFLY in combination with carboplatin and pemetrexed is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung carcinoma who do not have EGFR or ALK positive mutations based on interim results from study HLX10-002-NSCLC301; this is a pivotal Phase III clinical study, patients treated with serplulimab in combination with carboplatin and pemetrexed showed statistically significant and clinically meaningful benefits in the efficacy endpoint results compared with those who received placebo with carboplatin and pemetrexed. As a consequence, sections 4.1, 4.8, 5.1, 5.2 of of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.

Action: For adoption

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

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include, in combination with fluoropyrimidine- and platinum-based chemotherapy, the first-line treatment of adult patients with unresectable, locally advanced/recurrent or metastatic oesophageal squamous cell carcinoma whose tumours express PD-L1 with a CPS ≥ 1 for HETRONIFLY, based on results from study HLX10-007-EC301; this is a randomized, double-blind, multi-center, phase III clinical study comparing the clinical efficacy and safety of HLX10 or placebo combined with chemotherapy in first-line treatment of locally advanced/metastatic esophageal squamous cell carcinoma (ESCC) patients. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted.

Action: For adoption

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

Applicant: AstraZeneca AB

PRAC Rapporteur: Kimmo Jaakkola

Scope: Update of section 4.4 of the SmPC in order to add a new warning on cardiovascular and/or thrombo-embolic events, based on the currently available safety information including the updated post-authorisation data. The Package Leaflet is updated accordingly. The RMP version 2 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.32. Sonidegib – ODOMZO (CAP) – EMA/VR/0000268112

Applicant: Sun Pharmaceutical Industries (Europe) B.V.

PRAC Rapporteur: Petar Mas

Scope: Update of sections 5.3 and 6.6 of the SmPC in order to update non-clinical safety information on carcinogenicity based on final results from studies 8371102 and BRT_17_037G_TN; this is a 26-Week Oral Gavage Carcinogenicity Study with LDE225 in Transgenic Mice (RasH2 [001178-T (hemizigous), CByB6F1-Tg(HRAS)2Jic]) and a 104-Week Carcinogenicity Study of LDE225 in Wistar Rats by Oral Route, respectively. Sections 5.3 and 6.6 of the SmPC were also updated to include a statement on risk to the environment in line with the commitment following EMEA/H/C/002839/IB/0056. The RMP version 8.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to introduce editorial changes, and to bring the PI in line with the latest QRD template.

Action: For adoption

5.3.33. Sugemalimab – CEJEMLY (CAP) – EMA/VR/0000261157

Applicant: Cstone Pharmaceuticals Ireland Limited

PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include the treatment of unresectable stage III non-small-cell lung cancer (NSCLC) with no sensitising EGFR mutations, or ALK, ROS1 genomic tumour aberrations in adults whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy for CEJEMLY, based on final results from study CS1001-301; this is a Phase III, multicentre, randomised, double-blind, placebo-controlled study assessing the efficacy and safety of sugemalimab as consolidation therapy versus placebo in participants with locally advanced or unresectable stage III NSCLC who have not progressed after concurrent or sequential chemoradiotherapy. 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 2.0 of the RMP has also been submitted.

Action: For adoption

5.3.34. Tafasitamab – MINJUVI (CAP) – EMA/VR/0000255975

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include in combination with lenalidomide and rituximab treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least one line of systemic therapy for MINJUVI, based on interim results from study INCMOR 0208-301 (inMIND); this is a phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of tafasitamab plus lenalidomide and rituximab vs lenalidomide and rituximab in patients with relapsed/refractory (R/R) follicular lymphoma grade 1 to 3a or R/R marginal zone lymphoma. As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.35. Tecovirimat – TECOVIRIMAT SIGA (CAP) – EMA/VR/0000244868

Applicant: Siga Technologies Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Update of section 4.5 of the SmPC in order to add drug-drug interaction information with Calcium acetate, Lanthanum carbonate, Sevelamer carbonate, and Sucroferric oxyhydroxide based on final results from study SIGA-246-023. This is a safety, tolerability, and efficacy study of 4 phosphate binders on tecovirimat in adults. The Package Leaflet has been updated accordingly. The RMP version 2.1 has also been submitted.

Action: For adoption

5.3.36. Tirzepatide – MOUNJARO (CAP) – EMA/VR/0000281937

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise for MOUNJARO, based on final results from study I8F-MC-GPGV (SURPASS-PEDS); this is a study to evaluate efficacy, safety, and pharmacokinetics/pharmacodynamics of tirzepatide compared to placebo in paediatric and adolescent participants with type 2 diabetes mellitus inadequately controlled with metformin, or basal insulin, or both. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has also been submitted.

