7 July 2025
EMA/PRAC/202278/2025
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 07-10 July 2025

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

07 July 2025, 13:00 – 19:30, room 1C

08 July 2025, 08:30 – 19:30, room 1C

09 July 2025, 08:30 – 19:30, room 1C

10 July 2025, 08:30 – 16:00, room 1C

Organisational, regulatory and methodological matters (ORGAM)

31 July 2025, 09:00 – 12:00, via teleconference

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PRAC plenary session to be held 07–10 July 2025. See July 2025 PRAC minutes (to be published post September 2025 PRAC meeting).

1.2. Agenda of the meeting on 07-10 July 2025

Action: For adoption

1.3. Minutes of the previous meeting on 03-06 July 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

3.3.1. Chikungunya vaccine (live) – IXCHIQ (CAP) – EMA/REF/0000269473

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Gabriele Maurer; PRAC Co-rapporteur: Jean-Michel Dogné

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

Action: For adoption

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. Bosutinib – BOSULIF (CAP); NAP

Applicant: Pfizer Europe MA EEIG (Bosulif), various

PRAC Rapporteur: Martin Huber

Scope: Signal of cutaneous vasculitis

Action: For adoption

EPITT 20184 – New signal

Lead Member State(s): DE

4.1.2. Datopotamab deruxtecan – DATROWAY (CAP)

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Mari Thorn

[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

Scope: Signal of anaphylactic reaction

Action: For adoption

EPITT 20181 – New signal

Lead Member State(s): SE

4.1.3. Sulfasalazine (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of idiopathic intracranial hypertension (Pseudotumor cerebri)

Action: For adoption

EPITT 20188 – New signal

Lead Member State(s): DK

4.1.4. Valproate (NAP) and related substances[3]

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of neurodevelopmental disorders with paternal exposure

Action: For adoption

EPITT 20191 – New signal

Lead Member State(s): NL

4.2. Signals follow-up and prioritisation

4.2.1. Ciltacabtagene autoleucel – CARVYKTI (CAP) - EMEA/H/C/005095/SDA/021; idecabtagene vicleucel – ABECMA (CAP) - EMEA/H/C/004662/SDA/024; tisagenlecleucel - KYMRIAH (CAP) - EMEA/H/C/004090/SDA/026

Applicants: Bristol-Myers Squibb Pharma EEIG (Abecma), Janssen-Cilag International NV (Carvykti), Novartis Europharm Limited (Kymriah), ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Signal of progressive multifocal leukoencephalopathy

Action: For adoption

EPITT 20153 – Follow up to February 2025

4.2.2. Clozapine (NAP)

Applicant(s): various

[3] Valproic acid, sodium valproate, valproate semisodium, valpromide,

PRAC Rapporteur: Amelia Cupelli

Scope: Signal of new aspect of the known risk of neutropenia/agranulocytosis with potential impact on the risk minimisation measures

Action: For adoption

EPITT 20141 – Follow up to January 2025

4.2.3. Varicella vaccine (live) (NAP); measles, mumps, rubella and varicella vaccine (live) – PROQUAD (CAP); (NAP)

Applicant(s): MERCK SHARP & DOHME B.V. (Proquad), various

PRAC Rapporteur: Jean-Michel Dogné

Scope: Signal of new aspect of the known risk of encephalitis

Action: For adoption

EPITT 20180 – New signal

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. Acellular pertussis vaccine (CAP MAA) - EMEA/H/C/006304

Scope (pre D-180 phase): Indicated as active booster immunization against pertussis of persons aged 11 years onwards and passive protection against pertussis in early infancy following maternal immunization during pregnancy

Action: For adoption

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

ATMP

Scope (pre D-120 phase): Treatment of melanoma

Action: For adoption

5.1.3. Brensocatib (CAP MAA) - EMEA/H/C/005820, PRIME

Scope (pre D-120 phase, accelerated assessment): Treatment of non-cystic fibrosis bronchiectasis

Action: For adoption

5.1.4. Clascoterone (CAP MAA) - EMEA/H/C/006138

Scope (re-examination): Indicated for the topical treatment of acne vulgaris in adults and adolescents

Action: For adoption

5.1.5. Clesrovimab (CAP MAA) - EMEA/H/C/006497

Scope (pre D-180 phase): Prevention of infections with respiratory syncytial virus (RSV) and lower respiratory tract disease (LRTD)

Action: For adoption

5.1.6. Denosumab (CAP MAA) - EMEA/H/C/006239

Scope (pre D-180 phase): Prevention of skeletal related events in adults with advanced malignancies involving bone

Action: For adoption

5.1.7. Elinzanetant (CAP MAA) - EMEA/H/C/006298

Scope (pre D-180 phase): For the treatment of moderate to severe vasomotor symptoms (VMS)

Action: For adoption

5.1.8. Enzalutamide (CAP MAA) - EMEA/H/C/006612

Scope (pre D-180 phase): Treatment of prostate cancer

Action: For adoption

5.1.9. Insulin icodec / Semaglutide (CAP MAA) - EMEA/H/C/006279

Scope (pre D-180 phase): Treatment of adults with type 2 diabetes mellitus insufficiently controlled on basal insulin or glucagon-like peptide 1 (GLP-1) receptor agonists

Action: For adoption

5.1.10. Rilzabrutinib (CAP MAA) - EMEA/H/C/006425, Orphan

Applicant: Sanofi B.V.

Scope (pre D-180 phase): For the treatment of persistent or chronic immune thrombocytopenia (ITP)

Action: For adoption

5.1.11. Rivaroxaban (CAP MAA) - EMEA/H/C/006643

Scope (pre D-180 phase): Prevention of atherothrombotic events

Action: For adoption

5.1.12. Teduglutide (CAP MAA) - EMEA/H/C/006564

Scope (pre D-180 phase): Treatment of Short Bowel Syndrome

Action: For adoption

5.1.13. Ustekinumab (CAP MAA) - EMEA/H/C/006794

Scope (pre D-210 phase): Treatment of Crohn's Disease, treatment of plaque psoriasis and paediatric plaque psoriasis, Treatment of Psoriatic arthritis (PsA)

Action: For adoption

5.1.14. Vimseltinib (CAP MAA) - EMEA/H/C/006363, Orphan

Applicant: Deciphera Pharmaceuticals (Netherlands) B.V.

Scope (pre D-210 phase): Treatment of adult patients with tenosynovial giant cell tumour (TGCT) who are not amenable to surgery

Action: For adoption

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

5.2.1. Apixaban – ELIQUIS (CAP) – EMA/VR/0000262422

Applicants: Bristol-Myers Squibb, Pfizer EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Submission of an updated RMP version 22.0 and updated Annex II of the PI in order to discontinue the apixaban Prescriber Guide (PG) and Patient Alert Card (PAC) as an additional risk minimization measure (aRMM) for healthcare professionals (HCPs) and patients. Accordingly, information about PG and PAC is removed from Annexes III of the PI.

Action: For adoption

5.2.2. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/VR/0000262269

Applicant: BioNTech Manufacturing GmbH

PRAC Lead: Liana Martirosyan

Scope: A grouped application consisting of:

C.I.11.b: Submission of an updated RMP version 14.1 in order to revise key objectives, design and study population of study C4591048 according to protocol amendment 6.

C.I.11.b: Submission of an updated RMP version 14.1 in order to propose the removal of the missing information "Use in pregnancy and while breast feeding" from the list of the safety concerns with consequential removal of study C4591022 (US Pregnancy Postmarketing Requirement) study). In addition, the MAH took the opportunity to implement minor administrative changes to the RMP.

Action: For adoption

5.2.3. Darbepoetin alfa – ARANESP (CAP) – EMA/VR/0000267359

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of an updated RMP version 10.0 in order to remove the safety concern and risk minimisation measures regarding the 'Incorrect Use of the Pre-filled Pen Device Associated with Adverse Reactions, Including Underdose and Drug Dose Omission'. The Annex II is updated accordingly.

Action: For adoption

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

Applicant: Sanofi-Aventis Deutschland GmbH

PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

5.2.5. Levetiracetam – LEVETIRACETAM ACCORD (CAP) – EMA/VR/0000268045

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jo Robays

Scope: C.I.11.z - To update Risk Management Plan (v7.0) for Levetiracetam Accord to update safety concerns in line with EPAR for Risk-management-plan of reference product Keppra (Version 10.2, dated 07-Oct-2024) published on 6 January 2025.

Action: For adoption

5.2.6. Odevixibat – BYLVAY (CAP); KAYFANDA (CAP) – EMA/VR/0000268240

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: C.I.11.z - to submit, for both Kayfanda and Bylvay, the consolidated version (version 7.0) of odevixibat's EU RMP combining all the approved changes from EU RMP versions 6.2 and 6.3.

Action: For adoption

5.2.7. Pemetrexed – ARMISARTE (CAP); NAP – EMA/VR/0000246752

Applicant: Actavis Group Ptc ehf.

PRAC Rapporteur: Tiphaine Vaillant

Scope: To update of the Risk Management Plan in order to remove the Important potential risk of 'Medication errors' in line with PRAC PSUR assessment report.

Action: For adoption

5.2.8. Rituximab – RIXATHON (CAP); RIXIMYO (CAP) – EMA/VR/0000249103

Applicant: Sandoz GmbH

PRAC Rapporteur: Karin Erneholm

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

Action: For adoption

5.2.9. Sodium zirconium cyclosilicate – LOKELMA (CAP) – EMA/VR/0000264628

Applicant: AstraZeneca AB

PRAC Rapporteur: Terhi Lehtinen

Scope: Submission of an updated RMP version 3.1 in order to include 'new onset cardiac failure' as an important potential risk.

