01 September 2025
EMA/PRAC /234907/2025
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 01-04 September 2025

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

01 September 2025, 10:30 – 19:30, via teleconference

02 September 2025, 08:30 – 19:30, via teleconference

03 September 2025, 08:30 – 19:30, via teleconference

04 September 2025, 08:30 – 16:00, via teleconference

Organisational, regulatory and methodological matters (ORGAM)

18 September 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 01-04 September 2025. See September 2025 PRAC minutes (to be published post October 2025 PRAC meeting).

1.2. Agenda of the meeting on 01-04 September 2025

Action: For adoption

1.3. Minutes of the previous meeting on 07-10 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

3.1.1. Levamisole (NAP) – EMA/REF/0000293746

Applicant(s): various

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

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

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

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination procedures[1]

None

3.5. Others

None

4. Signals assessment and prioritisation[2]

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

4.1.1. Amlodipine (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of subacute cutaneous lupus erythematosus

Action: For adoption

EPITT 20203 – New signal

Lead Member State: DK

4.1.2. Cefazolin (NAP); cefazolin, lidocaine hydrochloride (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

[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 Kounis syndrome

Action: For adoption

EPITT 20204 – New signal

Lead Member State: AT

4.1.3. Erdafitinib - BALVERSA (CAP)

Applicant: Janssen Cilag International

PRAC Rapporteur: Bianca Mulder

Scope: Signal of growth accelerated

Action: For adoption

EPITT 20194 – New signal

Lead Member State: NL

4.1.4. Folic acid (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of increased risk of cancer with high-dose folic acid (⩾1mg)

Action: For adoption

EPITT 20183 – New signal

Lead Member State: DK

4.1.5. Galantamine (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of nightmares

Action: For adoption

EPITT 20196 – New signal

Lead Member State: SE

4.1.6. Mepolizumab – NUCALA (CAP)

Applicant: GlaxoSmithKline Trading Services

PRAC Rapporteur: Gabriele Maurer

Scope: Signal of alopecia

Action: For adoption

EPITT 20197 – New signal

Lead Member State: DE

4.1.7. Pegylated liposomal doxorubicin – CAELYX PEGYLATED LIPOSOMAL (CAP); CELDOXOME PEGYLATED LIPOSOMAL (CAP); ZOLSKETIL PEGYLATED LIPOSOMAL (CAP); NAP

Applicants: Accord Healthcare S.L.U. (Zolsketil pegylated liposomal), Baxter Holding B.V. (Caelyx pegylated liposomal, Celdoxome pegylated liposomal), various

PRAC Rapporteur: To be appointed

Scope: Signal of renal-limited thrombotic microangiopathy

Action: For adoption

EPITT 20193 – New signal

Lead Member State: CZ

4.1.8. Pemetrexed – ALIMTA (CAP); ARMISARTE (CAP); PEMETREXED ACCORD (CAP); PEMETREXED FRESENUIS KABI (CAP); PEMETREXED MEDAC (CAP); PEMETREXED PFIZER (CAP); NAP

Applicants: Accord Healthcare S.L.U. (Pemetrexed accord), Actavis Group Ptc ehf. (Armisarte), Eli Lilly Nederland B.V. (Alimta), Fresenius Kabi Deutschland GmbH (Pemetrexed fresenuis kabi), Medac Gesellschaft für klinische Spezialpräparate mbH (Pemetrexed medac), Pfizer Europe MA EEIG (Pemetrexed pfizer), various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Signal of lupus erythematosus

Action: For adoption

EPITT 20185 – New signal

Lead Member State: FR

4.1.9. Risankizumab – SKYRIZI (CAP)

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Signal of pemphigoid

Action: For adoption

EPITT 20192 – New signal

Lead Member State: NL

4.2. Signals follow-up and prioritisation

4.2.1. Binimetinib – MEKTOVI (CAP) - EMEA/H/C/004579/SDA/007; cobimetinib – COTELLIC (CAP) - EMEA/H/C/003960/SDA/007; dabrafenib – TAFINLAR (CAP) - EMEA/H/C/002604/SDA/025, FINLEE (CAP) - EMEA/H/C/005885/SDA/004;

encorafenib – BRAFTOVI (CAP) - EMEA/H/C/004580/SDA/007; trametinib – MEKINIST (CAP) - EMEA/H/C/002643/SDA/020, SPEXOTRAS (CAP) - EMEA/H/C/005886/SDA/003; vemurafenib – ZELBORAF (CAP) - EMEA/H/C/002409/SDA/040

Applicants: Novartis Europharm Limited (Finlee, Mekinist, Spexotras, Tafinlar), Pierre Fabre Medicament (Braftovi, Mektovi), Roche Registration GmbH (Cotellic, Zelboraf)

PRAC Rapporteur: Mari Thorn

Scope: Signal of tattoo associated skin reaction

Action: For adoption

EPITT 20160 – Follow-up to March 2025

4.2.2. Dabigatran etexilate - DABIGATRAN ETEXILATE ACCORD (CAP); DABIGATRAN ETEXILATE TEVA (CAP); PRADAXA (CAP) - EMEA/H/C/000829/SDA/055; NAP

Applicant(s): Boehringer Ingelheim International GmbH, various

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Signal of splenic rupture

Action: For adoption

EPITT 20164 – Follow-up to May 2025

4.2.3. Diazoxide (NAP)

Applicant(s): various

PRAC Rapporteur: Amelia Cupelli

Scope: Signal of necrotising enterocolitis neonatal

Action: For adoption

EPITT 20163 – Follow-up to April 2025

4.2.4. Dinutuximab beta - QARZIBA (CAP) - EMEA/H/C/003918/SDA/010

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Signal of atypical haemolytic uraemic syndrome

Action: For adoption of PRAC recommendation

EPITT 20169 – Follow-up to May 2025

4.2.5. Osimertinib - TAGRISSO (CAP) - EMEA/H/C/004124/SDA/009

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Signal of hepatitis B reactivation

Action: For adoption of PRAC recommendation

EPITT 20172 – Follow-up to May 2025

4.2.6. Somatrogon - NGENLA (CAP) - EMEA/H/C/005633/SDA/005

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Signal of lipoatrophy

Action: For adoption of PRAC recommendation

EPITT 20173 – Follow-up to May 2025

4.3. Variation procedure(s) resulting from signal evaluation

4.3.1. Leflunomide – ARAVA (CAP) – EMA/VR/0000279486

Applicant: Sanofi-Aventis Deutschland GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: To update section 4.8 of the SmPC and section 4 of the PL to implement the signal recommendations on pulmonary nodule (EPITT no 20155) adopted at the 13 March 2025 PRAC meeting. In addition, the MAH took the opportunity to update the EU local representatives.

Action: For adoption

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human Wiskott-Aldrich syndrome protein - (CAP MAA) - EMEA/H/C/006525, Orphan

Applicant: Fondazione Telethon Ets, ATMP

Scope (pre D-180 phase): Treatment of patients with Wiskott-Aldrich Syndrome (WAS)

Action: For adoption

5.1.2. Blarcamesine - (CAP MAA) - EMEA/H/C/006475

Scope (pre D-180 phase): Treatment of Alzheimer’s disease and dementia

Action: For adoption

5.1.3. Denosumab - (CAP MAA) - EMEA/H/C/006492

Scope (pre D-180 phase): Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, treatment of bone loss associated with hormone ablation in men with prostate cancer and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients

Action: For adoption

5.1.4. Denosumab - (CAP MAA) - EMEA/H/C/006797

Scope: Treatment of osteoporosis and bone loss

Action: For adoption

5.1.5. Donidalorsen - (CAP MAA) - EMEA/H/C/006554, Orphan

Applicant: Otsuka Pharmaceutical Netherlands B.V.

Scope (pre D-180 phase): For routine prevention of recurrent attacks of hereditary angioedema (HAE)

Action: For adoption

5.1.6. Doxecitine / Doxribtimine - (CAP MAA) - EMEA/H/C/005119, PRIME, Orphan

Applicant: UCB Pharma

Scope (pre D-180 phase): Indicated for the treatment of paediatric and adult patients with thymidine kinase 2 deficiency (TK2d) with an age of symptom onset on or before 12 years

Action: For adoption

5.1.7. Germanium (68Ge) chloride / Gallium (68Ga) chloride - (CAP MAA) - EMEA/H/C/006639

Scope (pre D-180 phase): Indicated for in vitro radiolabelling of specific carrier molecules to be used for positron emission tomography (PET) imaging

Action: For adoption

5.1.8. Iloperidone - (CAP MAA) - EMEA/H/C/006561

Scope (pre D-180 phase): Treatment of schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder

Action: For adoption

5.1.9. Imlunestrant - (CAP MAA) - EMEA/H/C/006184

Scope (pre D-180 phase): Treatment of adult patients with advanced or metastatic breast cancer

Action: For adoption

5.1.10. Insulin glargine - (CAP MAA) - EMEA/H/C/006136

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

Action: For adoption

5.1.11. COVID-19 mRNA vaccine - (CAP MAA) - EMEA/H/C/006428

Scope (pre D-180 phase): Active immunisation to prevent COVID 19 caused by SARS-CoV-2 in individuals 12 years of age and older.