Action: For adoption

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

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

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

Action: For adoption

5.3.38. 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

6. Periodic safety update reports (PSURs)

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

6.1.1. Aprocitentan – JERAYGO (CAP) – EMA/PSUR/0000274466

Applicant: Idorsia Pharmaceuticals Deutschland GmbH

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00011067/202503)

Action: For adoption

6.1.2. Axitinib – INLYTA (CAP) – EMA/PSUR/0000274426

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010022/202501)

Action: For adoption

6.1.3. Baloxavir marboxil – XOFLUZA (CAP) – EMA/PSUR/0000274449

Applicant: Roche Registration GmbH

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010895/202502)

Action: For adoption

6.1.4. Bempedoic acid / Ezetimibe – NILEMDO (CAP); NUSTENDI (CAP) – EMA/PSUR/0000274450

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010841/202502)

Action: For adoption

6.1.5. Bevacizumab – ABEVMY (CAP); ALYMSYS (CAP); AVASTIN (CAP); AVZIVI (CAP); AYBINTIO (CAP); MVASI (CAP); OYAVAS (CAP); VEGZELMA (CAP); ZIRABEV (CAP) – EMA/PSUR/0000274402

Applicants: Amgen Technology (Ireland) Unlimited Company, Biosimilar Collaborations Ireland Limited, Celltrion Healthcare Hungary Kft., FGK Representative Service GmbH,

Mabxience Research S.L., Pfizer Europe MA EEIG, Roche Registration GmbH, STADA Arzneimittel AG, Samsung Bioepis NL B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000403/202502)

Action: For adoption

6.1.6. Bictegravir / Emtricitabine / Tenofovir alafenamide – BIKTARVY (CAP) – EMA/PSUR/0000274445

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010695/202502)

Action: For adoption

6.1.7. Burosumab – CRYSVITA (CAP) – EMA/PSUR/0000274414

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010669/202502)

Action: For adoption

6.1.8. Cabotegravir – VOCABRIA (CAP) – EMA/PSUR/0000274453

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010900/202503)

Action: For adoption

6.1.9. Cabotegravir – APRETUDE (CAP) – EMA/PSUR/0000274427

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000116/202503)

Action: For adoption

6.1.10. Carglumic acid – CARBAGLU (CAP) – EMA/PSUR/0000274412

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00000564/202501)

Action: For adoption

6.1.11. Ciltacabtagene autoleucel – CARVYKTI (CAP) – EMA/PSUR/0000274460

Applicant: Janssen Cilag International

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00011000/202502)

Action: For adoption

6.1.12. Cipaglucosidase alfa – POMBILITI (CAP) – EMA/PSUR/0000274442

Applicant: Amicus Therapeutics Europe Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00011047/202503)

Action: For adoption

6.1.13. Dexamethasone – OZURDEX (CAP) – EMA/PSUR/0000274395

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00000985/202501)

Action: For adoption

6.1.14. Efanesoctocog alfa – ALTUVOCT (CAP) – EMA/PSUR/0000274459

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00011062/202502)

Action: For adoption

6.1.15. Eptinezumab – VYEPTI (CAP) – EMA/PSUR/0000274456

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010966/202502)

Action: For adoption

6.1.16. Ex vivo expanded autologous human corneal epithelial cells containing stem cells – HOLOCLAR (CAP) – EMA/PSUR/0000274435

Applicant: Holostem S.R.L.

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00010352/202502)

Action: For adoption

6.1.17. Fedratinib – INREBIC (CAP) – EMA/PSUR/0000274467

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010909/202502)

Action: For adoption

6.1.18. Fenofibrate / Simvastatin – CHOLIB (CAP) – EMA/PSUR/0000274431

Applicant: Viatris Healthcare Limited

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00010096/202502)

Action: For adoption

6.1.19. Fosdenopterin – NULIBRY (CAP) – EMA/PSUR/0000274447

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00011017/202502)

Action: For adoption

6.1.20. Fruquintinib – FRUZAQLA (CAP) – EMA/PSUR/0000274462

Applicant: Takeda Pharmaceuticals International AG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011069/202503)

Action: For adoption

6.1.21. Ganaxolone – ZTALMY (CAP) – EMA/PSUR/0000274432

Applicant: Immedica Pharma AB

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000093/202503)

Action: For adoption

6.1.22. Imlifidase – IDEFIRIX (CAP) – EMA/PSUR/0000274446

Applicant: Hansa Biopharma AB

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010870/202502)

Action: For adoption

6.1.23. Influenza vaccine (surface antigen, inactivated, adjuvanted) – FLUAD (CAP); FLUAD TETRA (CAP) – EMA/PSUR/0000274436

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010300/202503)

Action: For adoption

6.1.24. influenza vaccine (surface antigen, inactivated, prepared in cell cultures) – FLUCELVAX (CAP); FLUCELVAX TETRA (CAP) – EMA/PSUR/0000274448

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010737/202503)

Action: For adoption

6.1.25. Miglustat – OPFOLDA (CAP) – EMA/PSUR/0000274388

Applicant: Amicus Therapeutics Europe Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00000077/202503)

Action: For adoption

6.1.26. Mitapivat – PYRUKYND (CAP) – EMA/PSUR/0000274443

Applicant: Agios Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011025/202502)

Action: For adoption

6.1.27. Momelotinib – OMJJARA (CAP) – EMA/PSUR/0000274423

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00000263/202503)

Action: For adoption

6.1.28. Nitisinone – ORFADIN (CAP) – EMA/PSUR/0000274398

Applicant: Swedish Orphan Biovitrum International AB

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00002169/202502)