Action: For adoption

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

5.3.1. Adalimumab - IDACIO (CAP) - EMEA/H/C/004475/II/0024/G

Applicant: Fresenius Kabi Deutschland GmbH

PRAC Rapporteur: Karin Bolin

Scope: Quality

Action: For adoption

5.3.2. 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 nAMD and 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

5.3.3. 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 introduction of 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

5.3.4. Asciminib – SCEMBLIX (CAP) – EMA/X/0000256688

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Eva Jirsová

Scope: Extension application to introduce a new strength (100 mg film-coated tablets) grouped with a type II variation (C.I.6.a) to add a new indication (treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) harbouring the T315I mutation), based on final results from study CABL001X2101 and study CABL001A2004. Study CABL001X2101 is a Phase I, multicenter, open-label, dose escalation FIH study to define the MTD/RDEs, to characterize safety and tolerability, and to assess the PK profile and preliminary evidence of efficacy of asciminib given as single agent or in combination with either nilotinib or imatinib or dasatinib in patients with Ph+ CML or Ph+ ALL.

Study CABL001A2004 assessed the real-world effectiveness of asciminib and treatment patterns in patients with Chronic Myeloid Leukemia with T315I mutation. As a consequence, sections 1, 2, 3, 4, 5, 6 and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

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

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

5.3.6. Baricitinib – OLUMIANT (CAP) – EMA/X/0000257923

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to introduce a new pharmaceutical form (oral suspension) associated with a new strength (2 mg/ml).

Action: For adoption

5.3.7. Budesonide – JORVEZA (CAP) – EMA/X/0000257468

Applicant: Dr. Falk Pharma GmbH

PRAC Rapporteur: Zane Neikena

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (0.2 mg/ml oral suspension). The new presentation is indicated for paediatric patients 2 to 17 years of age.

Action: For adoption

5.3.8. 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

5.3.9. Clopidogrel - CLOPIDOGREL ZENTIVA (CAP) - EMEA/H/C/000975/II/0092

Applicant: Zentiva k.s.

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include, in combination with acetylsalicylic acid (ASA), patients with ST segment elevation acute myocardial infarction (STEMI) who are undergoing percutaneous coronary intervention (PCI) for CLOPIDOGREL ZENTIVA. As a consequence, sections 4.1, 4.2, 4.4 and 5.1 of the SmPC are updated. Version 0.1 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, introduce minor editorial changes to the PI and bring it in line with the latest QRD template version 10.4.

Action: For adoption

5.3.10. COVID-19 mRNA vaccine – SPIKEVAX (CAP) – EMA/VR/0000278795

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Quality

Action: For adoption

5.3.11. Enzalutamide - ENZALUTAMIDE VIATRIS (CAP) - EMEA/H/C/006299/X/0003

Applicant: Viatris Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension application to add a new strength of 160 mg for solution for film-coated tablets. The RMP (version 1.0) is updated in accordance.

Action: For adoption

5.3.12. Florbetaben (18F) – NEURACEQ (CAP) – EMA/VR/0000227744

Applicant: Life Molecular Imaging GmbH

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include monitoring of the biological treatment response to pharmacological and non-pharmacological interventions for NEURACEQ, based on supporting literature. As a consequence, sections 4.1, 4.4 and 5.1 of the SmPC are updated. The Package Leaflet (PL) is updated in accordance. Version 6.91 of the RMP has also been submitted. In addition, the MAH took the opportunity to include the proposal to discontinue the inclusion of a paper copy of the SmPC with the product package.

Action: For adoption

5.3.13. Fosnetupitant / Netupitant / Palonosetron – AKYNZEO (CAP) – EMA/X/0000258060

Applicant: Helsinn Birex Pharmaceuticals Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new pharmaceutical form (300 mg / 0.5 ml oral suspension).

Action: For adoption

5.3.14. Gadopiclenol – ELUCIREM (CAP); VUEWAY (CAP) – EMA/VR/0000249008

Applicants: Bracco Imaging S.p.A., Guerbet

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include treatment of new population (0 to 2 years of age patients) for ELUCIREM / VUEWAY, based on final results from study GDX-44-015; this is a phase ii clinical study concerning gadopiclenol pharmacokinetics, safety and efficacy in pediatric patients < 2 years of age undergoing contrast-enhanced MRI; extension of indication is also supported with the non-clinical data. 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 0.4 of the RMP has also been submitted. In addition, the Marketing

authorisation holder (MAH) took the opportunity to remove Annex IV from the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.15. Ganaxolone - ZTALMY (CAP) - EMEA/H/C/005825/II/0015/G, Orphan

Applicant: Immedica Pharma AB

PRAC Rapporteur: Adam Przybylkowski

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

C.I.13: Submission of the final report from non-clinical study 1022-9241 listed as a category 3 study in the RMP. This is a 26-Week Toxicity Study of Ganaxolone Metabolite, M2, by Oral Gavage in the Sprague-Dawley rat with a 2-Week Recovery Period. The RMP version 3 has also been submitted.
C.I.13: Submission of the final report from non-clinical study 20447815 listed as a category 3 study in the RMP. This is a An Oral (Gavage) Study of the Effects of M2 (Ganaxolone Metabolite) Administration on Embryo/Fetal Development in CD (Sprague Dawley) IGS Rat. The RMP version 3 has also been submitted.
C.I.13: Submission of the final report from Weight of Evidence (WoE) assessment to evaluate the need for a 2-year carcinogenicity study in rats with GNX, listed as a category 3 study in the RMP.
C.I.13: Submission of the final report from WoE assessment to evaluate the need for a 2-year carcinogenicity study in rats with M2, listed as a category 3 study in the RMP.
C.I.13: Submission of the final report from WoE assessment to evaluate the need for a juvenile toxicity study with M2, listed as a category 3 study in the RMP.

Action: For adoption

5.3.16. Ganaxolone – ZTALMY (CAP) – EMA/VR/0000263646

Applicant: Immedica Pharma AB

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application consisting of:

C.I.4: Update of section 5.3 of the SmPC in order to update non-clinical information based on final results from a transgenic mouse carcinogenicity study listed as a category 3 study in the RMP; this is a 26-week Oral Gavage Carcinogenicity Study of Ganaxolone in Hemizygous CByB6F1-Tg(HRAS)2Jic Mice; The RMP version 3.2 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

C.I.4: Update of section 5.3 of the SmPC in order to update non-clinical information based on final results from non-clinical study for juvenile toxicity in M2 (metabolite) listed as a category 3 study in the RMP; this is an Oral (Gavage) administration juvenile toxicity study of M2 (Ganaxolone Metabolite) in CD (Sprague Dawley) IGS Rats.

Action: For adoption

5.3.17. Glucagon – BAQSIMI (CAP) – EMA/VR/0000244909

Applicant: Amphastar France Pharmaceuticals

PRAC Rapporteur: Eamon O Murchu

Scope: Extension of indication to include treatment of severe hypoglycaemia in paediatric patients aged 1 and over with diabetes mellitus for BAQSIMI, based on final results from study I8R-MC-IGBO; this is an Open-Label, Multi-Center, Single-Dose Study to Assess the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of Nasal Glucagon in Paediatric Patients with Type 1 Diabetes Aged 1 to <4 years; 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 1.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce a correction in the Package Leaflet.

Action: For adoption

5.3.18. Herpes zoster vaccine (recombinant, adjuvanted) – SHINGRIX (CAP) – EMA/VR/0000267360

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Sonja Radowan

Scope: Update of section 5.1 of the SmPC to include the final results of study ZOSTER-073, listed as a category 3 study in the RMP. This is a phase IIIB, open label, long term follow-up study to assess persistence of immune responses to GSK's HZ/su vaccine 4-7 years after primary vaccination; and immunogenicity and safety assessment of revaccination with 2 additional doses of HZ/su vaccine, administered 1-2 months apart, 6-8 years after primary vaccination of adults with renal transplant from study ZOSTER-041. The RMP version 12.0 has also been included.

Action: For adoption

5.3.19. Imipenem / Cilastatin / Relebactam – RECARBRIO (CAP) – EMA/VR/0000265089

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to extend the approved adult indications for RECARBRIO to include treatment of paediatric population from birth to <18 years of age, based on final results from two paediatric studies (MK-7655A-021 and MK-7655A-020); phase 2/3 study MK-7655A-021 addressed safety, tolerability, efficacy and PK, and phase 1b study MK-7655A-020 addressed PK, safety, and tolerability of MK-7655A in paediatric subjects from birth to less than 18 years of age with confirmed or suspected gram-negative infections. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and implement minor editorial corrections.

Action: For adoption

5.3.20. Infliximab - REMSIMA (CAP) - EMEA/H/C/002576/X/0149

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension application to introduce a new pharmaceutical form (concentrate for solution for infusion) associated with a new strength (40 mg/ml).

Action: For adoption

5.3.21. Inotuzumab ozogamicin – BESPONSA (CAP) – EMA/VR/0000257310

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include treatment of paediatric patients 1 year and older with relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukaemia (ALL) for BESPONSA, based on final results from studies ITCC-059 (WI203581) and INO-Ped-ALL-1 (WI235086).