Action: For adoption

5.1.12. Onasemnogene abeparvovec - (CAP MAA) - EMEA/H/C/006498, Orphan

Applicant: Novartis Europharm Limited, ATMP

Scope (pre D-120 phase): Treatment of 5q spinal muscular atrophy (SMA)

Action: For adoption

5.1.13. Teplizumab - (CAP MAA) - EMEA/H/C/005496, PRIME

Scope (pre D-180 phase): To delay both the onset of Stage 3 type 1 diabetes (T1D) and the progression of Stage 3 T1D

Action: For adoption

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

5.2.1. Aripiprazole - ARIPIPRAZOLE SANDOZ (CAP) - EMA/VR/0000272677; NAP

Applicant(s): Sandoz GmbH, various

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: To update the RMP in line with the reference product of Aripiprazole Sandoz. In addition, the MAH has taken the opportunity to include the 20 mg tablets to the RMP in line with the approved SmPC and to reflect the change in MAH.

Action: For adoption

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

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Submission of an updated RMP version 4.3 for Tecartus and version 11.1 for Yescarta following the PRAC recommendation for the Secondary malignancy of T-cell origin

signal (EPITT no: 20040), and of a PASS protocol for a framework for the sampling and testing of secondary malignancies of T-cell origin.

Action: For adoption

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. Denosumab – XGEVA (CAP) – EMA/VR/0000272344

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Mari Thorn

Scope: Submission of an updated RMP version 37.0 in order to modify and update the list of safety concerns based on previously completed post-authorization safety studies, including registry study 20101102 and the long-term safety follow-up study 20140114.

Action: For adoption

5.2.5. Dolutegravir – TIVICAY (CAP); Dolutegravir / Abacavir / Lamivudine - TRIUMEQ (CAP); Dolutegravir / Lamivudine - DOVATO (CAP); Dolutegravir / Rilpivirine – JULUCA (CAP) - EMA/VR/0000278110

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: To update the RMP with the latest available post-authorisation exposure data and to include the 2024 Antiretroviral Pregnancy Registry data. To update the submission date for the final CSR for category 3 PASS study DOLOMITE-NEAT ID (208759) from 30 September 2025 to 30 September 2026 for Tivicay, Triumeq and Juluca.

Action: For adoption

5.2.6. Emtricitabine / Tenofovir disoproxil – TRUVADA (CAP) – EMA/VR/0000280828

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: A grouped application consisting of:

C.I.11: Submission of an updated RMP version 19.1 in order to remove targeted questionnaires (related to TDF) concerning (1) Renal events including tubulopathy, and (2) Bone events due to proximal renal tubulopathy/loss of BMD.

C.I.11: Submission of an updated RMP version 19.1 in order to remove missing information concerning Safety in pregnancy and lactation (related to TDF), and consequently remove 'Antiretroviral Pregnancy Registry' listed as a Category 3 Additional Pharmacovigilance Activity.

Action: For adoption

5.2.7. Fezolinetant – VEOZA (CAP) – EMA/VR/0000255134

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Martin Huber

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

Action: For adoption

5.2.8. Fingolimod – FINGOLIMOD MYLAN (CAP) - EMA/VR/0000280709; NAP

Applicant(s): Mylan Pharmaceuticals Limited, various

PRAC Rapporteur: Tiphaine Vaillant

Scope: C.I.11.z - to implement changes to the Risk Management Plans for Fingolimod Mylan and Mulfiyna, following relevant updates to the Risk Management Plan of the innovator product Gilenya (Novartis Europharm Limited, EMEA/H/C/002202).

Action: For adoption

5.2.9. Idursulfase – ELAPRASE (CAP) – EMA/VR/0000279282

Applicant: Takeda Pharmaceuticals International AG

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of an updated RMP version 5.2 in order to reflect the completion of the Hunter Outcome Survey (HOS) study following procedure EMEA/H/C/PSUSA/00001722/202407; update the exposure data with information from the ongoing study SHP-ELA-401; include template updates; remove all safety concerns, including missing information, in alignment with GVP Module V, Revision 2.

Action: For adoption

5.2.10. Pegfilgrastim – NEULASTA (CAP) – EMA/VR/0000274974

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Submission of an updated RMP version 11.0 in order to remove of Sickle cell crisis in patients with sickle cell disease and Glomerulonephritis as important identified risks.

Action: For adoption

5.2.11. Pregabalin – PREGABALIN SANDOZ (CAP) – EMA/VR/0000273334; NAP

Applicant(s): Hexal AG, various

PRAC Rapporteur: Liana Martirosyan

Scope: To align the RMP to the currently approved RMP of the reference product, e.g. removing the important identified risk of "Abuse and drug dependence".

Action: For adoption

5.2.12. Romiplostim – NPLATE (CAP) – EMA/VR/0000276333

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Monica Martinez Redondo

Scope: Update of section 4.8 of the SmPC in order to remove language regarding the testing for suspected neutralizing antibodies (Immunogenicity) following RMP update in EMEA/H/C/000942/II/0091.

Action: For adoption

5.2.13. Tenofovir disoproxil – VIREAD (CAP) – EMA/VR/0000280825

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Zoubida Amimour

Scope: Submission of an updated RMP version 26.2 in order to remove missing information concerning Safety in pregnancy and lactation, to remove 'Antiretroviral Pregnancy Registry' listed as a Category 3 Additional Pharmacovigilance Activity, and to implement PRAC agreed changes during procedure EMEA/H/C/PSUSA/00002892/202303 in relation to safety concerns associated with renal and bone adverse events.

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

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

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

Action: For adoption

5.3.3. Aflibercept – AHZANTIVE (CAP); BAIAMA (CAP) – EMA/VR/0000255900

Applicant: Formycon AG

PRAC Rapporteur: Zoubida Amimour

Scope: Quality

Action: For adoption

5.3.4. Aflibercept – OPUVIZ (CAP) – EMA/VR/0000280586

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Quality

ction: For adoption

5.3.5. Amivantamab – RYBREVANT (CAP) – EMA/X/0000268898

Applicant: Janssen Cilag International

PRAC Rapporteur: Gabriele Maurer

Scope: Extension application to add a new strength of 2400 mg and 3520 mg (solution for injection) grouped with the following variations:

C.I.4: Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 6.6 in order to include the Q3W dosing regimen based on data from relevant cohorts from the Phase 2 bridging study PALOMA-2 (NSC2002) and supported by data from the Phase 1 PALOMA study (NSC1003). The Package Leaflet and Labelling are updated accordingly. The RMP version 7.1 has also been submitted.

C.I.4: Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 6.6 in order to introduce a new Q4W dosing regimen based on data from the PALOMA-2 study (NSC2002) and supported by data from the Phase 1 PALOMA study (NSC1003). The Package Leaflet and Labelling are updated accordingly. The RMP version 7.1 has also been submitted.

Action: For adoption

5.3.6. Anakinra – KINERET (CAP) – EMA/VR/0000249038

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Karin Erneholm

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

Action: For adoption

5.3.7. Asciminib – SCEMBLIX (CAP) – EMA/VR/0000280241

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Eva Jirsová

Scope: Submission of the final report from study CABL001A2301 listed as a category 3 study in the RMP; this is a phase 3, multicenter, open-label, randomized study of oral asciminib vs bosutinib in patients with CML-CP previously treated with two or more tyrosine kinase inhibitors. The RMP version 5.0 has also been submitted.

Action: For adoption

5.3.8. Avapritinib – AYVAKYT (CAP) – EMA/VR/0000275571

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with CYP3A substrates based on the final results from study BLU-285-1107 listed as a category 3 study in the RMP. This is a drug-drug interaction study to investigate the effect of 300 mg once daily avapritinib on the pharmacokinetics (PK) of midazolam in patients with unresectable or metastatic Gastrointestinal Stromal Tumors (GIST) and other Advanced Solid Tumors. The MAH also updated PBPK model to extend the clinical findings of Study BLU-285-1107 and simulate the effects of lower doses of avapritinib on the pharmacokinetics of midazolam and its metabolite. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet to bring the PI in line with the latest QRD template version 10.4. The RMP version 5.0 has also been submitted.

Action: For adoption

5.3.9. Avelumab – BAVENCIO (CAP) – EMA/VR/0000261861

Applicant: Merck Europe B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add "Gastritis" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on postmarketing data and literature. The Package Leaflet is updated accordingly. The RMP version 9.1 has also been submitted.

Action: For adoption

5.3.10. Berotralstat – ORLADEYO (CAP) – EMA/X/0000268892

Applicant: Biocryst Ireland Limited

PRAC Rapporteur: Julia Pallos

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

Action: For adoption

5.3.11. Budesonide / Formoterol - BIRESP SPIROMAX (CAP) – EMEA/H/C/WS2806/G; Budesonide / Formoterol - DUORESP SPIROMAX (CAP) - EMEA/H/C/WS2806/G

Applicant: Teva Pharma B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: A grouped application consisting of:
C.I.6: Extension of the asthma indication to include the anti-inflammatory reliever (AIR) use for DuoResp Spiromax and BiResp Spiromax, based on the latest GINA report, the European Respiratory Society guidelines, and literature data. In addition, the Applicant referred to changes made for Symbicort (UK). As a consequence, sections 4.1, 4.2, 4.4, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI introduced editorial changes, and is brought in line with the latest QRD template version. The RMP version 4.0 has also been submitted.
C.I.2.a: To update sections 4.5, and 5.1 of the SmPC following assessment of the same change for the reference product Symbicort Turbohaler (SE/H/0229/001- 002) and also Symbicort (UK).