Action: For adoption

6.1.29. Nivolumab / Relatlimab – OPDUALAG (CAP) – EMA/PSUR/0000274454

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011018/202503)

Action: For adoption

6.1.30. Odronextamab – ORDSPONO (CAP) – EMA/PSUR/0000274458

Applicant: Regeneron Ireland Designated Activity Company

PRAC Rapporteur: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00011074/202502)

Action: For adoption

6.1.31. Omaveloxolone – SKYCLARYS (CAP) – EMA/PSUR/0000274406

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000245/202502)

Action: For adoption

6.1.32. Oritavancin – TENKASI (CAP) – EMA/PSUR/0000274430

Applicant: Menarini International Operations Luxembourg S.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010368/202503)

Action: For adoption

6.1.33. Pegfilgrastim – CEGFILA (CAP); FULPHILA (CAP); GRASUSTEK (CAP); NEULASTA (CAP); NYVEPRIA (CAP); PELGRAZ (CAP); PELMEG (CAP); STIMUFEND (CAP); ZIEXTENZO (CAP) – EMA/PSUR/0000274399

Applicants: Accord Healthcare S.L.U., Amgen Europe B.V., Biosimilar Collaborations Ireland Limited, Fresenius Kabi Deutschland GmbH, Juta Pharma GmbH, Mundipharma Corporation (Ireland) Limited, Pfizer Europe MA EEIG, Sandoz GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00002326/202501)

Action: For adoption

6.1.34. Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted)– MOSQUIRIX (Art 58)[3] – EMA/PSUR/0000273313

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption

6.1.35. Polihexanide – AKANTIOR (CAP) – EMA/PSUR/0000274457

Applicant: SIFI S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011082/202502)

Action: For adoption

6.1.36. Ponesimod – PONVORY (CAP) – EMA/PSUR/0000274452

Applicant: Laboratoires Juvise Pharmaceuticals

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00010940/202503)

Action: For adoption

[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)

6.1.37. Ribociclib – KISQALI (CAP) – EMA/PSUR/0000274416

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010633/202503)

Action: For adoption

6.1.38. Rilpivirine – REKAMBYS (CAP) – EMA/PSUR/0000274451

Applicant: Janssen Cilag International

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010901/202503)

Action: For adoption

6.1.39. Rimegepant – VYDURA (CAP) – EMA/PSUR/0000274465

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00010997/202502)

Action: For adoption

6.1.40. Ruxolitinib – JAKAVI (CAP) – EMA/PSUR/0000274417

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010015/202502)

Action: For adoption

6.1.41. Sodium thiosulfate – PEDMARQSI (CAP) – EMA/PSUR/0000274389

Applicant: Norgine B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000066/202503)

Action: For adoption

6.1.42. Solriamfetol – SUNOSI (CAP) – EMA/PSUR/0000274441

Applicant: Atnahs Pharma Netherlands B.V.

PRAC Rapporteur: Julia Pallos

Scope: Evaluation of a PSUSA procedure (PSUSA/00010831/202503)

Action: For adoption

6.1.43. Sparsentan – FILSPARI (CAP) – EMA/PSUR/0000274455

Applicant: Vifor France

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00011060/202502)

Action: For adoption

6.1.44. Spesolimab – SPEVIGO (CAP) – EMA/PSUR/0000274439

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00011033/202503)

Action: For adoption

6.1.45. Teclistamab – TECVAYLI (CAP) – EMA/PSUR/0000274444

Applicant: Janssen Cilag International

PRAC Rapporteur: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00011010/202502)

Action: For adoption

6.1.46. Tildrakizumab – ILUMETRI (CAP) – EMA/PSUR/0000274440

Applicant: Almirall S.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010720/202503)

Action: For adoption

6.1.47. Tivozanib – FOTIVDA (CAP) – EMA/PSUR/0000274415

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00010636/202502)

Action: For adoption

6.1.48. Valoctocogene roxaparvovec – ROCTAVIAN (CAP) – EMA/PSUR/0000274464

Applicant: Biomarin International Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011009/202502)

Action: For adoption

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

6.2.1. Ciclosporin – IKERVIS (CAP); VERKAZIA (CAP); VEVIZYE (CAP); NAP – EMA/PSUR/0000274428

Applicants: Laboratoires Thea, Santen Oy, various

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010362/202503)

Action: For adoption

6.2.2. Dexrazoxane – SAVENE (CAP); NAP – EMA/PSUR/0000274404

Applicants: Cnx Therapeutics Ireland Limited, various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00001001/202502)

Action: For adoption

6.2.3. Orlistat – XENICAL (CAP); ALLI (CAP); NAP – EMA/PSUR/0000274400

Applicants: Cheplapharm Arzneimittel GmbH, GlaxoSmithKline Dungarvan Limited, various

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00002220/202502)

Action: For adoption

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

6.3.1. Amlodipine / atorvastatin (NAP) – EMA/PSUR/0000274424

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00000177/202501)

Action: For adoption

6.3.2. Atenolol (NAP) – EMA/PSUR/0000274425

Applicants: various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000259/202502)