Study WI203581 is a Phase 1/2, multicenter, European, multi-cohort, open-label study in pediatric patients (≥1 and <18 years of age) with R/R CD22-positive ALL; Study WI235086 is an open-label, Phase 1 study to assess safety and tolerability of InO in Japanese pediatric patients with R/R CD22-positive AL.

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 4.0 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.

Action: For adoption

5.3.22. Ixekizumab - TALTZ (CAP) - EMEA/H/C/003943/II/0053

Applicant: Eli Lilly and Co (Ireland) Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include treatment of juvenile idiopathic arthritis for TALTZ, based on week 16 results from study I1F-MC-RHCG; this is a multicenter, open-label, efficacy, safety, tolerability, and pharmacokinetic study (COSPIRIT-JIA) of subcutaneous ixekizumab with adalimumab reference arm, in children from 2 to less than 18 years of age with juvenile idiopathic arthritis subtypes of enthesitis-related arthritis (including juvenile-onset ankylosing spondylitis) and juvenile psoriatic arthritis was performed to evaluate the efficacy and safety of ixekizumab for 16 weeks after treatment initiation. 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 8.1 of the RMP has also been submitted. Furthermore, the PI is in line with the latest QRD template version 10.4.

Action: For adoption

5.3.23. Leuprorelin – CAMCEVI (CAP) – EMA/X/0000258054

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to add a new strength of 21 mg for Leuproelin prolonged-release suspension for injection pre-filled syringe, for subcutaneous (SC) administration.

Action: For adoption

5.3.24. Lisocabtagene maraleucel / Lisocabtagene maraleucel – BREYANZI (CAP) – EMA/VR/0000265024

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

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

Type II (C.I.6): Extension of indication to include the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor for BREYANZI, based on results from the pivotal Study 017001 MCL Cohort (TRANSCEND-NHL-001); this is a Phase 1, Multicenter, Open-Label Study of JCAR017, CD19-targeted Chimeric Antigen Receptor (CAR) T Cells, for Relapsed and Refractory (R/R) B-cell Non-Hodgkin Lymphoma (NHL). As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package leaflet is updated in accordance. Version 7.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.25. 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

5.3.26. Lomitapide – LOJUXTA (CAP) – EMA/X/0000258068

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Bianca Mulder

Scope: Extension application to add a new strength of 2 mg hard capsules.

This application is grouped with

- type II variation (C.I.6.a): an Extension of Indication to include treatment of paediatric patients aged 5 years and older with homozygous familial hypercholesterolaemia (HoFH) for LOJUXTA, based on final results from the pivotal paediatric study APH-19; this is a phase 3, single-arm, open-label, international, multi-centre study to evaluate the efficacy and safety of lomitapide in paediatric patients with homozygous familial hypercholesterolaemia (HOFH) on stable lipid-lowering therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Annex II and Package Leaflet are updated accordingly. The RMP version 7.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.

- 3 x type IB variations (C.I.7.b): to delete the 30 mg, 40 mg and 60 mg strengths from the Lojuxta marketing authorisation (EU/1/13/851/004 - 006).

Action: For adoption

5.3.27. Maralixibat - LIVMARLI (CAP) - EMEA/H/C/005857/X/0015, Orphan

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to introduce a new pharmaceutical form (tablet) associated with new strengths 10 mg, 15mg, 20 mg and 30 mg.
The RMP (version 5.0) is updated in accordance.

Action: For adoption

5.3.28. Marstacimab – HYMPAVZI (CAP) – EMA/VR/0000268024

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to add information regarding thromboembolic events and to add "thrombosis" to the list of adverse drug reactions (ADRs) with frequency uncommon based on a review of clinical data, post marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes and corrections to the PI, including Annex II.

Action: For adoption

5.3.29. 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

5.3.30. Mitapivat - PYRUKYND (CAP) - EMEA/H/C/005540/X/0010/G, Orphan

Applicant: Agios Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to introduce a new strength (100 mg film-coated tablet) associated with a new orphan indication for the "treatment of adult patients with non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassaemia". The extension application is grouped with a type II variation (C.I.4) to update of sections 4.2 and 5.2 of the SmPC in order to update pharmacokinetic information based on final results from study AG348-C-024 listed as a category 3 study in the RMP; this is a Phase 1, Open-label, Single-dose, Pharmacokinetic Study of Mitapivat in Subjects with Moderate Hepatic Impairment Compared to Matched Healthy Control Subjects with Normal Hepatic Function. The RMP (version 1.1) is updated in accordance.

Action: For adoption

5.3.31. 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

5.3.32. Pembrolizumab – KEYTRUDA (CAP) – EMA/VR/0000245108

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include, KEYTRUDA as monotherapy, for the treatment of resectable locally advanced head and neck squamous cell carcinoma (HNSCC) as neoadjuvant treatment, continued as adjuvant treatment in combination with radiation therapy with or without platinum-containing chemotherapy and then as monotherapy in adults, based on the results of study P689V01MK3475 (KEYNOTE-689); this is a Phase 3,

randomised, open-label study evaluating pembrolizumab as neoadjuvant therapy and in combination with standard of care as adjuvant therapy for stage III or IVA, resectable, locoregionally advanced head and neck squamous cell carcinoma. Consequently, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 48.1 has also been submitted. In addition, the MAH took the opportunity to introduce some minor editorial changes to the PI.

Action: For adoption

5.3.33. Ponatinib – ICLUSIG (CAP) – EMA/VR/0000263550

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of adult patients with newly-diagnosed Ph+ ALL for ICLUSIG, based on interim results from study Ponatinib-3001 (PhALLCON); this is a phase 3, randomized, open-label, multicenter study comparing ponatinib versus imatinib, administered in combination with reduced intensity chemotherapy, in patients with newly diagnosed Ph+ ALL; supportive data were derived from two single-arm, open-label clinical studies (AP24534 11 001 in combination with chemotherapy and INCB 84344-201 as monotherapy). 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 23.2 of the RMP has also been submitted. In addition, earlier approved updates were incorporated to the PI.

Action: For adoption

5.3.34. Posaconazole – NOXAFIL (CAP) – EMA/VR/0000263360

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Extension of indication for NOXAFIL to include treatment of patients two years of age and older for invasive aspergillosis (IA) based on final results from study MK-5592-104 (P104); this is a Phase 2, open-label, noncomparative clinical study that evaluated the safety, efficacy, and PK of POS in pediatric participants aged 2 to <18 years with IA. 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 18.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the PI.

Action: For adoption

5.3.35. Ranibizumab – RIMMYRAH (CAP) – EMA/VR/0000246182

Applicant: QILU Pharma Spain S.L.

PRAC Rapporteur: Karin Bolin

Scope: Quality

Action: For adoption

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

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

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

Action: For adoption

5.3.37. 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 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

5.3.38. 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

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

Applicant: Atnahs Pharma Netherlands B.V.

PRAC Rapporteur: Julia Pallos

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

Action: For adoption

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

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Monica Martinez Redondo

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

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

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Martin Huber

Scope: Grouped extension of indication application to include treatment of children born small for gestational age (SGA), Noonan syndrome (NS) and idiopathic short stature (ISS)

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

Action: For adoption

5.3.42. 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

5.3.43. 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

5.3.44. Talquetamab – TALVEY (CAP) – EMA/VR/0000264615

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Submission of the interim report from study 64407564MMY1001 listed as a Specific Obligation in the Annex II of the Product Information. This is a phase 1/2, first-in-human, open-label, dose escalation study of talquetamab, a humanized GPRC5D x CD3 bispecific antibody, in subjects with relapsed or refractory multiple myeloma. Safety data were revised based on the 2-year follow-up analysis for the pivotal RP2D population The Annex II and the RMP version 3.2 are updated accordingly.

Action: For adoption

5.3.45. Tasimelteon - HETLIOZ (CAP) - EMEA/H/C/003870/X/0039, Orphan

Applicant: Vanda Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (4 mg/ml oral solution). The new formulation is indicated for the treatment of night time sleep disturbances in Smith-Magenis Syndrome (SMS) in paediatric patients 3 to 15 years of age. The RMP (version 5.0) is updated in accordance.

Action: For adoption

5.3.46. Tezepelumab – TEZSPIRE (CAP) – EMA/VR/0000245013

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include treatment of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) for Tezspire, based on results from study WAYPOINT (D5242C00001); this is a global, multicentre, randomised, double-blind, parallel-group, placebo-controlled study that evaluated the efficacy and safety of tezepelumab compared with placebo in the treatment of CRSwNP. 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 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to update the PI and the Package Leaflet in accordance with the latest EMA excipients guideline.

Action: For adoption

5.3.47. Tezepelumab – TEZSPIRE (CAP) – EMA/VR/0000262075

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Submission of the final report from study D5180C00021 listed as a category 3 study in the RMP. This is a Regional, Multicentre, Randomized, Double-Blind, Placebo Controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Tezepelumab in Adults with Severe Uncontrolled Asthma (DIRECTION). The RMP version 5 has also been submitted.

Action: For adoption

5.3.48. Tislelizumab – TEVIMBRA (CAP) – EMA/VR/0000269879

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: A grouped application consisting of:

C.I.4: Update of sections 4.2, 5.1, 5.2, and 6.6 of the SmPC in order to introduce an alternative dosing regimen of 400 mg every 6 weeks (Q6W) based on POP-PK and exposure-response analyses, and observed clinical data, and update safety information based on data collected in studies BGB-A317-315 and BGB-A317-212 (400 mg Q6W), and study BGB-A317-001; the Package Leaflet is updated accordingly. The RMP version 4.1 has also been submitted.