Action: For adoption

5.3.12. Burosumab – CRYSVITA (CAP) – EMA/VR/0000261369

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: A grouped application consisting of:

C.I.4: Update of sections 4.4, 4.5, and 4.8 of the SmPC in order to update safety information about Severe Hypercalcaemia in patients with Tertiary Hyperparathyroidism based on data from clinical trials and post-authorisation data sources; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted. In addition, the MAH took the opportunity (1) to improve the existing guidance in section 4.2 based on the accumulated clinical experience, (2) to introduce editorial changes to the PI, (3) to bring the PI in line with the latest QRD template, current guidelines, and PEI requests.

C.I.4: Update of section 4.8 of the SmPC in order to add urticaria to the list of adverse drug reactions (ADRs) with frequency common based on data from clinical trials and post-authorisation data sources; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted.

Action: For adoption

5.3.13. Dabrafenib – TAFINLAR (CAP); Trametinib - MEKINIST (CAP) – EMA/VR/0000271728

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of unresectable or metastatic melanoma with a BRAF V600 mutation and adjuvant treatment of Stage III melanoma with a BRAF V600 mutation for adolescents aged 12 years and older for TAFINLAR and MEKINIST, based on an extrapolation report using a modelling and simulation approach to demonstrate PK, PD and efficacy of dabrafenib and trametinib in adolescent patients. 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. RMP versions 13.0 and 21.0 for Tafinlar and Mekinist, respectively, have also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and to update list of local representatives in the Package Leaflet.

Action: For adoption

5.3.14. Darunavir / Cobicistat – REZOLSTA (CAP) – EMA/X/0000268372

Applicant: Janssen Cilag International

PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (600 mg darunavir/90 mg cobicistat dispersible tablet). The new presentation is indicated to include treatment for paediatric patients aged ≥ 3 years and older weighing at least 15 kg and less than 25 kg. The extension application is grouped with a type II clinical variation (C.I.4) to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 in order to add efficacy and PK data in children based on final results from study GS-US-215-0128; this is a Phase 2/3, Multicentre, Open-label, Multicohort Study Evaluating Pharmacokinetics (PK), Safety, and Efficacy of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 Infected, Virologically Suppressed Paediatric Participants. The Package Leaflet and Labelling are updated in accordance. Version 7.2 of the RMP has also been submitted.

Action: For adoption

5.3.15. Dengue tetravalent vaccine (live, attenuated) - – DENGUE TETRAVALENT VACCINE (LIVE, ATTENUATED) TAKEDA (CAP); QDENGA (CAP) – EMA/VR/0000266281

Applicant: Takeda GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

C.I.13: Submission of the interim report from study DEN-301 Part 4 listed as a category 3 study in the RMP, and addressing PAM [MEA] and PAM [REC] #1. This is a phase 3, double-blind, randomized, placebo-controlled trial to investigate the efficacy, safety and immunogenicity of a Tetravalent Dengue Vaccine (TDV) administered subcutaneously in healthy children aged 4 -16 years old, investigating a TDV booster dose in the booster phase (Parts 4 and 5) of the trial. The RMP version 3.1 has also been submitted.

C.I.13: Submission of the final report from study DEN-303 listed as a category 3 study in the RMP, and addressing PAM [MEA], PAM [REC] #1 and PAM [P46]. This is a phase 3, follow-up trial to evaluate long-term safety and antibody persistence, and the impact of a booster dose of a Tetravalent Dengue Vaccine candidate in healthy adolescents and adults in areas non endemic for dengue. The RMP version 3.1 has also been submitted.

Action: For adoption

5.3.16. Ferric maltol – FERACCRU (CAP) – EMA/VR/0000268118

Applicant: Norgine B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of paediatric population (adolescents aged 12 years and above) for FERACCRU, based on results from phase 1 study ST10-01-103, phase 3 study ST10-01-305 and a supportive phase 1 study ST10-01-104. 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 9.1 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 to implement editorial changes to the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

Action: For adoption

5.3.17. Inebilizumab - UPLIZNA (CAP) - EMEA/H/C/005818/II/0012

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Extension of indication to include treatment of adult patients with Immunoglobulin G4-Related Disease (IgG4-RD) for UPLIZNA, based on primary analysis results from study MITIGATE (VIB0551.P3.S2) for all subjects from the completed 52-week randomised-controlled period. This is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adult

subjects with IgG4-RD. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to bring it 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

5.3.18. 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

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

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Sonja Radowan

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

Action: For adoption

5.3.20. Ivacaftor / Tezacaftor / Elexacaftor – KAFTRIO (CAP) – EMA/VR/0000280845

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Martin Huber

Scope: Submission of the 96-weeks of treatment report (Part A) for study VX20-445-112 (Study 112), listed as a category 3 study in the RMP; this is a Phase 3, open-label, extension study evaluating the long-term safety and efficacy of ELX/TEZ/IVA combination therapy in subjects with cystic fibrosis who are 2 years of age and older. The RMP version 10.1 has also been submitted.

Action: For adoption

5.3.21. Lutetium (^{177}Lu) oxodotreotide - LUTATHERA (CAP) - EMEA/H/C/004123/II/0058, Orphan

Applicant: Advanced Accelerator Applications

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include the treatment of unresectable or metastatic, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adolescents aged 12 years and older for LUTATHERA based on primary analysis results from study CAAA601A32201 (also referred to as NETTER-P) as well as results from modelling and simulation analysis of PK and dosimetry data of Lutathera in adolescents. NETTER-P study is a Phase II, multicenter open-label study which evaluated the safety and dosimetry of Lutathera in adolescent patients with somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) and pheochromocytoma and paragangliomas (PPGLs). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 11 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted.

Action: For adoption

5.3.22. Macitentan / Tadalafil – YUVANCI (CAP) – EMA/VR/0000280219

Applicant: Janssen Cilag International

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Update of section 4.8 of the SmPC in order to update safety information based on final results from Phase 3 study AC-077A301 A DUE (Open Label); this is a multi-center, double-blind, randomized, active-controlled, triple-dummy, parallel-group, group-sequential, adaptive study conducted to evaluate the efficacy and safety of Macitentan/Tadalafil Fixed Dose Combination, versus macitentan or tadalafil monotherapy in participants with PAH. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to update the active metabolite to its INN name throughout the PI.

Action: For adoption

5.3.23. Maralixibat - LIVMARLI (CAP) - EMEA/H/C/005857/X/0016, Orphan

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to add a new strength (19 mg/ml oral solution). In addition, the MAH took the opportunity to implement editorial changes in sections 4.2 and 4.8. of the SmPC and Point 4 of PL of Livmarli, 9.5 mg/ml oral solution.

Action: For adoption

5.3.24. 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

5.3.25. Mexiletine – NAMUSCLA (CAP) – EMA/X/0000258210

Applicant: Lupin Europe GmbH

PRAC Rapporteur: Eva Jirsová

Scope: Extension application to add new strengths of 62 mg and 83 mg grouped with an extension of indication to include the symptomatic treatment of myotonia in children and adolescents (from 6 to 18 years of age) with non-dystrophic myotonic disorders for NAMUSCLA, based on final results from study MEX-NM-301 as well as population pharmacokinetic analysis of mexiletine in healthy volunteers and myotonic patients; MEX-NM-301 is an open-label, multi-centre, single arm, interventional study to describe the steady-state PK, safety, and efficacy of mexiletine in paediatric patients (6 to <18 years of age) with myotonic disorders. As a consequence, sections 4.1, 4.2 and 5.1 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 introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.26. 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

5.3.27. Mosunetuzumab - LUNSUMIO (CAP) - EMEA/H/C/005680/X/0015, Orphan

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Extension application to introduce a new pharmaceutical form (solution for injection) associated with two new strengths (5 mg and 45 mg) and new route of administration

(subcutaneous use). The RMP (version 3.0) is updated in accordance.

Action: For adoption

5.3.28. Nivolumab – OPDIVO (CAP) – EMA/VR/0000279319

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Update of section 5.1 of the SmPC in order to add the final OS data based on final results from study CA209816. This is a randomized, Open-Label, Phase 3 Trial of Nivolumab plus Ipilimumab or Nivolumab plus Platinum-Doublet Chemotherapy versus Platinum-Doublet Chemotherapy in Early Stage NSCLC. The RMP version 47.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II.

Action: For adoption

5.3.29. Nivolumab – OPDIVO (CAP) – EMA/VR/0000278256

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of the final report for the OS final analysis from the post authorisation efficacy study (PAES) CA209577 listed as an obligation in the Annex II of the Product Information. This is a randomized, multicenter, double-blind phase 3 study of adjuvant nivolumab in subjects with resected oesophageal cancer or gastroesophageal cancer who have received CRT followed by surgery. The Annex II and the RMP (version 45.0) are updated accordingly.