Action: For adoption

6.3.3. Codeine (NAP) – EMA/PSUR/0000274397

Applicants: various

PRAC Lead: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00000843/202501)

Action: For adoption

6.3.4. Cyclophosphamide (NAP) – EMA/PSUR/0000274403

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000901/202501)

Action: For adoption

6.3.5. Dienogest / ethinylestradiol (prolonged-release tablet) (NAP) – EMA/PSUR/0000274463

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00011084/202503)

Action: For adoption

6.3.6. Dorzolamide (NAP) – EMA/PSUR/0000274429

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00003168/202502)

Action: For adoption

6.3.7. Gabapentin (NAP) – EMA/PSUR/0000274393

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00001499/202502)

Action: For adoption

6.3.8. Glipizide (NAP) – EMA/PSUR/0000274392

Applicants: various

PRAC Lead: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00001535/202501)

Action: For adoption

6.3.9. Hydroxyethyl starch / sodium chloride (NAP) – EMA/PSUR/0000274390

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00001694/202503)

Action: For adoption

6.3.10. Influenza vaccine (split virion, inactivated) (non centrally authorised products) (NAP) – EMA/PSUR/0000274438

Applicants: various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010298/202503)

Action: For adoption

6.3.11. Influenza vaccine (surface antigen, inactivated) (NAP) – EMA/PSUR/0000274391

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00001744/202503)

Action: For adoption

6.3.12. Interferon gamma (NAP) – EMA/PSUR/0000274394

Applicants: various

PRAC Lead: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00001760/202501)

Action: For adoption

6.3.13. Lisdexamfetamine (NAP) – EMA/PSUR/0000274437

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010289/202502)

Action: For adoption

6.3.14. Lorazepam (NAP) – EMA/PSUR/0000274396

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00001909/202501)

Action: For adoption

6.3.15. Mesterolone (NAP) – EMA/PSUR/0000274418

Applicants: various

PRAC Lead: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010551/202501)

Action: For adoption

6.3.16. Pimozide (NAP) – EMA/PSUR/0000274421

Applicants: various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00002413/202502)

Action: For adoption

6.3.17. Potassium para-aminobenzoate (NAP) – EMA/PSUR/0000274434

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010130/202502)

Action: For adoption

6.3.18. Prednisone (NAP) – EMA/PSUR/0000274401

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00002510/202501)

Action: For adoption

6.3.19. Propylthiouracil (NAP) – EMA/PSUR/0000274409

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00002558/202501)

Action: For adoption

6.3.20. Sevoflurane (NAP) – EMA/PSUR/0000274405

Applicants: various

PRAC Lead: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00002698/202501)

Action: For adoption

6.3.21. Sodium citrate / sodium lauryl sulfoacetate, sodium citrate / sodium lauryl sulfoacetate / sorbitol (NAP) – EMA/PSUR/0000274413

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00002735/202501)

Action: For adoption

6.3.22. Tofisopam (NAP) – EMA/PSUR/0000274410

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00002982/202501)

Action: For adoption

6.3.23. Trimethoprim (NAP) – EMA/PSUR/0000274411

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00003045/202501)

Action: For adoption

6.3.24. Vancomycin (NAP) – EMA/PSUR/0000274422

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00003097/202501)

Action: For adoption

6.3.25. Warfarin (NAP) – EMA/PSUR/0000274420

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00003129/202501)

Action: For adoption

6.3.26. Xipamide, triamterene / xipamide (NAP) – EMA/PSUR/0000274419

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00003133/202501)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Dapagliflozin – EDISTRIDE (CAP); FORXIGA (CAP) – EMA/PAM/0000289605

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Follow-up LEG (from EMEA/H/C/PSUSA/00010029/202410): Review of all cases related to the potential association between dapagliflozin exposure and prolonged ketoacidosis and prolonged glucosuria.

Action: For adoption

6.4.2. Ravulizumab – ULTOMIRIS (CAP) – EMA/PAM/0000287237

Applicant: Alexion Europe

PRAC Rapporteur: Kimmo Jaakkola

Scope: PAM-LEG to address a question from the PRAC Rapporteur's PSUR Assessment report related to the Ultomiris PSUR #9 reporting period 01 Jan 2024 – 31 Dec 2024, procedure number

EMA/PSUR/0000257874 (EURD no.: PSUSA/00010787/202412) dated 10 July 2025. The MAH should submit a cumulative review of all available data concerning liver injury and hepatic enzyme elevations in ravulizumab treated patients until the DLP of this PSUR. In view of totality of the data, the MAH is requested to update the product information of ravulizumab (SmPC and PL), as warranted.

Action: For adoption

6.5. Variation procedure(s) resulting from PSUSA evaluation

None

6.6. Expedited summary safety reviews[4]

None

7. Post-authorisation safety studies (PASS)

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

7.1.1. Beremagene geperpavec – VYJUVEK (CAP) – EMA/PASS/0000287685

Applicant: Krystal Biotech Netherlands B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: PASS protocol [107n]: A prospective, non-interventional, multi-country study to confirm the long-term safety profile, including in paediatric patients less than 6 months of age, of B-VEC for the treatment of DEB wounds in a real-life clinical setting.