Action: For adoption

5.3.49. Tislelizumab - TEVIMBRA (CAP) - EMEA/H/C/005919/II/0018

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication for Tevimbra in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, for the treatment of adult patients with resectable NSCLC based on interim results from study BGB-A317-315. Study BGB-A317-315 is a phase 3 randomized, placebo-controlled, double-blind study to compare the efficacy and safety of neoadjuvant treatment with tislelizumab plus platinum-based doublet chemotherapy followed by adjuvant tislelizumab versus neoadjuvant treatment with placebo plus platinum-based doublet chemotherapy followed by adjuvant placebo in patients with resectable Stage II or IIIA NSCLC. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.7 of the RMP has also been submitted.

Action: For adoption

5.3.50. Venetoclax – VENCLYXTO (CAP) – EMA/VR/0000246380

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Update of sections 4.2, 4.9 and 5.2 of the SmPC in order to inform no adjustment is needed in patients with ESRD requiring dialysis and to add information on the pharmacokinetics data for patients with ESRD requiring dialysis, based on final results from study M19-065, "Evaluation of the Pharmacokinetics and Safety of Venetoclax in Subjects with Impaired Renal Function". The RMP version 10.0 has also been submitted.

Action: For adoption

5.3.51. Vonicog alfa – VEYVONDI (CAP) – EMA/VR/0000264863

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of haemorrhage in children aged less than 18 years for VEYVONDI, based on results from studies 071102 and SHP677-304. Study 071102 is a phase 3, prospective, multicenter, uncontrolled, open-label clinical study to determine the efficacy, safety, and tolerability of rVWF with or without ADVATE in the treatment and control of bleeding episodes, the efficacy and safety of rVWF in elective and emergency surgeries, and the pharmacokinetics (PK) of rVWF in children diagnosed with severe VWD; study SHP677-304 is a phase 3B, prospective, open-label, uncontrolled, multicenter study on long term safety and efficacy of vonicog alfa in pediatric and adult subjects with severe VWD.

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 accordingly. Version 6.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI.

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. Adagrasib – KRAZATI (CAP) – EMA/PSUR/0000257790

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00000214/202412)

Action: For adoption

6.1.2. Arpraziquantel - ARPRAZIQUANTEL (Art 58) - EMEA/H/W/004252/PSUV/0004

Applicant: Merck Europe B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUR procedure

Action: For adoption

6.1.3. Atidarsagene autotemcel – LIBMELDY (CAP) – EMA/PSUR/0000257860

Applicant: Orchard Therapeutics (Netherlands) B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010899/202412)

Action: For adoption

6.1.4. Berotralstat – ORLADEYO (CAP) – EMA/PSUR/0000257866

Applicant: Biocryst Ireland Limited

PRAC Rapporteur: Julia Pallos

Scope: Evaluation of a PSUSA procedure (PSUSA/00010930/202412)

Action: For adoption

6.1.5. Bevacizumab gamma – LYTENAVA (CAP) – EMA/PSUR/0000257885

Applicant: Outlook Therapeutics Limited

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00011065/202411)

Action: For adoption

6.1.6. Budesonide – KINPEYGO (CAP) – EMA/PSUR/0000257894

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011007/202412)

Action: For adoption

6.1.7. Buprenorphine – SIXMO (CAP) – EMA/PSUR/0000257873

Applicant: L. Molteni & C. Dei Fratelli Alitti Societa' Di Esercizio S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010778/202411)

Action: For adoption

6.1.8. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/PSUR/0000257861

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010898/202412)

Action: For adoption

6.1.9. COVID-19 mRNA vaccine – SPIKEVAX (CAP) – EMA/PSUR/0000257883

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010897/202412)

Action: For adoption

6.1.10. COVID-19 vaccine (recombinant, adjuvanted) – NUVAXOVID (CAP) – EMA/PSUR/0000257887

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010972/202412)

Action: For adoption

6.1.11. Cabozantinib – CABOMETYX (CAP); COMETRIQ (CAP) – EMA/PSUR/0000257853

Applicant: Ipsen Pharma

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010180/202411)

Action: For adoption

6.1.12. Cefepime / Enmetazobactam – EXBLIFEP (CAP) – EMA/PSUR/0000257800

Applicant: Advanz Pharma Limited

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000305/202412)

Action: For adoption

6.1.13. Dantrolene sodium hemiheptahydrate – AGILUS (CAP) – EMA/PSUR/0000257902

Applicant: Norgine B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011063/202411)

Action: For adoption

6.1.14. Daratumumab – DARZALEX (CAP) – EMA/PSUR/0000257879

Applicant: Janssen Cilag International

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010498/202411)

Action: For adoption

6.1.15. Dopamine hydrochloride – NEOATRICON (CAP) – EMA/PSUR/0000257893

Applicant: BrePco Biopharma Limited

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00011066/202411)

Action: For adoption

6.1.16. Efgartigimod alfa – VYVGART (CAP) – EMA/PSUR/0000257895

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00011014/202412)

Action: For adoption

6.1.17. Elacestrant – ORSERDU (CAP) – EMA/PSUR/0000257797

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000120/202412)

Action: For adoption

6.1.18. Eladocagene exuparvovec – UPSTAZA (CAP) – EMA/PSUR/0000257869

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011004/202412)

Action: For adoption

6.1.19. Elafibranor – IQIRVO (CAP) – EMA/PSUR/0000257878

Applicant: Ipsen Pharma

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00011092/202412)

Action: For adoption

6.1.20. Elotuzumab – EMPLICITI (CAP) – EMA/PSUR/0000257854

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010500/202411)

Action: For adoption

6.1.21. Enfortumab vedotin – PADCEV (CAP) – EMA/PSUR/0000257872

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00010989/202412)

Action: For adoption

6.1.22. Entrectinib – ROZLYTREK (CAP) – EMA/PSUR/0000257876

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010874/202412)

Action: For adoption

6.1.23. Etelcalcetide – PARSABIV (CAP) – EMA/PSUR/0000257856

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010533/202411)

Action: For adoption

6.1.24. Ethinylestradiol / Norelgestromin – EVRA (CAP) – EMA/PSUR/0000257812

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001311/202411)

Action: For adoption

6.1.25. Fidanacogene elaparvovec – BEQVEZ (SRD[4]) – EMA/PSUR/0000257889

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011079/202412)

Action: For discussion

6.1.26. Flortaucipir (^{18}F) – TAUVID (CAP) – EMA/PSUR/0000257881

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011073/202411)

Action: For adoption

6.1.27. Fondaparinux sodium – ARIXTRA (CAP) – EMA/PSUR/0000257813

Applicant: Viatris Healthcare Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00001467/202412)

Action: For adoption

6.1.28. Formoterol / Glycopyrronium bromide / Budesonide – RILTRAVA AEROSPHERE (CAP); TRIXEO AEROSPHERE (CAP) – EMA/PSUR/0000257877

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010908/202412)

Action: For adoption

6.1.29. Inclisiran – LEQVIO (CAP) – EMA/PSUR/0000257862

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010904/202412)

[4] European Commission implementing decision for the withdrawal of Beqvez (fidanacogene elaparvovec), at the holder's request: 15 May 2025

Action: For adoption

6.1.30. Inebilizumab – UPLIZNA (CAP) – EMA/PSUR/0000257868

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010996/202412)

Action: For adoption

6.1.31. Inotuzumab ozogamicin – BESPONSA (CAP) – EMA/PSUR/0000257859

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010659/202412)

Action: For adoption

6.1.32. Iptacopan – FABHALTA (CAP) – EMA/PSUR/0000257901

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure (PSUSA/00011054/202412)

Action: For adoption

6.1.33. Iron – VELPHORO (CAP) – EMA/PSUR/0000257848

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010296/202411)

Action: For adoption

6.1.34. Ketoconazole – KETOCONAZOLE ESTEVE (CAP) – EMA/PSUR/0000257850

Applicant: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010316/202411)

Action: For adoption

6.1.35. Lamivudine - EPIVIR (CAP); Lamivudine / Zidovudine - COMBIVIR (CAP) – EMA/PSUR/0000257847

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00009207/202411)

Action: For adoption

6.1.36. Larotrectinib – VITRAKVI (CAP) – EMA/PSUR/0000257875

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00010799/202411)

Action: For adoption

6.1.37. Levodopa – INBRIJA (CAP) – EMA/PSUR/0000257892

Applicant: Acorda Therapeutics Ireland Limited

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00107800/202412)

Action: For adoption

6.1.38. Maribavir – LIVTENCITY (CAP) – EMA/PSUR/0000257897

Applicant: Takeda Pharmaceuticals International AG

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011024/202411)

Action: For adoption

6.1.39. Mosunetuzumab – LUNSUMIO (CAP) – EMA/PSUR/0000257870

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010999/202412)

Action: For adoption

6.1.40. Nirmatrelvir / Ritonavir – PAXLOVID (CAP) – EMA/PSUR/0000257871

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010984/202412)

Action: For adoption

6.1.41. Octreotide – MYCAPSSA (SRD[5])– EMA/PSUR/0000257899

Applicant: Amryt Pharmaceuticals Designated Activity Company

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00011036/202412)

Action: For adoption

6.1.42. Olaparib – LYNPARZA (CAP) – EMA/PSUR/0000257846

Applicant: AstraZeneca AB

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010322/202412)