Action: For adoption

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

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Gabriele Maurer

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

Action: For adoption

5.3.31. Nusinersen - SPINRAZA (CAP) - EMEA/H/C/004312/X/0038, Orphan

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Karin Bolin

Scope: Extension application to add a new strength of 28 mg and 50 mg. The RMP (version 12.x) is updated in accordance (version 12.2 is under assessment in procedure EMEA/H/C/004312/II/0034/G).

Action: For adoption

5.3.32. Pegcetacoplan – ASPAVELI (CAP) – EMA/VR/0000248937

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of adults and adolescents aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulopathy (IC-MPGN) for ASPAVELI, based on interim results from study APL2-C3G-310; this is a randomized, placebo-controlled, double-blinded, multicenter study to evaluate the safety and efficacy of twice-weekly s.c. infusions of pegcetacoplan in patients diagnosed with C3G or primary IC-MPGN and results from Phase 2 study APL2-C3G-204, an open-label, randomized, controlled study to evaluate the efficacy and safety of pegcetacoplan in posttransplant recurrence of C3G or primary IC-MPGN. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

Action: For adoption

5.3.33. Pembrolizumab – KEYTRUDA (CAP) – EMA/X/0000248795

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension application to introduce a new pharmaceutical form (solution for injection) associated with two new strengths (790 mg and 395 mg) and new route of administration (subcutaneous use). The RMP (version 49.1) is updated in accordance.

Action: For adoption

5.3.34. 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

5.3.35. rADAMTS13 – ADZYNMA (CAP) – EMA/VR/0000255553

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Maia Uusküla

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

Action: For adoption

5.3.36. Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E – AREXVY (CAP) – EMA/VR/0000276225

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 18 years of age and older for AREXVY, based on results from study 222253 (RSV OA=ADJ-025); this is a Phase 3b, open-label study to evaluate the non-inferiority of the immune response and to evaluate the safety of the RSVPreF3 OA investigational vaccine in adults 18-49 years of age at increased risk of respiratory syncytial virus disease, compared to older adults ≥60 years of age. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.3.37. 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/VR/0000280470

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

C.I.4: To update sections 4.4, 4.8, 5.1 of the SmPC to include safety and immunogenicity data following the results from study referred to as V920-015 ACHIV, listed as a category 3 study in the RMP; this is a Phase 2 Randomized, Multi-Center Double-Blind, Placebo-Controlled Study to evaluate the safety and immunogenicity of the V920/Ervebo (rVSVΔG-ZEBOV-GP) Ebola virus vaccine candidate in HIV-Infected adults and adolescents. The RMP

version 2.1 has also been submitted. In addition, the Applicant took the opportunity to remove the complete list of local representatives, as suggested by the EMA during the review of specimens for the current ongoing renewal. Instead, the contact details of the MAH are included for ease of contact.

C.I.11.b: Submission of an updated RMP version 2.1 in order to summarize the safety and effectiveness of Ervebo administered in the context of Expanded Access Protocol (EAP) 5 compassionate ring vaccination study.

Action: For adoption

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

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

5.3.39. Retifanlimab – ZYNYZ (CAP) – EMA/VR/0000247788

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include in combination with carboplatin and paclitaxel treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC) for ZYNYZ, based on interim results from study INCMGA 0012-303 (POD1UM-303/InterAACT-2); this is a phase 3 global, multicenter, double-blind randomized study of carboplatin-paclitaxel with retifanlimab or placebo in participants with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal not previously treated with systemic chemotherapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.40. Ritonavir – NORVIR (CAP) – EMA/VR/0000249795

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

Type II (C.I.6.a): To modify the approved therapeutic indication to reflect current clinical use as a pharmacokinetic enhancer of other antiretroviral products only. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.8 and 5.1 of the SmPC. The Package Leaflet is updated accordingly. The updated RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

Action: For adoption

5.3.41. Selumetinib – KOSELUGO (CAP) – EMA/VR/0000245231

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication for KOSELUGO to include treatment of adults based on results from study D134BC00001 (KOMET). This is a phase III, multicentre, international study with a parallel, randomised, double-blind, placebo-controlled, 2 arm design that assesses efficacy and safety of selumetinib in adult participants with NF1 who have Symptomatic Inoperable Plexiform Neurofibromas. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC. As part of the application the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.42. Talquetamab – TALVEY (CAP) – EMA/VR/0000258454

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add a new warning on Ataxia/Balance disorder based on post-marketing data. The Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted.

Action: For adoption

5.3.43. 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

5.3.44. 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 nighttime 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

5.3.45. 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

5.3.46. Tirzepatide – MOUNJARO (CAP) – EMA/VR/0000271898

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Update of section 4.6 of the SmPC in order to include information on breast-feeding based on results from study I8F-MC-GPIN (GPIN); this was a Phase I, single-site, open-label, single-treatment arm, single-dose, lactation study, assessing pharmacokinetics of tirzepatide in breastmilk and plasma in healthy lactating women. The Package Leaflet is also updated accordingly. The RMP version 6.1 has also been submitted.

Action: For adoption

5.3.47. Tralokinumab – ADTRALZA (CAP) – EMA/VR/0000254976

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Kimmo Jaakkola

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

Action: For adoption

5.3.48. Tucatinib – TUKYSA (CAP) – EMA/VR/0000280202

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Submission of the final report from study SGNTUC-016 listed as a category 3 study in the RMP. This is a randomized, double blind, phase 3 study of Tucatinib or Placebo in combination with Ado-Trastuzumab Emtansine (T-DM1) for subjects with unresectable locally advanced or metastatic HER2+ Breast Cancer. Primary objective is to compare progression-free survival (PFS) by investigator per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 between treatment arms. The RMP version 2.0 has also been submitted.

Action: For adoption

6. Periodic safety update reports (PSURs)

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

6.1.1. Amifampridine – FIRDAPSE (CAP) – EMA/PSUR/0000269014

Applicant: Serb

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00000141/202412)

Action: For adoption

6.1.2. Apalutamide – ERLEADA (CAP) – EMA/PSUR/0000269021

Applicant: Janssen Cilag International

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00010745/202502)

Action: For adoption

6.1.3. Avapritinib – AYVAKYT (CAP) – EMA/PSUR/0000268946

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010878/202501)

Action: For adoption

6.1.4. Baricitinib – OLUMIANT (CAP) – EMA/PSUR/0000268999

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010578/202502)

Action: For adoption

6.1.5. Birch bark extract – FILSUVEZ (CAP) – EMA/PSUR/0000268967

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00010446/202501)

Action: For adoption

6.1.6. Brexucabtagene autoleucel – TECARTUS (CAP) – EMA/PSUR/0000268989

Applicant: Kite Pharma EU B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010903/202501)

Action: For adoption

6.1.7. Concentrate of proteolytic enzymes enriched in bromelain – NEXOBRID (CAP) – EMA/PSUR/0000269011

Applicant: MediWound Germany GmbH

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010028/202412)

Action: For adoption

6.1.8. Crovalimab – PIASKY (CAP) – EMA/PSUR/0000268996

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011071/202502)

Action: For adoption

6.1.9. Danicopan – VOYDEYA (CAP) – EMA/PSUR/0000269006

Applicant: Alexion Europe

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00011056/202501)

Action: For adoption

6.1.10. Dapivirine – DAPIVIRINE VAGINAL RING 25 MG (CAP) – EMA/PSUR/0000267345 (Art 58[3])

Applicant: International Partnership For Microbicides

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUV Dapivirine)

Action: For adoption

6.1.11. Daridorexant – QUVIVIQ (CAP) – EMA/PSUR/0000269025

Applicant: Idorsia Pharmaceuticals Deutschland GmbH

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010993/202501)

Action: For adoption

6.1.12. Dasiglucagon – ZEGALOGUE (CAP) – EMA/PSUR/0000269023

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00011078/202501)

Action: For adoption

[3] Article 58 of Regulation (EC) No 726/2004 allows the Committee for Medicinal Products for Human Use (CHMP) to give opinions, in co-operation with the World Health Organisation (WHO) on medicinal products for human use that are intended exclusively for markets outside of the European Union (EU)

6.1.13. Decitabine / Cedazuridine – INAQOVI (CAP) – EMA/PSUR/0000268951

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000118/202501)

Action: For adoption

6.1.14. Defatted powder of *Arachis hypogaea L.*, semen (peanuts) – PALFORZIA (CAP) – EMA/PSUR/0000268968

Applicant: Stallergenes

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010902/202501)

Action: For adoption

6.1.15. Delgocitinib – ANZUPGO (CAP) – EMA/PSUR/0000269028

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011091/202501)

Action: For adoption

6.1.16. Dolutegravir – TIVICAY (CAP); Dolutegravir / Abacavir / Lamivudine - TRIUMEQ (CAP); Dolutegravir / Lamivudine - DOVATO (CAP) – EMA/PSUR/0000269008

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010075/202501)

Action: For adoption

6.1.17. Elbasvir / Grazoprevir – ZEPATIER (CAP) – EMA/PSUR/0000268984

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010519/202501)

Action: For adoption

6.1.18. Elranatamab – ELREXFIO (CAP) – EMA/PSUR/0000268954

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00000225/202502)

Action: For adoption

6.1.19. Entacapone – COMTAN (CAP); COMTESS (CAP); ENTACAPONE ORION (CAP) – EMA/PSUR/0000269013

Applicant: Orion Corporation

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001223/202501)