Action: For adoption

7.1.2. Ketoconazole – KETOCONAZOLE ESTEVE (CAP) – EMA/PASS/0000287667

Applicant: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Petar Mas

Scope: PASS amendment [107o]: Prospective, Multi-Country, Observational Registry to collect clinical information on patients with endogenous CS exposed to Ketoconazole ESTEVE (using the existing European Registry on CS (ERCUSYN)), to assess drug utilization pattern

[4] Submission of expedited summary safety reports for review in addition to the requirements for submission of PSUR(s) falling within the pandemic period and requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC
[5] In accordance with Article 107n of Directive 2001/83/EC

and to document the safety (e.g. hepatotoxicity, QT prolongation) and effectiveness of Ketoconazole ESTEVE.

Action: For adoption

7.1.3. Odevixibat – KAYFANDA (CAP) – EMA/PASS/0000262884

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: PASS protocol [107n]: Prospective non-interventional study evaluating the long-term safety of odevixibat in patients with Alagille Syndrome (ALGS)

Action: For adoption

7.1.4. Teduglutide – REVESTIVE (CAP) – EMA/PASS/0000269314

Applicant: Takeda Pharmaceuticals International AG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: PASS amendment [107o]: Substantial amendment to a prospective, multi-center registry for patients with Short Bowel Syndrome (TED-R13-002)

Action: For adoption

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

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

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Gabriele Maurer

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

Action: For adoption

7.2.2. Etrasimod – VELSIPITY (CAP) – EMA/PAM/0000287646

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Bolin

Scope: Study C5041046 - non-imposed non-interventional PASS protocol amendment: An Active Surveillance, Post-Authorization Safety Study to Characterize the Safety of Etrasimod in Patients with Ulcerative Colitis Using Real-World Data in the European Union

[6] In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

Action: For adoption

7.2.3. Inotersen – TEGSEDI (CAP) – EMA/PAM/0000286818

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: The MAH Akcea Therapeutics Ireland Limited submitted a revised PASS protocol version 3.0 to the European Medicines Agency (EMA) for Inotersen (Tegsedi). The PAM refers to A Retrospective, Non-interventional, Multi-centre Study of TEGSEDI-treated Patients to Evaluate Real-world Adherence to, and Effectiveness of the Recommendations for Platelet Monitoring, Dose Adjustment, and Steroid Initiation to Manage Risk of Thrombocytopenia

Action: For adoption

7.2.4. Romosozumab – EVENITY (CAP) – EMA/PAM/0000264559

Applicant: UCB Pharma

PRAC Rapporteur: Tiphaine Vaillant

Scope: Protocol amendment for PASS No. OP0006: European non-interventional post-authorisation safety study (PASS) related to serious infections risk for romosozumab by the EU-ADR Alliance to evaluate potential differences in terms of serious infection between romosozumab and currently available therapies used in comparable patients in real-world conditions.

Action: For adoption

7.2.5. Romosozumab – EVENITY (CAP) – EMA/PAM/0000264555

Applicant: UCB Pharma

PRAC Rapporteur: Tiphaine Vaillant

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

Action: For adoption

7.2.6. Spesolimab – SPEVIGO (CAP) – EMA/PAM/0000254921

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Zoubida Amimour

Scope: Updated protocol of PASS 1368-0128 - A 5-year active surveillance, post-authorisation safety study to characterise the safety of spesolimab for flare treatment in patients with GPP. Response to MEA 003.2 RSI adopted on 30 January 2025.

Action: For adoption

7.2.7. Sutimlimab – ENJAYMO (CAP) – EMA/PAM/0000287395

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Jan Neuhauser

Scope: Revised Study Protocol v. 3.0 for sutimlimab A Survey of Healthcare Professionals in Europe to Evaluate the Effectiveness of the ENJAYMO Physician's Guide (HCP Survey, CEF-0205) a multinational, non-interventional, cross-sectional survey study.

Action: For adoption

7.2.8. Sutimlimab – ENJAYMO (CAP) – EMA/PAM/0000287412

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Jan Neuhauser

Scope: Revised Registry Study Protocol v. 6 for sutimlimab Cold Agglutinin Disease Real World Evidence Registry (CADENCE, OBS16454) a multinational, multi-center, observational, prospective, longitudinal disease registry. Former MEA 003.1-2

Action: For adoption

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

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Gabriele Maurer

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

Action: For adoption

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

7.3.1. Eliglustat – CERDELGA (CAP) – EMA/PASS/0000287682

Applicant: Sanofi B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: PASS results [107q]: A prospective multicenter observational post-authorization safety sub-registry study (PASS) to characterize the long-term safety profile of commercial use of eliglustat (Cerdelga) in adult patients with Gaucher disease.

Action: For adoption

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

7.3.2. Methylphenidate hydrochloride (NAP) – EMA/PASS/0000248031

Applicant(s): various

PRAC Rapporteur: Martin Huber

Scope: PASS 107q: Final study report for a multi-centre, observational, prospective PASS to evaluate the safety concerns of long-term cardiovascular and psychiatric risks within the adult attention deficit/hyperactivity disorder (ADHD) population taking Medikinet retard according to normal standard clinical practice.