Action: For adoption

6.1.43. Pegzilarginase – LOARGYS (CAP) – EMA/PSUR/0000257794

Applicant: Immedica Pharma AB

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000222/202412)

Action: For adoption

6.1.44. Piflufolastat (^{18}F) – PYLCLARI (CAP) – EMA/PSUR/0000257788

Applicant: Curium Pet France

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00000097/202411)

Action: For adoption

6.1.45. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) – PREVENAR 20 (CAP) – EMA/PSUR/0000257867

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010981/202412)

[5] European Commission implementing decision for the withdrawal of Mycapssa (octreotide), at the holder's request: 27 February 2025

Action: For adoption

6.1.46. Quizartinib – VANFLYTA (CAP) – EMA/PSUR/0000257791

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00000176/202412)

Action: For adoption

6.1.47. Ravulizumab – ULTOMIRIS (CAP) – EMA/PSUR/0000257874

Applicant: Alexion Europe

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010787/202412)

Action: For adoption

6.1.48. Respiratory syncytial virus mRNA vaccine (nucleoside modified) – MRESVIA (CAP) – EMA/PSUR/0000257880

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00011075/202411)

Action: For adoption

6.1.49. Respiratory syncytial virus vaccine (bivalent, recombinant) – ABRYSVO (CAP) – EMA/PSUR/0000257789

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000102/202411)

Action: For adoption

6.1.50. Ritlecitinib – LITFULO (CAP) – EMA/PSUR/0000257795

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000133/202412)

Action: For adoption

6.1.51. Roxadustat – EVRENZO (CAP) – EMA/PSUR/0000257864

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Anna Mareková

Scope: Evaluation of a PSUSA procedure (PSUSA/00010955/202412)

Action: For adoption

6.1.52. Rozanolixizumab – RYSTIGGO (CAP) – EMA/PSUR/0000257792

Applicant: UCB Pharma

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00000216/202412)

Action: For adoption

6.1.53. Sapropterin – KUVAN (CAP) – EMA/PSUR/0000257835

Applicant: Biomarin International Limited

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00002683/202412)

Action: For adoption

6.1.54. Setmelanotide – IMCIVREE (CAP) – EMA/PSUR/0000257865

Applicant: Rhythm Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Anna Mareková

Scope: Evaluation of a PSUSA procedure (PSUSA/00010941/202411)

Action: For adoption

6.1.55. Sofosbuvir – SOVALDI (CAP) – EMA/PSUR/0000257852

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010134/202412)

Action: For adoption

6.1.56. Sotorasib – LUMYKRAS (CAP) – EMA/PSUR/0000257886

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010970/202411)

Action: For adoption

6.1.57. Sugemalimab – CEJEMLY (CAP) – EMA/PSUR/0000257890

Applicant: Cstone Pharmaceuticals Ireland Limited

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00011080/202412)

Action: For adoption

6.1.58. Tabelecleucel – EBVALLO (CAP) – EMA/PSUR/0000257898

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00011028/202412)

Action: For adoption

6.1.59. Tenofovir alafenamide – VEMLIDY (CAP) – EMA/PSUR/0000257857

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010575/202411)

Action: For adoption

6.1.60. Tezepelumab – TEZSPIRE (CAP) – EMA/PSUR/0000257896

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00011015/202412)

Action: For adoption

6.1.61. Thyrotropin alfa – THYROGEN (CAP) – EMA/PSUR/0000257839

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00002940/202411)

Action: For adoption

6.1.62. Tirbanibulin – KLISYRI (CAP) – EMA/PSUR/0000257888

Applicant: Almirall S.A.

PRAC Rapporteur: Anna Mareková

Scope: Evaluation of a PSUSA procedure (PSUSA/00010943/202412)

Action: For adoption

6.1.63. Tislelizumab – TEVIMBRA (CAP) – EMA/PSUR/0000257798

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000136/202412)

Action: For adoption

6.1.64. Toripalimab – LOQTORZI (CAP) – EMA/PSUR/0000257891

Applicant: Topalliance Biosciences Europe Limited

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00011094/202412)

Action: For adoption

6.1.65. Tralokinumab – ADTRALZA (CAP) – EMA/PSUR/0000257863

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010937/202412)

Action: For adoption

6.1.66. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/PSUR/0000257882

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010894/202412)

Action: For adoption

6.1.67. Ublituximab – BRIUMVI (CAP) – EMA/PSUR/0000257796

Applicant: Neuraxpharm Pharmaceuticals S.L.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000045/202412)

Action: For adoption

6.1.68. Vadadustat – VAFSEO (CAP) – EMA/PSUR/0000257900

Applicant: Medice Arzneimittel Puetter GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00011050/202412)

Action: For adoption

6.1.69. Venetoclax – VENCLYXTO (CAP) – EMA/PSUR/0000257855

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00010556/202412)

Action: For adoption

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

6.2.1. Azathioprine – JAYEMPI (CAP); NAP – EMA/PSUR/0000257799

Applicants: Lipomed GmbH, various

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000275/202412)

Action: For adoption

6.2.2. Bosentan – STAYVEER (CAP); TRACLEER (CAP); NAP – EMA/PSUR/0000257801

Applicants: Janssen Cilag International, various

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00000425/202411)

Action: For adoption

6.2.3. Levetiracetam – KEPPRA (CAP); NAP – EMA/PSUR/0000257824

Applicants: UCB Pharma, various

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00001846/202411)

Action: For adoption

6.2.4. Sufentanil – DZUVEO (CAP); NAP – EMA/PSUR/0000257838

Applicants: Laboratoire Aguettant, various

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00002798/202411)

Action: For adoption

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

6.3.1. Acetylsalicylic acid / bisoprolol (NAP) – EMA/PSUR/0000257841

Applicant(s): various

PRAC Lead: Anna Mareková

Scope: Evaluation of a PSUSA procedure (PSUSA/00010287/202411)

Action: For adoption

6.3.2. Acetylsalicylic acid/ caffeine/ paracetamol (NAP) – EMA/PSUR/0000257831

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00002291/202412)

Action: For adoption

6.3.3. Acrivastine , acrivastine / pseudoephedrine (NAP) – EMA/PSUR/0000257787

Applicant(s): various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000054/202412)

Action: For adoption

6.3.4. Antazoline / tetryzoline (NAP) – EMA/PSUR/0000257793

Applicant(s): various

PRAC Lead: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00000219/202412)

Action: For adoption

6.3.5. Bisoprolol / hydrochlorothiazide (NAP) – EMA/PSUR/0000257832

Applicant(s): various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00000420/202411)

Action: For adoption

6.3.6. Ceftobiprole (NAP) – EMA/PSUR/0000257858

Applicant(s): various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010734/202411)

Action: For adoption

6.3.7. Chlorphenamine / dextromethorphan hydrobromide / paracetamol (NAP) – EMA/PSUR/0000257817

Applicant(s): various

PRAC Lead: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure (PSUSA/00000699/202411)

Action: For adoption

6.3.8. Cinolazepam (NAP) – EMA/PSUR/0000257808

Applicant(s): various

PRAC Lead: Anna Mareková

Scope: Evaluation of a PSUSA procedure (PSUSA/00000769/202412)

Action: For adoption

6.3.9. Clotrimazole / dexamethasone (NAP) – EMA/PSUR/0000257805

Applicant(s): various

PRAC Lead: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00000830/202411)

Action: For adoption

6.3.10. Clotrimazole / hydrocortisone (NAP) – EMA/PSUR/0000257806

Applicant(s): various

PRAC Lead: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00000831/202411)

Action: For adoption

6.3.11. Clotrimazole / metronidazole (NAP) – EMA/PSUR/0000257815

Applicant(s): various

PRAC Lead: Roxana Dondera

Scope: Evaluation of a PSUSA procedure (PSUSA/00000832/202411)

Action: For adoption

6.3.12. Cyanocobalamin / folic acid / pyridoxine (NAP) – EMA/PSUR/0000257803

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000893/202411)

Action: For adoption

6.3.13. Dermatan sulfate (NAP) – EMA/PSUR/0000257818

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000957/202411)

Action: For adoption

6.3.14. Dextromethorphan / paracetamol / phenylephrine (NAP) – EMA/PSUR/0000257849

Applicant(s): various

PRAC Lead: Anna Mareková

Scope: Evaluation of a PSUSA procedure (PSUSA/00009247/202411)

Action: For adoption

6.3.15. Dextromethorphan hydrobromide / diphenhydramine hydrochloride / levomenthol (NAP) – EMA/PSUR/0000257802

Applicant(s): various

PRAC Lead: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00001013/202411)

Action: For adoption

6.3.16. Dextromethorphan hydrobromide / paracetamol / promethazine hydrochloride (NAP) – EMA/PSUR/0000257833

Applicant(s): various

PRAC Lead: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00002300/202411)

Action: For adoption

6.3.17. Dextromethorphan hydrobromide / pseudoephedrine hydrochloride / triprolidine hydrochloride (NAP) – EMA/PSUR/0000257809

Applicant(s): various

PRAC Lead: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure (PSUSA/00001021/202411)

Action: For adoption

6.3.18. Diamorphine (NAP) – EMA/PSUR/0000257810

Applicant(s): various

PRAC Lead: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00001028/202411)

Action: For adoption

6.3.19. Dihydroxyaluminum sodium carbonate, dihydroxyaluminum sodium carbonate / dimeticone (NAP) – EMA/PSUR/0000257816

Applicant(s): various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00001098/202411)