Action: For adoption

6.1.20. Epinephrine – EURNEFFY (CAP) – EMA/PSUR/0000269019

Applicant: Alk-Abello A/S

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011081/202502)

Action: For adoption

6.1.21. Evinacumab – EVKEEZA (CAP) – EMA/PSUR/0000268966

Applicant: Ultragenyx Germany GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010945/202502)

Action: For adoption

6.1.22. Faricimab – VABYSMO (CAP) – EMA/PSUR/0000268993

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00011016/202501)

Action: For adoption

6.1.23. Gefapixant – LYFNUA (CAP) – EMA/PSUR/0000268941

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000132/202501)

Action: For adoption

6.1.24. Lisocabtagene maraleucel / Lisocabtagene maraleucel – BREYANZI (CAP) – EMA/PSUR/0000269003

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010990/202502)

Action: For adoption

6.1.25. Lonoctocog alfa – AFSTYLA (CAP) – EMA/PSUR/0000268994

Applicant: CSL Behring GmbH

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010559/202501)

Action: For adoption

6.1.26. Melphalan flufenamide – PEPAXTI (CAP) – EMA/PSUR/0000268987

Applicant: Oncopeptides AB

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00011013/202502)

Action: For adoption

6.1.27. Metreleptin – MYALEPTA (CAP) – EMA/PSUR/0000269015

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010700/202501)

Action: For adoption

6.1.28. Odevixibat – BYLVAY (CAP); KAYFANDA (CAP) – EMA/PSUR/0000268956

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010949/202501)

Action: For adoption

6.1.29. Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) – INCELLIPAN (CAP); Zoonotic influenza vaccine (H5N1)

(surface antigen, inactivated, adjuvanted, prepared in cell cultures) - CELLDEMIC (CAP)– EMA/PSUR/0000268985

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00011057/202501)

Action: For adoption

6.1.30. Perflutren – LUMINITY (CAP); OPTISON (CAP) – EMA/PSUR/0000268958

Applicants: GE Healthcare AS, Lantheus EU Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00002350/202412)

Action: For adoption

6.1.31. Pirtobrutinib – JAYPIRCA (CAP) – EMA/PSUR/0000268970

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000155/202501)

Action: For adoption

6.1.32. Pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) – VAXNEUVANCE (CAP) – EMA/PSUR/0000268990

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010975/202501)

Action: For adoption

6.1.33. Quadrivalent influenza vaccine (recombinant, prepared in cell culture) – SUPEMTEK TETRA (CAP) – EMA/PSUR/0000268982

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00010886/202501)

Action: For adoption

6.1.34. Relugolix – ORGOVYX (CAP) – EMA/PSUR/0000268974

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00010994/202501)

Action: For adoption

6.1.35. Risdiplam – EVRYSDI (CAP) – EMA/PSUR/0000268972

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010925/202502)

Action: For adoption

6.1.36. Romosozumab – EVENITY (CAP) – EMA/PSUR/0000268947

Applicant: UCB Pharma

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00010824/202501)

Action: For adoption

6.1.37. Salmeterol / Fluticasone propionate – BROPAIR SPIROMAX (SRD[4]); SEFFALAIR SPIROMAX (CAP) – EMA/PSUR/0000268979

Applicant: Teva B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010928/202501)

Action: For adoption

6.1.38. Simoctocog alfa – NUWIQ (CAP); VIHUMA (CAP) – EMA/PSUR/0000268960

Applicant: Octapharma AB

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010276/202501)

Action: For adoption

6.1.39. Smallpox and monkeypox vaccine (live modified vaccinia virus Ankara) – IMVANEX (CAP) – EMA/PSUR/0000269020

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Gabriele Maurer

[4] European Commission decision for the withdrawal of the marketing authorisation, at the holder's request: 23 May 2025

Scope: Evaluation of a PSUSA procedure (PSUSA/00010119/202501)

Action: For adoption

6.1.40. Sodium phenylbutyrate – AMMONAPS (CAP); PHEBURANE (CAP) – EMA/PSUR/0000268988

Applicants: Eurocept International B.V., Immedica Pharma AB

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00002758/202412)

Action: For adoption

6.1.41. Sutimlimab – ENJAYMO (CAP) – EMA/PSUR/0000268980

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011023/202502)

Action: For adoption

6.1.42. Tafasitamab – MINJUVI (CAP) – EMA/PSUR/0000269001

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010951/202501)

Action: For adoption

6.1.43. Talquetamab – TALVEY (CAP) – EMA/PSUR/0000268940

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00000099/202502)

Action: For adoption

6.1.44. Tecovirimat – TECOVIRIMAT SIGA (CAP) – EMA/PSUR/0000268964

Applicant: Siga Technologies Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010971/202501)

Action: For adoption

6.1.45. Tezacaftor / Ivacaftor – SYMKEVI (CAP) – EMA/PSUR/0000269024

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00010730/202502)

Action: For adoption

6.1.46. Umeclidinium / Vilanterol – ANORO ELLIPTA (CAP); LAVENTAIR ELLIPTA (CAP) – EMA/PSUR/0000268953

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010264/202412)

Action: For adoption

6.1.47. Umeclidinium bromide – INCRUSE ELLIPTA (CAP); ROLUFTA ELLIPTA (CAP) – EMA/PSUR/0000268992

Applicants: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010263/202412)

Action: For adoption

6.1.48. Vericiguat – VERQUVO (CAP) – EMA/PSUR/0000269002

Applicant: Bayer AG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010950/202501)

Action: For adoption

6.1.49. Verteporfin – VISUDYNE (CAP) – EMA/PSUR/0000269026

Applicant: Cheplapharm Arzneimittel GmbH

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00003110/202412)

Action: For adoption

6.1.50. Voclosporin – LUPKYNIS (CAP) – EMA/PSUR/0000268975

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011020/202501)

Action: For adoption

6.1.51. Voxelotor – OXBRYTA (CAP) – EMA/PSUR/0000268973

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00010983/202502)

Action: For adoption

6.1.52. Ziconotide – PRIALT (CAP) – EMA/PSUR/0000269017

Applicant: Esteve Pharmaceuticals GmbH

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00003142/202412)

Action: For adoption

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

6.2.1. Caspofungin – CANCIDAS (CAP); NAP – EMA/PSUR/0000268976

Applicants: Merck Sharp & Dohme B.V., various

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00000576/202412)

Action: For adoption

6.2.2. Macimorelin – GHRYVELIN (CAP); NAP – EMA/PSUR/0000268945

Applicants: Atnahs Pharma Netherlands B.V., various

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010746/202501)

Action: For adoption

6.2.3. Nitric oxide – INOMAX (CAP); NAP – EMA/PSUR/0000268961

Applicants: Linde Healthcare AB, various

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00002172/202412)

Action: For adoption

6.2.4. Sorafenib – NEXAVAR (CAP); NAP – EMA/PSUR/0000268978

Applicants: Bayer AG, various

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00002773/202412)

Action: For adoption

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

6.3.1. Alitretinoin (oral use) (NAP) – EMA/PSUR/0000269007

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010710/202501)

Action: For adoption

6.3.2. Amino acid combinations / glucose / triglyceride combinations (e.g. olive oil, soya bean oil, fish oil)/ with or without electrolytes/ mineral compounds (i.v. application) - only for the drug Numeta (NAP) – EMA/PSUR/0000269010

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010190/202412)

Action: For adoption

6.3.3. Anthrax vaccine (NAP) – EMA/PSUR/0000268943

Applicants: various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010771/202412)

Action: For adoption

6.3.4. Bendamustine hydrochloride (NAP) – EMA/PSUR/0000269009

Applicants: various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00003162/202501)

Action: For adoption

6.3.5. Botulinum neurotoxin type a (150 kd) free from complexing proteins (NAP) – EMA/PSUR/0000269022

Applicants: various

PRAC Lead: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00009084/202412)

Action: For adoption

6.3.6. Botulinum toxin a (except for centrally authorised products) (NAP) – EMA/PSUR/0000268948

Applicants: various

PRAC Lead: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00000426/202412)

Action: For adoption

6.3.7. Botulinum toxin a-haemagglutinin complex (NAP) – EMA/PSUR/0000268981

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00000427/202412)

Action: For adoption

6.3.8. Bupropion (NAP) – EMA/PSUR/0000268977

Applicants: various

PRAC Lead: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000461/202412)

Action: For adoption

6.3.9. Camellia sinensis, leaf, dry extract refined (derived from *Camellia sinensis, L.* O.KUNTZE) (topical use) (NAP) – EMA/PSUR/0000269000

Applicants: various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010569/202412)

Action: For adoption

6.3.10. Cefotaxime (NAP) – EMA/PSUR/0000268997

Applicants: various

PRAC Lead: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000599/202412)

Action: For adoption

6.3.11. Ciclosporin (systemic use) (NAP) – EMA/PSUR/0000269012

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00000745/202412)

Action: For adoption

6.3.12. Cyanocobalamin / diclofenac / pyridoxine / thiamine (NAP) – EMA/PSUR/0000269016

Applicants: various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00001041/202501)

Action: For adoption

6.3.13. Dexketoprofen / tramadol (NAP) – EMA/PSUR/0000268986

Applicants: various

PRAC Lead: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure (PSUSA/00010468/202501)