Action: For adoption

7.3.3. Sodium valproate (NAP) – EMA/PASS/0000287665

Applicant(s): various

PRAC Rapporteur: Liana Martirosyan

Scope: valproate PASS results [107q]: Final study results for Drug Utilisation Study extension of valproate and related substances in Europe, using databases.

Action: For adoption

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

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

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Karin Bolin

Scope: A grouped application comprised of:

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

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

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

Action: For adoption

7.4.2. Alpelisib – PIQRAY (CAP) – EMA/VR/0000275207

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Bianca Mulder

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

Scope: Submission of the final report for study CBYL719C2005, listed as a category 3 study in the RMP. This is a non-interventional Post-authorisation Safety Study (PASS)/survey that was conducted to assess healthcare professionals' knowledge on management of hyperglycemia when using alpelisib in selected EU/EEA countries. The Annex II has been updated accordingly. Version 9.0 of the RMP has also been submitted.

Action: For adoption

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

Applicant: Teva B.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of section 4.8 of the SmPC to update the safety information based on the final results from PASS C18477-ONC-50025 listed as a category 3 study in the RMP; this is an observational Post-Authorisation Long-Term Retrospective Safety Cohort Study of Arsenic Trioxide in First Line Low-to-Intermediate-Risk Acute Promyelocytic Leukaemia (APL) Patients. The updated RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

7.4.4. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/VR/0000282346

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final report for the non-interventional study C4591038, listed as category 3 study in the RMP. This is a Post Conditional approval active surveillance study among individuals in Europe receiving the Pfizer BioNTech Coronavirus Disease 2019 (COVID-19) vaccine. Sub-study to investigate natural history of post-vaccination myocarditis and pericarditis.

Action: For adoption

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

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: A grouped application consisting of:

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

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

Action: For adoption

7.4.6. COVID-19 mRNA vaccine – SPIKEVAX (CAP) – EMA/VR/0000282182

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Submission of final report from study mRNA-1273-P910 listed as category 3 study in the RMP. This is a multi-database observational study that utilized routinely collected secondary data in the European region to investigate the natural course of myocarditis and pericarditis following administration of Moderna vaccines targeting SARS-CoV-2 in terms of morbidity and identified relevant prognostic factors.

Action: For adoption

7.4.7. Herpes zoster vaccine (recombinant, adjuvanted) – SHINGRIX (CAP) – EMA/VR/0000263592

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Sonja Radowan

Scope: Update of sections 4.4 and 4.8 of the SmPC to add "Guillain-Barre syndrome" to the list of adverse drug reactions with frequency "very rare" based on the results from study EPI-ZOSTER-032 VS US DB, listed as a category 3 study in the RMP. This is a non-interventional PASS to evaluate the safety of Shingrix in adults ≥ 65 years of age in the United States. The Package Leaflet is updated accordingly. The RMP version 11.0 has also been submitted.

Action: For adoption

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

Applicant: Sanofi B.V.

PRAC Rapporteur: Zoubida Amimour

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

Action: For adoption

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

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Martin Huber

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

Action: For adoption

7.4.10. Natalizumab – TYSABRI (CAP) – EMA/VR/0000262419

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: A grouped application consisting of:

C.I.4: Update of sections 4.4 and 5.1 of the SmPC in order to update pharmacodynamic information based on final results from study 101MS411, listed as a category 3 study in the RMP; this is an observational study utilising data from the US Tysabri TOUCH programme and select EU MS registries to estimate the risk of progressive multifocal leukoencephalopathy (PML) and other serious opportunistic infections among patients who were exposed to an MS disease modifying treatment prior to treatment with Tysabr. The RMP version 32.2 has also been submitted.

C.I.4: Update of section 5.1 of the SmPC in order to update pharmacodynamic information based on final results from study IMA 06 02 (TOP) listed as a category 3 study in the RMP. This is an observational study to evaluate the long-term safety and impact on disease activity and progression of Tysabri as a single disease-modifying agent in patients with RRMS in a clinical practice setting.

Action: For adoption

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

7.5.1. Blinatumomab – BLINCYTO (CAP) – EMA/PAM/0000287482

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Veronika Macurova

Scope: Submission of the second interim study report for Blincyto (blinatumomab) non-interventional post-authorisation safety study PASS 20180130 (category 1): Evaluation of Long-term Safety in Paediatric Patients With B-precursor Acute Lymphoblastic Leukemia

(ALL) who Have Been Treated with Either Blinatumomab or Chemotherapy, Followed by Transplantation listed within the EU Risk Management Plan.

Action: For adoption

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

Applicant: Janssen Cilag International

PRAC Rapporteur: Jo Robays

Scope: Post-authorization Safety Study Survey to Evaluate the Effectiveness of the Ciltacabtagene Autoleucel HCP Educational Program and the Product Handling Training

Action: For adoption

7.5.3. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/PAM/0000286143

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the 5th Interim CSR for study C4591036; this is a category 3 study to characterize the clinical course, risk factors, long-term sequelae, and quality of life in children and young adults <21 years with acute post-vaccine myocarditis.