Action: For adoption

6.3.20. Diphenhydramine / paracetamol (NAP) – EMA/PSUR/0000257807

Applicant(s): various

PRAC Lead: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00001110/202411)

Action: For adoption

6.3.21. Domperidone (NAP) – EMA/PSUR/0000257804

Applicant(s): various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00001158/202411)

Action: For adoption

6.3.22. Drospirenone / estradiol (NAP) – EMA/PSUR/0000257811

Applicant(s): various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001184/202412)

Action: For adoption

6.3.23. Estradiol (17-beta) / progesterone (NAP) – EMA/PSUR/0000257845

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00009145/202412)

Action: For adoption

6.3.24. Human coagulation factor VIII (antihemophilic factor A) (NAP) – EMA/PSUR/0000257822

Applicant(s): various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00001620/202411)

Action: For adoption

6.3.25. Hydromorphone (NAP) – EMA/PSUR/0000257819

Applicant(s): various

PRAC Lead: Polona Golmajer

Scope: Evaluation of a PSUSA procedure (PSUSA/00001686/202411)

Action: For adoption

6.3.26. Ketamine (NAP) – EMA/PSUR/0000257820

Applicant(s): various

PRAC Lead: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00001804/202412)

Action: For adoption

6.3.27. Levamisole hydrochloride (NAP) – EMA/PSUR/0000268962

Applicant(s): various

PRAC Lead: Roxana Dondera

Scope: Evaluation of a PSUSA procedure (PSUSA/00001845/202501)

Action: For discussion

6.3.28. Lornoxicam (NAP) – EMA/PSUR/0000257821

Applicant(s): various

PRAC Lead: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure (PSUSA/00001911/202412)

Action: For adoption

6.3.29. Metamizole sodium / pitofenone hydrochloride (NAP) – EMA/PSUR/0000257834

Applicant(s): various

PRAC Lead: Anna Mareková

Scope: Evaluation of a PSUSA procedure (PSUSA/00002443/202412)

Action: For adoption

6.3.30. Methocarbamol (NAP) - EMA/PSUR/0000257823

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00002011/202412)

Action: For adoption

6.3.31. Methocarbamol / paracetamol (NAP) – EMA/PSUR/0000257826

Applicant(s): various

PRAC Lead: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure (PSUSA/00002013/202412)

Action: For adoption

6.3.32. Metoclopramide (NAP) - EMA/PSUR/0000257825

Applicant(s): various

PRAC Lead: Pernille Harg

Scope: Evaluation of a PSUSA procedure (PSUSA/00002036/202411)

Action: For adoption

6.3.33. Mexazolam (NAP) – EMA/PSUR/0000257830

Applicant(s): various

PRAC Lead: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00002047/202412)

Action: For adoption

6.3.34. Natamycin (NAP) – EMA/PSUR/0000257843

Applicant(s): various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00003179/202411)

Action: For adoption

6.3.35. Neomycin sulfate / nystatin / polymyxin b sulfate (NAP) – EMA/PSUR/0000257827

Applicant(s): various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00002139/202411)

Action: For adoption

6.3.36. Nicotine (NAP) - EMA/PSUR/0000257828

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00002153/202412)

Action: For adoption

6.3.37. Oxygen (NAP) – EMA/PSUR/0000257829

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00002257/202412)

Action: For adoption

6.3.38. Paracetamol / pseudoephedrine hydrochloride / triprolidine hydrochloride (NAP) – EMA/PSUR/0000257840

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010270/202411)

Action: For adoption

6.3.39. Phosphocreatine (NAP) – EMA/PSUR/0000257837

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00002398/202411)

Action: For adoption

6.3.40. Tapentadol (NAP) – EMA/PSUR/0000257836

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00002849/202411)

Action: For adoption

6.3.41. Tibolone (NAP) – EMA/PSUR/0000257844

Applicant(s): various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00002947/202412)

Action: For adoption

6.3.42. Undecylenic acid (NAP) – EMA/PSUR/0000257842

Applicant(s): various

PRAC Lead: Polona Golmajer

Scope: Evaluation of a PSUSA procedure (PSUSA/00003076/202411)

Action: For adoption

6.3.43. Urea hydrogen peroxide (NAP) – EMA/PSUR/0000257851

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00009326/202411)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Dapagliflozin – FORXIGA (CAP) – EMA/PAM/0000278022

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 Drug reaction with eosinophilia and systemic symptoms (DRESS)

Action: For adoption

6.4.2. Dolutegravir – TIVICAY (CAP) – EMA/PAM/0000268716

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Responses to request for supplementary information on PAM/LEG submission for Tivicay, Dovato, Triumeq regarding diabetes and hypertension evaluation.

Action: For adoption

6.4.3. Dolutegravir / Abacavir / Lamivudine - TRIUMEQ (CAP) – EMA/PAM/0000268721

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Responses to request for supplementary information on PAM/LEG submission for Tivicay, Dovato, Triumeq regarding diabetes and hypertension evaluation.

Action: For adoption

6.4.4. Dolutegravir / Lamivudine - DOVATO (CAP) – EMA/PAM/0000268725

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: David Olsen

Scope: Responses to request for supplementary information on PAM/LEG submission for Tivicay, Dovato, Triumeq regarding diabetes and hypertension evaluation.

Action: For adoption

6.5. Variation procedure(s) resulting from PSUSA evaluation

None

6.6. Expedited summary safety reviews[6]

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[7]

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

Applicant: Eisai GmbH

PRAC Rapporteur: Eva Jirsová

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

Action: For adoption

7.1.2. Lisocabtagene maraleucel / Lisocabtagene maraleucel – BREYANZI (CAP) – EMA/PASS/0000269320

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: PASS amendment [107o]: Substantial amendment to a protocol for a non-interventional PASS of patients treated with commercially available liso-cel (lisocabtagene maraleucel) for relapsed/refractory diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma, and follicular lymphoma Grade 3B after 2 or more lines of systemic therapy in the postmarketing setting

Action: For adoption

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

Applicant: Takeda Pharmaceuticals International AG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

[6] 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

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

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

Action: For adoption

7.1.4. Valproate (NAP) and related substances[8] – EMA/PASS/0000272975

Applicant: Sanofi S.r.l. (on behalf of a consortium)

PRAC Rapporteur: Liana Martirosyan

Scope: Valproate PASS protocol (107n): MAH's response to EMEA/H/N/PSP/J/0108.1 [Paternal exposure to valproate, further investigation on the risk of Neuro Developmental Disorders (NDD) and Congenital Malformation (CM) in Offspring: A Non-Interventional Post-Authorization Safety Study (PASS)] as per the RSI adopted in Oct 2024.]

Action: For adoption

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[9]

7.2.1. Cannabidiol - EPIDYOLEX (CAP) – EMA/PAM/0000269446

Applicant: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: PASS GWEP21042: Proposal for change in data collection. A Prospective, Observational Cohort Study to Assess Long-Term Safety in Patients Prescribed Epidyolex with a Focus on Drug-induced Liver Injury (DILI).

Action: For adoption

7.2.2. Efgartigimod alfa – VYVGART (CAP) – EMA/PAM/0000268754

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Revised protocol for PASS: Evaluation of long-term risk of malignancies in patients with myasthenia gravis (MG) treated with efgartigimod compared to MG patients on any other MG therapy and who do not have malignancy history in the lookback period.

Action: For adoption

7.2.3. Exagamglogene autotemcel - CASGEVY (CAP) – EMA/PAM/0000268688

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Bianca Mulder

[8] Valproic acid, sodium valproate, valproate pivoxil, valproate semisodium, valpromide, valproate bismuth, calcium valproate, valproate magnesium
[9] In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

Scope: On 7 April 2025, the MAH submitted responses to the PRAC Rapporteur's requests and an updated study protocol (version 3.0) of study Healthcare Professional Survey (HCP) to Assess the Effectiveness of the Additional Risk Minimization Measures (aRMM) for Casgevy® (exagamglogene autotemcel)

Action: For adoption

7.2.4. Fenfluramine – FINTEPLA (CAP) – EMA/PAM/0000268726

Applicant: UCB Pharma

PRAC Rapporteur: Martin Huber

Scope: PASS EP0219 (former ZX008-2102) protocol: A Drug Utilisation Study of Fenfluramine In Europe (DUS).

Action: For adoption

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

Applicant: CSL Behring GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

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

Action: For adoption

7.2.6. Golimumab – SIMPONI (CAP) – EMA/PAM/0000268768

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Karin Bolin

Scope: PASS No. MK-8259-050: An observational post-approval safety study of golimumab in treatment of poly-articular Juvenile Idiopathic Arthritis (pJIA) using the German Biologics JIA Registry (BiKeR).

Action: For adoption

7.2.7. Lebrikizumab – EBGLYSS (CAP) – EMA/PAM/0000267190

Applicant: Almirall S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Protocol for PASS J2T-MC-B003: an Observational Database Study of Pregnancy and Infant Outcomes among Women Exposed to Lebrikizumab During Pregnancy

Action: For adoption

7.2.8. Linzagolix choline – YSELTY (CAP) – EMA/PAM/0000268672

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Protocol amendment (version 0.6): a multinational PASS on real-world treatment in patients receiving YSELTY (linzagolix choline) for moderate to severe symptoms of uterine fibroids, to evaluate routinely collected data on bone mineral density and to assess safety during long term (>12 months) use for linzagolix 200mg (with ABT) and 100mg (with and without ABT) dosing regimen. This is study DAISY (Bone Mineral Density Appraisal and other Important long-term Safety endpoints of Yselty).