Action: For adoption

6.3.14. Disodium hydrogen phosphate / sodium dihydrogen phosphate, phosphate sodium (NAP) – EMA/PSUR/0000268965

Applicants: various

PRAC Lead: Guðrún Stefánsdóttir

Scope: Evaluation of a PSUSA procedure (PSUSA/00002737/202501)

Action: For adoption

6.3.15. Flumazenil (NAP) – EMA/PSUR/0000269027

Applicants: various

PRAC Lead: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00001413/202412)

Action: For adoption

6.3.16. Flunitrazepam (NAP) – EMA/PSUR/0000268937

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00001418/202501)

Action: For adoption

6.3.17. Haloperidol (NAP) – EMA/PSUR/0000268939

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00001587/202501)

Action: For adoption

6.3.18. Human alfa1-proteinase inhibitor (apart from the centrally authorised product) (NAP) – EMA/PSUR/0000268942

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000108/202412)

Action: For adoption

6.3.19. Levamisole (NAP) – EMA/PSUR/0000268962

Applicants: various

PRAC Lead: Roxana Dondera

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

Action: For adoption

6.3.20. Lidocaine / phenazone (NAP) – EMA/PSUR/0000268949

Applicants: various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00002359/202501)

Action: For adoption

6.3.21. Menotrophin (NAP) – EMA/PSUR/0000268950

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00001972/202412)

Action: For adoption

6.3.22. Metamizole sodium / triacetonamine tosilate (NAP) – EMA/PSUR/0000268944

Applicants: various

PRAC Lead: Maria Popova-Kiradjieva

Scope: Evaluation of a PSUSA procedure (PSUSA/00001999/202501)

Action: For adoption

6.3.23. Myristalkonium, benzalkonium (vaginal use only) (NAP) – EMA/PSUR/0000268969

Applicants: various

PRAC Lead: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure (PSUSA/00010987/202501)

Action: For adoption

6.3.24. Niflumic acid (NAP) – EMA/PSUR/0000268983

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00002157/202412)

Action: For adoption

6.3.25. Omega-3-acid ethyl esters (NAP) – EMA/PSUR/0000268957

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010312/202501)

Action: For adoption

6.3.26. Phenylephrine (ophthalmic formulations) (NAP) – EMA/PSUR/0000268963

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00010402/202501)

Action: For adoption

6.3.27. Pirenoxine (NAP) – EMA/PSUR/0000268955

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00002431/202501)

Action: For adoption

6.3.28. Rosuvastatin / Omega-3-acid ethyl esters (NAP) – EMA/PSUR/0000268971

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010915/202501)

Action: For adoption

6.3.29. Roxithromycin (NAP) – EMA/PSUR/0000269004

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00002669/202412)

Action: For adoption

6.3.30. Testosterone (all formulations apart from topical use) (NAP) – EMA/PSUR/0000269018

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00010631/202412)

Action: For adoption

6.3.31. Testosterone (topical use) (NAP) – EMA/PSUR/0000268995

Applicants: various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00002908/202412)

Action: For adoption

6.3.32. Tizanidine (NAP) – EMA/PSUR/0000269005

Applicants: various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00002977/202412)

Action: For adoption

6.3.33. Typhoid vaccine (live, attenuated) (NAP) – EMA/PSUR/0000268991

Applicants: various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00003067/202412)

Action: For adoption

6.3.34. Valaciclovir (NAP) – EMA/PSUR/0000268998

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00003086/202412)

Action: For adoption

6.3.35. Varicella- Zoster immunoglobuline (NAP) – EMA/PSUR/0000268952

Applicants: various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010266/202412)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Ustekinumab – STELARA (CAP) – EMA/PAM/0000274988

Applicant: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Responses to the LEG 058 RSI adopted on 27 March 2025 - From PSUSA/00003085/202312: An updated cumulative review (clinical trial, registry, post-

marketing, literature and other sources) of severe depression/suicidal ideation, using an appropriate SMQ (Depression and suicide/self injury) for all relevant data streams.

Action: For adoption

6.5. Variation procedure(s) resulting from PSUSA evaluation

None

6.6. Expedited summary safety reviews[5]

None

7. Post-authorisation safety studies (PASS)

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

7.1.1. Avapritinib – AYVAKYT (CAP) – EMA/PASS/0000282408

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

Scope: PASS amendment [107o]: BLU-285-1406: an observational study evaluating safety and efficacy of avapritinib in the first line treatment of patients with Platelet derived Growth Factor Alpha D842V mutated gastrointestinal stromal tumor.

Action: For adoption

7.1.2. rADAMTS13 – ADZYNMA (CAP) – EMA/PASS/0000253115

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Maia Uusküla

Scope: PASS 107n [PASS protocol]: A Post-Authorization Safety Study (PASS) to Further Evaluate Real-World Safety in Patients with Congenital Thrombotic Thrombocytopenic Purpura (cTTP) Treated with Adzynma

Action: For adoption

7.1.3. Tofersen – QALSODY (CAP) – EMA/PASS/0000264233

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

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

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

Scope: PASS protocol [107n]: An observational registry-based study utilising data from two disease registry networks precision ALS and ALS/MND NHC to evaluate the long-term safety of tofersen in people with SOD1-ALS [MAH's response to EMEA/H/C/PSP/S/0109]

Action: For adoption

7.1.4. Topiramate (NAP) – EMA/PASS/0000281792

Applicant: Janssen Cilag International

PRAC Rapporteur: Karin Bolin

Scope: Topiramate PASS amendment [107o]: Substantial amendment to a PASS survey among healthcare professionals and patients to assess their knowledge and behaviour regarding the risks of topiramate use during pregnancy, the measures implemented to prevent pregnancy, and the receipt/use of educational materials as part of the pregnancy prevention program.

Action: For adoption

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

7.2.1. Abaloparatide – ELADYNOS (CAP) – EMA/PAM/0000281538

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Karin Erneholm

Scope: Protocol amendment for Study EUPAS1000000613 (MEA 001: European non-interventional post-authorization safety study (PASS) to evaluate cardiovascular (CV) events in patients newly exposed to abaloparatide or teriparatide)

Action: For adoption

7.2.2. Capivasertib – TRUQAP (CAP) – EMA/PAM/0000281199

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Protocol amendment for study D3612R00020 (CAPIseid): a database study of the safety and effectiveness of TRUQAP (capivasertib) + fulvestrant in patients with advanced breast cancer and type 1 or type 2 diabetes. (NINI; RMP) along with MAH's responses to questions/comments raised as part of Truqap MEA 001.

Action: For adoption

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

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

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

7.2.4. Concizumab – ALHEMO (CAP) – EMA/PAM/0000280062

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Submission of the category 3 PASS NN7415-7533 protocol: A registry-based observational cohort study to characterise the safety profile of concizumab in people with haemophilia in the real-world setting.

Action: For adoption

7.2.5. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/PAM/0000273399

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the interim clinical study report, Protocol and Amendment 2 and, the updated statistical Analysis Plan 1 for study C4591052; this is a post-authorisation safety observational study to determine whether there is an increased risk of pre-specified adverse events of special interests following the administration of Comirnaty bivalent BA.1 or Comirnaty bivalent BA.4-5 compared with not receiving any COVID-19 vaccine.

Action: For adoption

7.2.6. COVID-19 vaccine (recombinant, adjuvanted) – NUVAXOVID (CAP) – EMA/PAM/0000273311

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of a revised PASS protocol version 7.0 for study 2019nCoV-404 for COVID-19 vaccine (recombinant, adjuvanted) (Nuvaxovid)

Action: For adoption

7.2.7. COVID-19 vaccine (recombinant, adjuvanted) – NUVAXOVID (CAP) – EMA/PAM/0000273301

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of a revised PASS protocol version 7.0 for study 2019nCoV-402 for COVID-19 vaccine (recombinant, adjuvanted) (Nuvaxovid), to assess the safety of the Novavax COVID-19 vaccine in England using a self-controlled case series design (PASS using data from the Clinical Practice Research Datalink (CPRD) Aurum and linked databases)

Action: For adoption

7.2.8. Crovalimab – PIASKY (CAP) – EMA/PAM/0000281171

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Responses to the List of Questions raised in the assessment report of EMEA/H/C/006061/MEA/002 and submission of the revised draft NI-PASS protocol MO45473. This is a post-authorization safety study (PASS) to characterize safety events and special conditions such as pregnancy and infant outcomes, in paroxysmal nocturnal hemoglobinuria (PNH) patients treated with crovalimab within the IPIG registry (Study MO45473).

Action: For adoption

7.2.9. Danicopan – VOYDEYA (CAP) – EMA/PAM/0000285097

Applicant: Alexion Europe

PRAC Rapporteur: Martin Huber

Scope: Responses to the request for supplementary information (MEA 2.1). Submission of a revised protocol for the non-imposed non-interventional PASS study ALX-PNH-502 - an observational cohort study to assess long-term safety of danicopan add-on therapy in patients with paroxysmal nocturnal hemoglobinuria: analysis of IPIG-registry data.

Action: For adoption

7.2.10. Dimethyl fumarate – SKILARENCE (CAP) – EMA/PAM/0000280214

Applicant: Almirall S.A.