Action: For adoption

7.5.4. Givosiran – GIVLAARI (CAP) – EMA/PAM/0000266973

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission within 3 months after PSUSA finalisation all available data, whether these are CIOMS forms, TQ responses or other follow-up information, eCRFs or other documents that may apply on all potential DILI cases up to a DLP of January 31, 2025 as well as the complete assessment of the MAH on these cases as part of a post-authorisation measure.

Action: For adoption

7.5.5. 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

7.5.6. Nirmatrelvir / Ritonavir – PAXLOVID (CAP) – EMA/PAM/0000287758

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: Following the CHMP outcome for Post-Authorisation Measure MEA 008.2 (first Interim Report for PASS C4671037 (analysis to characterise the safety profile of Paxlovid during pregnancy and breastfeeding women)), the company addresses the request to consider the inclusion of additional data sources. Additionally, the company is submitting the revised Interim Report 1 with corrections due to identified data errors in a database.

Action: For adoption

7.5.7. Nirmatrelvir / Ritonavir – PAXLOVID (CAP) – EMA/PAM/0000289516

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: Following the CHMP outcome for Post-Authorisation Measure MEA 009.3, the MAH is hereby submitting the responses to the Request for Supplementary Information to the interim report of study PASS C4671047 to characterise the safety profile of Paxlovid in patients with COVID-19 and moderate or severe hepatic impairment or moderate or severe renal impairment. In addition, the request to consider the inclusion of additional data sources is addressed.

Action: For adoption

7.5.8. Odevixibat – BYLVAY (CAP) – EMA/PAM/0000287652

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: PAM MEA: Second interim study report for the registry-based PASS A4250-019 (Prospective Registry-Based Study of the Long-Term Safety of Odevixibat in Patients with Progressive Familial Intrahepatic Cholestasis (PFIC))

Action: For adoption

7.5.9. Respiratory syncytial virus vaccine (bivalent, recombinant) – ABRYSVO (CAP) – EMA/PAM/0000286222

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Assessment of the first interim report of the PASS category 3 to evaluate the safety of Abrysvo in all pregnant women and their offspring including immunocompromised pregnant women and high-risk pregnancies (C3671026)

Action: For adoption

7.6. New Scientific Advice

7.7. Ongoing Scientific Advice

7.8. 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. Dinutuximab beta – QARZIBA (CAP) – EMA/S/0000282178

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.2. Ebola vaccine (Ad26.ZEBOV-GP [recombinant]) – ZABDENO (CAP) – EMA/S/0000281512

Applicant: Janssen Cilag International

PRAC Rapporteur: Jean-Michel Dogné

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. Ebola vaccine (MVA-BN-Filo [recombinant]) – MVABEA (CAP) – EMA/S/0000281447

Applicant: Janssen Cilag International

PRAC Rapporteur: Jean-Michel Dogné

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.4. Eladocagene exuparvovec – UPSTAZA (CAP) – EMA/S/0000293355

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

8.2.1. Belzutifan – WELIREG (CAP) – EMA/R/0000290222

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Martin Huber

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.2. Etranacogene dezaparvovec – HEMGENIX (CAP) – EMA/R/0000288354

Applicant: CSL Behring GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.3. Exagamglogene autotemcel – CASGEVY (CAP) – EMA/R/0000290395

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.4. Repotrectinib – AUGTYRO (CAP) – EMA/R/0000282425

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.5. Seladelpar lysine dihydrate – LYVDELZI (CAP) – EMA/R/0000290389

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Amelia Cupelli

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.6. Selpercatinib – RETSEVMO (CAP) – EMA/R/0000286890

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Abiraterone acetate – ABIRATERONE KRKA (CAP) – EMA/R/0000284809

Applicant: KRKA tovarna zdravil d.d. Novo mesto

PRAC Rapporteur: Maria del Pilar Rayon

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.2. Berotralstat – ORLADEYO (CAP) – EMA/R/0000282356

Applicant: Biocryst Ireland Limited

PRAC Rapporteur: Julia Pallos

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.3. Fedratinib – INREBIC (CAP) – EMA/R/0000264185

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Sonja Radowan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.4. Lenalidomide – LENALIDOMIDE KRKA (CAP) – EMA/R/0000272358

Applicant: KRKA tovarna zdravil d.d. Novo mesto

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Salmeterol / Fluticasone propionate – SEFFALAIR SPIROMAX (CAP) – EMA/R/0000280812

Applicant: Teva B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. Thiotepa – THIOTEPA RIEMSER (CAP) – EMA/R/0000282361

Applicant: Esteve Pharmaceuticals GmbH

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspections

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

9.3. Others

None

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

10.1. Safety related variations of the marketing authorisation

10.1.1. Voxelotor – OXBRYTA (CAP) - EMEA/H/A-20/1538/C/004869/0014

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jo Robays

Scope: PRAC consultation on a referral procedure under Article 20 of Regulation (EC) No 726/2004 regarding risk minimisation measures to effectively mitigate the risk of vaso-occlusive crises (VOC) in any subset of the authorised patient population for Oxbryta, at request of CHMP