Action: For adoption

7.2.9. Mogamulizumab – POTELIGEO (CAP) – EMA/PAM/0000264422

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Post-authorisation safety study (PASS) of allogeneic haematopoietic cell transplantation in patients treated with mogamulizumab (Poteligeo)".- observational CIBMTR cohort to collect real-world data with the aim to evaluate non-relapse mortality (NRM) and toxicities in patients with cutaneous T-cell lymphoma (CTCL) or adult T-cell leukemia/lymphoma (ATLL) treated with mogamulizumab pre- or post- allogeneic hematopoietic cell transplantation (alloHCT)

Action: For adoption

7.2.10. Nemolizumab - NEMLUVIO (CAP) – EMA/PAM/0000269409

Applicant: Galderma International

PRAC Rapporteur: Liana Martirosyan

Scope: First study protocol for a non-imposed non-interventional PASS to evaluate fetal and infant outcomes following maternal exposure to nemolizumab for treatment of moderate to severe AD or PN during pregnancy.

Action: For adoption

7.2.11. Netarsudil – RHOKIINSA (CAP) – EMA/PAM/0000272898

Applicant: Santen Oy

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of information with supportive rationale and justification with annexes to withdraw the protocol and non-interventional post-authorisation safety study (PASS), Study number STN1013900-SA01 (previously submitted as original PASS Protocol designed by Aerie Pharmaceuticals Ireland Limited: AR-13324-OBS02), for netarsudil mesylate (Rhokiinsa)

Action: For adoption

7.2.12. Rimegepant – VYDURA (CAP) – EMA/PAM/0000267777

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the fourth annual interim report of category 3 PASS C4951006
Responses to RSI raised in the EMEA/H/C/005725/MEA/002.3
An updated study protocol version 7.0

Action: For adoption

7.2.13. Rimegepant – VYDURA (CAP) – EMA/PAM/0000267781

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the fourth annual interim report of category 3 PASS C4951005, including an updated study protocol version 6.0.

Action: For adoption

7.2.14. Ustekinumab – STELARA (CAP) – EMA/PAM/0000264394

Applicant: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Updated Study Protocol (PCSIMM002807, Version 7.0, Amendment 2); SWIBREG - An Observational Postauthorization Safety Study to Describe The Safety of Ustekinumab and Other Biologic Treatments in a Cohort of Patients With Ulcerative Colitis or Crohn's Disease Using Compulsory Swedish Nationwide Healthcare Registers and the Independent Swedish National Quality Register for Inflammatory Bowel Disease. Response to Issues adopted by CHMP on 30 January 2025 for MEA 047.5

Action: For adoption

7.2.15. Ustekinumab – STELARA (CAP) – EMA/PAM/0000264398

Applicant: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Second Progress Report and updated study protocol (Version 6.0, Amendment 2) for An Observational Post-authorization Safety Study to Describe the Safety of Ustekinumab and Other Treatments of Ulcerative Colitis in a Cohort of Patients with Ulcerative Colitis Using the French Nationwide Claims Database (SNDS); Responses to the RSI adopted by the CHMP on 30 January 2025 (MEA 48.5)

Action: For adoption

7.3. Results of PASS imposed in the marketing authorisation(s)[10]

None

7.4. Results of PASS non-imposed in the marketing authorisation(s)[11]

7.4.1. Baricitinib – OLUMIANT (CAP) – EMA/VR/0000266452

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Submission of the final report from the non-interventional Study I4V-MC-B025 listed as a category 3 study in the RMP. This is a rheumatologist and dermatologist survey to assess the effectiveness of the risk minimisation measures (RMM) for Olumiant, a JAK1/2 inhibitor. The RMP version 25.1 has also been submitted. In addition, the MAH took the opportunity to request an extension to the PASS commitment date for non-interventional Study I4V-MC-B038 (B038).

Action: For adoption

7.4.2. Cinacalcet - MIMPARA (CAP) - EMEA/H/C/000570/II/0076

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Mari Thorn

Scope: Submission of the final report from study 20180204 listed as a category 3 study in the RMP. This is a non-interventional observational registry study to evaluate the use and safety of cinacalcet among paediatric patients with secondary hyperparathyroidism (HPT).

Action: For adoption

7.4.3. Conestat alfa – RUCONEST (CAP) – EMA/VR/0000263304

Applicant: Pharming Group N.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Submission of the final report from Ruconest EU registry listed as a category 3 study in the RMP. This is a non-imposed non-interventional PASS (phase IV) of C1 inhibitor Treatment Registry to assess the Safety and Immunological Profile of Ruconest in the treatment of HAE Attacks.

Action: For adoption

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

Applicant: Moderna Biotech Spain S.L.

[10] In accordance with Article 107p-q of Directive 2001/83/EC
[11] 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

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

7.4.5. Elosulfase alfa - VIMIZIM (CAP) – EMA/VR/0000268096

Applicant: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

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

Action: For adoption

7.4.6. Etanercept – BENEPALI (CAP) – EMA/VR/0000263971

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Monica Martinez Redondo

Scope: A grouped application consisting of:

C.I.13: Submission of the final report from study (ARTIS) listed as a category 3 study in the RMP. This is a national prospective, observational, uncontrolled cohort study whose objectives are to evaluate the risk of selected AEs in RA, juvenile idiopathic arthritis, and other rheumatic disease patients treated with etanercept. The RMP version 10.0 has also been submitted.

C.I.13: Submission of the final report from study (BSRBR-RA) listed as a category 3 study in the RMP. This is an established nationwide register for patients with rheumatological disorders treated with biologic agents.

Action: For adoption

7.4.7. Erenumab - AIMOVIG (CAP) – EMA/VR/0000267640

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Terhi Lehtinen

Scope: Submission of the final study report for the non-interventional (NIS) study CAMG334A2023; this is a non-interventional study to examine patient characteristics and drug utilization patterns in migraine patients treated with prophylactic drugs in Nordic countries, listed as a category 3 PASS in the RMP. The RMP version 5.0 has also been submitted.

Action: For adoption

7.4.8. Etanercept - ENBREL (CAP) - EMEA/H/C/000262/II/0255

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Monica Martinez Redondo

Scope: Update of sections 4.2 and 4.4 of the SmPC in order to remove information regarding the Patient Card, based on final results from study B1801309 (BSR Register of Anti-TNF Treated Patients and Prospective Surveillance Study for Adverse Events: Enbrel). This is a non-interventional PASS study listed as a category 3 study in the RMP. The Annex II and Package Leaflet are updated accordingly. The RMP version 7.7 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI as well as to update the list of local representatives in the Package Leaflet and align the PI with the QRD version 10.4.

Action: For adoption of PRAC Assessment Report

7.4.9. 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 study 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

7.4.10. Venetoclax – VENCLYXTO (CAP) – EMA/VR/0000245044

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Submission of the final report from study P22-907 listed as a category 3 PASS in the RMP. This is a non-interventional cross-sectional study evaluating the effectiveness of venetoclax risk minimisation measures among haematologists in Europe.

Action: For adoption

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

7.5.1. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence (CAP) – STRIMVELIS - EMA/PAM/0000264435

Applicant: Fondazione Telethon Ets

PRAC Rapporteur: Liana Martirosyan

Scope: The Marketing Authorisation Holder (MAH), Fondazione Telethon ETS, submitted version 4.0 of the interim study report of study STRIM-003, dated 20 March 2025: Adenosine Deaminase Severe Combined Immunodeficiency (ADA-SCID) Registry for Patients Treated with Strimvelis (or GSK2696273) Gene Therapy: Long-Term Prospective, Non- Interventional Follow-up of Safety and Effectiveness (EUPAS15795). The date of previous version of the interim study report (Version 3.0) was 21 March 2023. The list of milestones continues with 2-yearly interim study reports up to the final clinical study report

Action: For adoption

7.5.2. Brexucabtagene autoleucel – TECARTUS (CAP) – EMA/PAM/0000267756

Applicant: Kite Pharma EU B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Second Annual Interim Safety Report for the Category 1 (ANX) Non-interventional Post Authorisation Efficacy and Safety Study (PAES/PASS) for Tecartus (Study KT-EU-472-6036) for the MCL indication

Action: For adoption

7.5.3. Cabotegravir - VOCABRIA (CAP) – EMA/PAM/0000263322

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: 3rd interim report from the DUS study (study 215161, Cat. 1 study): Drug Utilization, Adherence, Effectiveness and Resistance: A Prospective Observational Cohort Study in People Living with HIV (PLWH) initiating ARV regimen CAB+RPV LA in Collaboration with EuroSIDA

Action: For adoption

7.5.4. Difelikefalin - KAPRUVIA (CAP) - EMA/PAM/0000265268

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: Responses to the CHMP's request for information on three Cat 3 studies raised during assessment of the post-authorisation measures MEA/002.2, MEA/003.2, MEA/004.2

(adopted in January 2025).