PRAC Rapporteur: Karin Bolin

Scope: Submission of amended protocol for the non-imposed (category 3) Post Authorisation Safety Study (PASS) M-41008-40, "An Observational Post-Authorisation Safety Study of Skilarence in European Psoriasis Registers"; Protocol, version 2.0, dated 27 May 2025; former MEA 001.9

Action: For adoption

7.2.11. Efanesoctocog alfa – ALTUVOCT (CAP) – EMA/PAM/0000269605

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Amelia Cupelli

Scope: Response to PRAC Rapporteur's Request for Supplementary Information of EMEA/H/C/005968/MEA/002.

Updated protocol of the Observational Registry Study in Previously Untreated Patients (PUPs) with Hemophilia A (ATHN), a non-imposed non-interventional post-authorization safety study (NI-PASS)

Action: For adoption

7.2.12. Etranacogene dezaparvovec – HEMGENIX (CAP) – EMA/PAM/0000248926

Applicant: CSL Behring GmbH

PRAC Rapporteur: Bianca Mulder

Scope: The MAH submitted a PASS protocol (version 1.0), which covers a Healthcare Professional Survey (HCP) to assess the effectiveness of the additional Risk Minimization Measures (aRMM) for Hemgenix (etranacogene dezaparvovec).

Action: For adoption

7.2.13. Human thrombin / Human fibrinogen – TACHOSIL (CAP) – EMA/PAM/0000247840

Applicant: Corza Medical GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Revised protocol for PASS PasTel: Short- and long-term safety evaluation of TachoSil in paediatric population

Action: For adoption

7.2.14. Marstacimab – HYMPAVZI (CAP) – EMA/PAM/0000255006

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

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

Action: For adoption

7.2.15. Marstacimab – HYMPAVZI (CAP) – EMA/PAM/0000273932

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Submission of responses to questions following the submission of the PASS protocol for the category 3 post-authorisation study B7841016, a Post-Authorisation Safety Study to Evaluate the Safety of Marstacimab Among Patients with Severe Haemophilia A or B using Real-World Data in European Haemophilia Register

Action: For adoption

7.2.16. Tofacitinib – XELJANZ (CAP) – EMA/PAM/0000276269

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of interim report covering a study period from 01 January 2018 to 31 December 2023 and a protocol amendment v.5 for A3921403 (RMP Category 3 Study - A Post-Authorisation Safety Study of the Utilisation and Prescribing Patterns of Xeljanz (tofacitinib) Using an Administrative Healthcare Database in France, SNDS); former MEA 025

Action: For adoption

7.2.17. Ustekinumab – STELARA (CAP) – EMA/PAM/0000281464

Applicant: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Protocol amendment 4 for the Paediatric Psoriasis Registry, study CNTO1275PSO4056 - the observational PASS (EUPAS19506) of Ustekinumab in the treatment of paediatric patients aged 6 years and older with moderate to severe plaque psoriasis; former MEA 044

Action: For adoption

7.2.18. Vamorolone – AGAMREE (CAP) – EMA/PAM/0000274869

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

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

Action: For adoption

7.2.19. Velaglucerase alfa – VPRIV (CAP) - EMA/PAM/0000248394

Applicant: Takeda Pharmaceuticals International AG

PRAC Rapporteur: Martin Huber

Scope: Submission of an updated study protocol number TAK-669-4018 (v6.0) for a non-interventional (Cat.3) PASS EUPAS49598 for Vpriv 400 U, powder for solution for infusion: A Survey among Patients, Caregivers and Home Infusion Nurses based in the European Union to Assess their Awareness and Understanding of Educational Materials (EM) Supporting VPRIV Infusion at Home. Submission includes updated Patient and Caregiver Questionnaire v.6.0 and updated Home Infusion Nurse Questionnaire v.6.0. Former MEA/030.

Action: For adoption

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

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

Applicants: Medice Arzneimittel Puetter GmbH & Co. KG

PRAC Rapporteur: Martin Huber

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

Action: For adoption

7.3.2. Pitolisant – WAKIX (CAP) – EMA/PASS/0000281790

Applicant: Bioprojet Pharma

PRAC Rapporteur: Terhi Lehtinen

Scope: PASS results[107q]: A 5-year multi-center, observational PASS to document the utilisation of Wakix in the treatment of narcolepsy with or without cataplexy and to collect information on its long-term safety when used in routine medical practice.

Action: For adoption

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

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

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

7.4.2. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence – STRIMVELIS (CAP) – EMA/VR/0000282021

Applicant: Fondazione Telethon Ets

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

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final report from study STRIM-005. This is a non-interventional methodology study to investigate the utility of retroviral insertion site analysis in samples from subjects treated with Strimvelis gene therapy. The RMP version 8.0 has also been submitted.

Action: For adoption

7.4.3. Avelumab – BAVENCIO (CAP) – EMA/VR/0000244307

Applicant: Merck Europe B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the final report from study MS100070-0031 listed as a category 3 PASS in the RMP. This is a non-interventional cohort efficacy and safety study to assess the characteristics and management of patients with Merkel cell carcinoma (MCC) in Germany.

Action: For adoption

7.4.4. Dabigatran etexilate – PRADAXA (CAP) – EMA/VR/0000256456

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Submission of the final report from the non-interventional paediatric PASS 1160.307, listed as a category 3 study in the RMP. This is an observational study to evaluate the safety of dabigatran etexilate for the treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from birth to less than 2 years of age in routine clinical practice setting. The RMP version 41.3 has also been submitted.

Action: For adoption

7.4.5. Deferasirox – EXJADE (CAP) – EMA/VR/0000280855

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of section D of Annex II of the PI based on the submission of the final report from study CICL670E2422, listed as an imposed PASS in the Annex II. This is an observational study that evaluated the safety of deferasirox in the treatment of pediatric patients with non-transfusion-dependent iron overload. The RMP version 23.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

Action: For adoption

7.4.6. Fingolimod – GILENYA (CAP) – EMA/VR/0000257758

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: A grouped application consisting of:

C.I.4: Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from Gilenya Pregnancy Registry (study CFTY720D2404) listed as a category 3 study in the RMP; this is a non-interventional, prospective, observational study in pregnant MS patients with confirmed or suspected maternal exposure to fingolimod; the Package Leaflet is updated accordingly. The RMP version 21.0 has also been submitted. In addition, the MAH took the opportunity to bring editorial changes to the PI.

C.I.4: Update of section 4.6 of the SmPC in order to update information on pregnancy based on the fingolimod Pregnancy outcomes Intensive Monitoring (PRIM) program to collect pregnancy outcome data from the Novartis global pharmacovigilance (PV) database; the Package Leaflet is updated accordingly. The RMP version 21.0 has also been submitted.

Action: For adoption

7.4.7. Icatibant - FIRAZYR (CAP) - EMEA/H/C/000899/II/0061

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Mari Thorn

Scope: Update of section 4.6 based on final results from the Icatibant Outcome Survey (IOS) registry listed as a category 3 study in the RMP; this is a prospective, observational disease registry. The RMP version 8 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

7.4.8. Radium-223 – XOFIGO (CAP) – EMA/VR/0000279392

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Submission of the final report from study 16913 (REASSURE) listed as a category 3 study in the RMP. This is a non-interventional safety study for the evaluation of long-term safety of Radium-223 used for the treatment of metastatic castration resistant prostate cancer.

Action: For adoption

7.4.9. Tocilizumab – ROACTEMRA (CAP) – EMA/VR/0000261482

Applicant: Roche Registration GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of the final report for study ML28664 (RABBIT), listed as a category 3 study in the RMP. This was a non-interventional post-authorisation safety study aimed at collecting and analysing safety data related to the use of tocilizumab in rheumatoid arthritis patients in Germany. The RMP version 30.0 has also been submitted. In addition, the MAH

removed the education materials from the RMP and PI as agreed by PRAC during procedure PSUSA/00002980/202204. Furthermore, the MAH took the opportunity to introduce editorial and formatting changes to the PI and to align the wording used for the pre-filled syringe and the pre-filled pen, as well as to update the list of local representatives in the Package Leaflet.

Action: For adoption

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

7.5.1. Aflibercept – EYLEA (CAP) – EMA/PAM/0000278528

Applicant: Bayer AG

PRAC Rapporteur: Zoubida Amimour

Scope: Interim study report for FIREFLEYE NEXT Study #20275: An extension study to evaluate the long-term outcomes of subjects who received treatment for retinopathy of prematurity in Study 20090 (non-imposed/interventional/RMP).

Action: For adoption

7.5.2. Avatrombopag – DOPTELET (CAP) – EMA/PAM/0000281531

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Monica Martinez Redondo

Scope: Category 3, MEA EMEA/H/C/ 004722/MEA/0002: Post authorisation Safety Study (PASS) of Avatrombopag in Patients With Severe Chronic Liver Disease (CLD).

Progress report

Action: For adoption

7.5.3. Beclometasone / Formoterol / Glycopyrronium bromide – TRYDONIS (CAP) – EMA/PAM/0000274900

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: PASS CLI-05993BA1-05 (TRIBE): Second interim report and Statistical analysis plan (SAP) v. 3.0 - Multinational database cohort study to assess adverse cardiovascular and cerebrovascular outcomes in patients with chronic obstructive pulmonary disease initiating a fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via dry powder inhaler (DPI) compared to pressurized metered dose inhaler (pMDI).