Action: For adoption

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. Acetylsalicylic acid (NAP) - FI/H/xxxx/WS/190

Applicant(s): Bayer Oy (Aspirin, Aspirin Cardio, Aspirin Zipp)

PRAC Lead: Terhi Lehtinen

Scope: PRAC consultation on a worksharing variation procedure (FI/H/xxxx/WS/190) to update the product information to add Kounis syndrome as undesirable effect with a frequency 'not known', at request of Finland

Action: For adoption

11.1.2. Ketoprofen (topical use) (NAP) - SE/H/xxxx/WS/961

Applicant: Sanofi AB (Orudis)

PRAC Lead: Karin Bolin

Scope: PRAC consultation on a worksharing variation procedure (SE/H/xxxx/WS/961) to update the product information of ketoprofen-containing medicinal products (topical use) regarding the risk of death secondary to cardiopulmonary and/or renal toxicity after exposure during pregnancy, at request of Sweden

Action: For adoption

11.1.3. Levonorgestrel (NAP) - SE/H/xxxx/WS/888

Applicant: Bayer (Mirena, Jaydess, Kyleena)

PRAC Lead: Karin Bolin

Scope: PRAC consultation on a worksharing variation procedure (SE/H/xxxx/WS/888) to update the product information of Mirena in order to amend the current warning regarding the risk of breast cancer and to include this information in the product information of Jaydess and Kyleena, at request of Sweden

Action: For adoption

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. 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. PRAC strategic review and learning meeting (SRLM) under the Danish presidency of the European Union (EU) Council – Copenhagen, Denmark, 10 – 12 November 2025 - agenda

PRAC lead: Marie Louise Schougaard Christiansen

Action: For discussion

12.5. Cooperation with International Regulators

None

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

None

12.7. PRAC work plan

None

12.8. Planning and reporting

12.8.1. Marketing authorisation applications (MAA) forecast for 2025 – planning update dated Q2/Q3 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: Peter Mas

Action: For discussion

12.10.3. PSURs repository

None

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

Action: For adoption

12.11. Signal management

12.11.1. Signals and safety analytics project – update on activities

Action: For discussion

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

12.20.1. DARWIN EU impact study to measure the effectiveness of risk minimisation measures implemented for medicines containing nomegestrol or chlormadinone for the risk of meningioma – regulatory follow-up

PRAC lead: Petar Mas

Action: For discussion

12.21. Others

12.21.1. Code of conduct of the European Medicines Agency – provisions for members and experts of scientific committees

Action: For information

12.21.2. Council for International Organizations of Medical Sciences (CIOMS) – Report on severe cutaneous adverse reactions (SCAR)

Action: For information

12.21.3. Good Pharmacovigilance Practice (GVP) Guideline on product or population specific considerations III: pregnancy and breastfeeding

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.21.4. IRIS regulatory procedure management transition - update

Action: For discussion

12.21.5. Serious cutaneous adverse reactions (SCARs) - PRAC guidance update

PRAC Lead(s): Ulla Wändel Liminga, Zane Neikena

Action: For discussion

13. Any other business

None

14. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

List of acronyms and abbreviations

For a list of acronyms and abbreviations used in the PRAC agenda, see:

List of abbreviations used in EMA human medicines scientific committees and CMDh documents, and in relation to EMA's regulatory activities

EU Referral procedures for safety reasons: Urgent EU procedures and Other EU referral procedures
(Items 2 and 3 of the PRAC agenda)
A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the European Union (EU). For further detailed information on safety related referrals please see: Referral procedures: human medicines | European Medicines Agency (europa.eu)

Signals assessment and prioritisation

(Item 4 of the PRAC agenda)
A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have a comprehensive knowledge of a medicine's benefits and risks.
The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.
The evaluation of safety signals may not necessarily conclude that the medicine caused the adverse event in question. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary and this usually takes the form of an update of the summary of product characteristics and the package leaflet.

Risk Management Plans (RMPs)

(Item 5 of the PRAC agenda)
The RMP describes what is known and not known about the side effects of a medicine and states how these risks will be prevented or minimised in patients. It also includes plans for studies and other activities to gain more knowledge about the safety of the medicine and risk factors for developing side effects.
RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available.

Assessment of Periodic Safety Update Reports (PSURs)

(Item 6 of the PRAC agenda)
A PSUR is a report providing an evaluation of the benefit-risk balance of a medicine, which is submitted by marketing authorisation holders at defined time points following a medicine's authorisation.
PSURs summarises data on the benefits and risks of a medicine and includes the results of all studies carried out with this medicine (in the authorised and unauthorised indications).

Post-authorisation Safety Studies (PASS)

(Item 7 of the PRAC agenda)
A PASS is a study of an authorised medicinal product carried out to obtain further information on its safety, or to measure the effectiveness of risk management measures. The results of a PASS help regulatory agencies to evaluate the safety and benefit-risk profile of a medicine.

Product related pharmacovigilance inspections

(Item 9 of the PRAC agenda)
Inspections carried out by regulatory agencies to ensure that marketing authorisation holders comply with their pharmacovigilance obligations.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/