This report covers the following post-authorisation commitments undertaken by the MAH:

- CR845-310501 A Two-part, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy and Safety of Oral Difelikefalin as Adjunct Therapy to a Topical Corticosteroid for Moderate-to- Severe Pruritus in Adult Subjects with Atopic Dermatitis (AD).
- CR845-310301 A Multicenter, Randomized, Double-blind, Placebo-controlled 12-Week Study to Evaluate the Safety and Efficacy of Oral Difelikefalin in Advanced Chronic Kidney Disease Subjects with Moderate-to-Severe Pruritus with an up to 52-Week Long-term Extension.
- CR845-310302 A Multicenter, Randomized, Double-blind, Placebo-controlled 12-Week Study to Evaluate the Safety and Efficacy of Oral Difelikefalin in Advanced Chronic Kidney Disease Subjects with Moderate-to-Severe Pruritus with an up to 52-Week Long-term Extension.

Action: For adoption

7.5.5. Inotersen - TEGSEDI (CAP) – EMA/PAM/0000263490

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: The first interim report of 'A prospective, non-interventional, long-term, multinational cohort safety study of patients with hereditary transthyretin amyloidosis with polyneuropathy (hATTR-PN)

Action: For adoption

7.5.6. Rilpivirine - REKAMBYS (CAP) – EMA/PAM/0000263320

Applicant: Janssen Cilag International

PRAC Rapporteur: Liana Martirosyan

Scope: 3rd interim report from the DUS study (study 215161, Cat. 1 study): Drug Utilization, Adherence, Effectiveness and Resistance: A Prospective Observational Cohort Study in People Living with HIV (PLWH) initiating ARV regimen CAB+RPV LA in Collaboration with EuroSIDA

Action: For adoption

7.5.7. Ustekinumab - STELARA (CAP) – EMA/PAM/0000264405

Applicant: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: 7th Annual Report for An Observational Post-authorization Safety Study of Ustekinumab in the Treatment of Pediatric Patients Aged 6 Years and Older With Moderate to Severe Plaque Psoriasis; Protocol No.: CNTO1275PSO4056 (MEA 44.20)

Action: For adoption

7.6. Others

7.6.1. Buprenorphine – SIXMO (CAP)– EMA/PAM/0000268762

Applicant: L. Molteni & C. Dei Fratelli Alitti Societa' Di Esercizio S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: First progress report of an observational cohort study to evaluate the incidence of breakages and insertion/removal complications of buprenorphine implants in routine clinical care in Europe, in adult patients with a diagnosis of opioid dependence (RE-START study - MOLTeNI-2019-01).

Action: For adoption

7.6.2. Nivolumab / Relatlimab - OPDUALAG (CAP) – EMA/PAM/0000263880

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Statistical analysis plan (SAP) for study CA224122, an observational cohort study of adolescent patients (≥ 12 to < 18 years of age) treated with nivolumab + relatlimab FDC for the approved indications in the EU, using secondary data from the DMTR registry.

Action: For adoption

7.6.3. Odevixibat - KAYFANDA (CAP) – EMA/PAM/0000262851

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: PASS CLIN-60240-034: Prospective Registry-Based Study of the Long-Term Safety of Odevixibat in Patients with Alagille syndrome (ALGS).

SOB - Feasibility assessment of a Specific Obligation (PASS in ALGS) -

EMEA/H/C/006462/SOB/001

Action: For adoption

7.6.4. Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) – MOSQUIRIX (CAP) – EMA/PAM/0000268751

Applicant(s): various

PRAC Rapporteur: Jean-Michel Dogné

Scope: Submission of the statistical analysis plan (SAP) for EPI-MAL-003 final analysis. EPI-MAL-003. EPI-MAL-003 is a category 3, prospective surveillance study to evaluate the safety, effectiveness and impact of Mosquirix in infants and young children in Sub-Saharan Africa.

Action: For adoption

7.6.5. Tezepelumab - TEZSPIRE (CAP) – EMA/PAM/0000268702

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Progress report of the post-authorisation safety study on the risk of congenital malformations, adverse pregnancy outcomes, and adverse birth outcomes in pregnancies and offspring of women who received tezepelumab for severe asthma during pregnancy and women who received other SOC treatments for severe asthma during pregnancy.

Action: For adoption

7.6.6. Tezepelumab - TEZSPIRE (CAP) – EMA/PAM/0000268709

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Progress report of the observational multi-country Post-Authorisation Safety Study to evaluate the risk of serious adverse cardiovascular events in adolescent and adult patients with severe asthma taking Tezepelumab (TRESPASS)

Action: For adoption

7.7. New Scientific Advice

7.8. Ongoing Scientific Advice

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

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Chenodeoxycholic acid – CHENODEOXYCHOLIC ACID LEADIANT (CAP) – EMA/S/0000264995

Applicant: Leadiant GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

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

Applicant: Serb

PRAC Rapporteur: Martin Huber

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. Idursulfase – ELAPRASE (CAP) – EMA/S/0000263922

Applicant: Takeda Pharmaceuticals International AG

PRAC Rapporteur: Liana Martirosyan

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.4. Maralixibat - LIVMARLI (CAP) - EMEA/H/C/005857/S/0019

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.5. Pegzilarginase – LOARGYS (CAP) – EMA/S/0000247405

Applicant: Immedica Pharma AB

PRAC Rapporteur: Martin Huber

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

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

Applicant: Siga Technologies Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.7. Velmanase alfa – LAMZEDE (CAP) – EMA/S/0000257415

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.8. Zanamivir – DECTOVA (CAP) – EMA/S/0000265004

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Karin Bolin

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

8.2.1. Elranatamab – ELREXFIO (CAP) – EMA/R/0000269600

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.2. Pirtobrutinib – JAYPIRCA (CAP) – EMA/R/0000264598

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.3. Tafasitamab – MINJUVI (CAP) – EMA/R/0000256675

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

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

Applicant: Biomarin International Limited

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Baloxavir marboxil – XOFLUZA (CAP) – EMA/R/0000265299

Applicant: Roche Registration GmbH

PRAC Rapporteur: Sonja Radowan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.2. Defatted powder of Arachis hypogaea L., semen (peanuts) – PALFORZIA (CAP) – EMA/R/0000264359

Applicant: Stallergenes

PRAC Rapporteur: Terhi Lehtinen

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. Fostemsavir – RUKOBIA (CAP) – EMA/R/0000264656

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Lumacaftor / Ivacaftor – ORKAMBI (CAP) – EMA/R/0000249341

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Eamon O Murchu

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. Pertuzumab / Trastuzumab – PHESGO (CAP) – EMA/R/0000258704

Applicant: Roche Registration GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.7. RECOMBINANT VESICULAR STOMATITIS VIRUS (STRAIN INDIANA) WITH A DELETION OF THE ENVELOPE GLYCOPROTEIN, REPLACED WITH THE ZAIRE EBOLAVIRUS (STRAIN KIKWIT-1995) SURFACE GLYCOPROTEIN – ERVEBO (CAP) – EMA/R/0000265014

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.8. Tagraxofusp – ELZONRIS (CAP) – EMA/R/0000261300

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.9. Tucatinib – TUKYSA (CAP) – EMA/R/0000262094

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

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

None

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

None

10.3. Other requests

None

10.4. Scientific Advice

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

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

11.1. Safety related variations of the marketing authorisation

11.1.1. Buprenorphine (NAP) - DK/H/1986/001-003/II/032; DK/H/0718/001007/II/060

Applicant(s): Mundipharma A/S (BuTrans, Norspan)

PRAC Lead: Karin Erneholm

Scope: PRAC consultation on variation procedures regarding an update of the product information to reflect the drug-drug interaction between buprenorphine and nalmefene, on request of Denmark

Action: For adoption

11.1.2. Carbamazepine (NAP) - DE/H/xxxx/WS/1925

Applicant(s): Novartis Pharma GmbH (Tegretal, Tegretol)

PRAC Lead: Martin Huber

Scope: PRAC consultation on a worksharing procedure regarding the update of the product information to reflect the risks for congenital malformations, microcephaly, and infants being small for gestational age (SGA) associated with *in utero* exposure to carbamazepine, on request of Germany

Action: For adoption

11.1.3. Modafinil (NAP) - DE/H/3259/001-002/II/042

Applicant(s): Teva GmbH (Vigil)

PRAC Lead: Martin Huber

Scope: PRAC consultation on a variation procedure regarding the update of the product information and the RMP based on the final results of the PASS: Assessment of Pregnancy Outcomes in Women Exposed to Modafinil/Armodafinil: Pregnancy Database Study (C10953-CNS-40155) and of the US Nuvigil and Provigil pregnancy registry, on request of Germany

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. Scientific Committee Meetings – face to face schedule for 2026

Action: For information

12.1.3. Vote by proxy

Action: For information

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

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

None

12.4. Cooperation within the EU regulatory network

None

12.5. Cooperation with International Regulators

12.5.1. International Conference on Harmonisation (ICH) – Additional values for E2B codelists

Action: For adoption

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

Action: For adoption

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

None

12.7. PRAC work plan

None

12.8. Planning and reporting

None

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

PRAC lead: Jana Lukačišinová

Action: For discussion

12.10.3. PSURs repository

None

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

Action: For adoption

12.11. Signal management

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

PRAC lead: Martin Huber

Action: For discussion

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Specific adverse drug reaction (ADR) follow-up questionnaire (FUQ) drafting group – update on the activities

PRAC lead: Tiphaine Vaillant

Action: For discussion

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

None

12.21. Others

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

PRAC lead: Ulla Wändel Liminga

Action: For discussion

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

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.21.3. Real world study to evaluate the safety of aliskiren by assessing the risk of cardiac events in patients with resistant hypertension DARWIN EU® - PRAC Sponsor's critical appraisal

PRAC lead: Amelia Cupelli

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/