Action: For adoption

7.5.4. Beclometasone / Formoterol / Glycopyrronium bromide – TRIMBOW (CAP) – EMA/PAM/0000274884

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: PASS CLI-05993BA1-05 (TRIBE): Second Interim Study and statistical analysis plan (SAP) v. 3.0 - Multinational database cohort study to assess adverse cardiovascular and cerebrovascular outcomes in patients with chronic obstructive pulmonary disease initiating a fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via dry powder inhaler (DPI) compared to pressurized metered dose inhaler (pMDI)

Action: For adoption

7.5.5. Brexucabtagene autoleucel – TECARTUS (CAP) – EMA/PAM/0000273165

Applicant: Kite Pharma EU B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Protocol amendment 6 for Study KT-EU-472-6036 (Long-term, non-interventional study of recipients of Tecartus for treatment of adult patients relapsed or refractory (r/r) mantle cell lymphoma (MCL) or adult patients with r/r B-cell precursor acute lymphoblastic leukemia (ALL)

Action: For adoption

7.5.6. Burosumab – CRYSVITA (CAP) – EMA/PAM/0000273741

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Follow-up to the 1st Interim Study Report in Adult population, PASS EUPAS32190: Non-interventional Post-Authorisation Safety Study of Burosumab in the Treatment of Children >1 year of age, Adolescents and Adults with X linked Hypophosphataemia (protocol number 2019-36-EU-CRY).

Action: For adoption

7.5.7. COVID-19 vaccine (recombinant, adjuvanted) – NUVAXOVID (CAP) – EMA/PAM/0000281402

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of the third interim study report 2019nCoV-405 (Study No EUPAS39096, Global Pregnancy and Infant Outcomes Study Using the COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER))

Action: For adoption

7.5.8. Dimethyl fumarate – SKILARENCE (CAP) – EMA/PAM/0000280759

Applicant: Almirall S.A.

PRAC Rapporteur: Karin Bolin

Scope: 7th Study Progress Report (2025 Annual Progress Report): "An observational Post-Authorisation Safety Study of Skilarence in European Psoriasis Registers" M-41008-40; follow on from MEA 001.8

Action: For adoption

7.5.9. Diroximel fumarate – VUMERITY (CAP) – EMA/PAM/0000281622

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of the second interim report of PASS 272MS403 An observational study utilising data from big MS data registries to evaluate the long-term safety of Vumerity and Tecfidera. Cat 3

Action: For adoption

7.5.10. Dolutegravir – TIVICAY (CAP) – EMA/PAM/0000276456

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: The 4th annual RESPOND (The International Cohort Consortium of Infectious Disease) study report from 2024 concerning dolutegravir (Tivicay), dolutegravir/abacavir/lamivudine (Triumeq) and dolutegravir/lamivudine (Dovato).

Action: For adoption

7.5.11. Dolutegravir / Abacavir / Lamivudine – TRIUMEQ (CAP) – EMA/PAM/0000276483

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: The 4th annual RESPOND (The International Cohort Consortium of Infectious Disease) study report from 2024 concerning dolutegravir (Tivicay), dolutegravir/abacavir/lamivudine (Triumeq) and dolutegravir/lamivudine (Dovato).

7.5.12. Dolutegravir / Lamivudine – DOVATO (CAP) – EMA/PAM/0000276335

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: David Olsen

Scope: The 4th annual RESPOND (The International Cohort Consortium of Infectious Disease) study report from 2024 concerning dolutegravir (Tivicay), dolutegravir/abacavir/lamivudine (Triumeq) and dolutegravir/lamivudine (Dovato).

Action: For adoption

7.5.13. Drospirenone / Estetrol – LYDISILKA (CAP) – EMA/PAM/0000281178

Applicant: Estetra

PRAC Rapporteur: Martin Huber

Scope: Second interim study report with cut-off date of 21 April 2025 of PASS study titled "International Active Surveillance Study: Native Estrogen Estetrol (E4) Safety Study (INAS-NEES)"

Action: For adoption

7.5.14. Drospirenone / Estetrol – DROVELIS (CAP) – EMA/PAM/0000281181

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Martin Huber

Scope: Second interim study report with cut-off date of 21 April 2025 of PASS study titled "International Active Surveillance Study: Native Estrogen Estetrol (E4) Safety Study (INAS-NEES)"

Action: For adoption

7.5.15. Efgartigimod alfa – VYVGART (CAP) – EMA/PAM/0000279810

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Submission of the first annual progress report for ARGX-113-PASS-2208 study: Post-authorisation safety study to characterize the risks and missing information outlined in the risk management plan including serious infections, use of live/attenuated vaccines, use with monoclonal antibodies, long-term safety and use in immunocompromised patients and evaluate whether there are specific and/or unexpected patterns of adverse events.

Action: For adoption

7.5.16. Fremanezumab – AJOVY (CAP) – EMA/PAM/0000280795

Applicant: TEVA GmbH

PRAC Rapporteur: Terhi Lehtinen

Scope: The interim report for PASS Study TV48125-MH-40217 in line with the defined milestones mentioned in the respective protocol (v1.0) and risk management plan (v6.0).

Action: For adoption

7.5.17. Galcanezumab – EMGALITY (CAP) – EMA/PAM/0000275530

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: Interim results of an ongoing non-interventional galcanezumab study I5Q-MC-B001, as agreed to in the RMP. This PAM covers responses to questions raised in MEA 004.3.

Action: For adoption

7.5.18. Lenalidomide – REVLIMID (CAP) – EMA/PAM/0000281668

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of an interim study report of study CC-5013-MM-034: A prospective non-interventional post-authorisation safety study (PASS) of lenalidomide in previously untreated adult multiple myeloma patients who are not eligible for transplant

Action: For adoption

7.5.19. Luspatercept – REBLOZYL (CAP) – EMA/PAM/0000280221

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Jo Robays

Scope: 5th annual report of Study No. ACE-536-LTFU-001.

To evaluate the long-term safety, including TEEs (only in the TD and non-TD β thalassaemia population with splenectomy), EMH masses (only in the TD and non-TD β-thalassaemia population), and progression to AML and/or other malignancies/ pre-malignancies, of luspatercept in patients who have participated in Acceleron or Celgene-sponsored luspatercept clinical trials.

Action: For adoption

7.5.20. Lutetium (177Lu) oxodotreotide – LUTATHERA (CAP) – EMA/PAM/0000279830

Applicant: Advanced Accelerator Applications

PRAC Rapporteur: Adam Przybylkowski

Scope: Study No. A-LUT-T-E02-402: An International, Non-Interventional, Post-Authorization LongTerm Safety Study of Lutathera, in Patients with Unresectable or Metastatic, Well-Differentiated, Somatostatin Receptor Positive, Gastroenteropancreatic Neuroendocrine Tumours (SALUS study).

Eighth PASS Yearly PROGRESS REPORT, Study No. A-LUT-T-E02-402, SALUS Study

Action: For adoption

7.5.21. Natalizumab – TYSABRI (CAP) – EMA/PAM/0000281383

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of the Annual interim report of the comparison between extended interval dosing (EID) versus standard interval dosing (SID) risk for PML from the TOUCH database and justification for cessation of EID vs. SID.

Action: For adoption

7.5.22. Neratinib – NERLYNX (CAP) – EMA/PAM/0000281194

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Bianca Mulder

Scope: Interim report of the NER7402 (NERLYFE) study, a category 3 PASS: a multicentre, multi-country, prospective, observational, post-authorisation safety study to describe the incidence of discontinuation due to diarrhoea within the first 3 months of a treatment with neratinib, in adult breast cancer patients treated in extended adjuvant in a real world setting.

Interim report for the combined NERLYFE/ELEANOR study, a category 3 PASS. The ELEANOR study is a multi-centric, multi-national, prospective, longitudinal, non-interventional study in Austria, Germany and Switzerland conducted with neratinib in patients with HER2+ breast cancer.

Action: For adoption

7.5.23. Octocog alfa – KOVALTRY (CAP) – EMA/PAM/0000273323

Applicant: Bayer AG

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of the category 3 post-authorisation measure to evaluate adverse events of special interest in the PedNet registry with the submission of interim results of the PedNet Annual Report 2024 for Kovaltry

Action: For adoption

7.5.24. Ravulizumab – ULTOMIRIS (CAP) – EMA/PAM/0000280924

Applicant: Alexion Europe

PRAC Rapporteur: Kimmo Jaakkola

Scope: Category 3 Study - Additional Pharmacovigilance Activity in the Risk Management Plan Submission of Paroxysmal Nocturnal Hemoglobinuria (PNH) Registry Biennial Report, Protocol M07-001, dated 12 Jun 2025.

This is the third biennial report for Ultomiris (ravulizumab).

Action: For adoption

7.5.25. Rurioctocog alfa pegol – ADYNOVI (CAP) – EMA/PAM/0000248808

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Bianca Mulder

Scope: 5th interim/progress report (dated 15 January 2025, with a data cut-off of 12 November 2024) for the ongoing Adynovi post-authorisation safety study (PASS) TAK-660-403 (EUPAS35698) which is a non-interventional, imposed study aimed to investigate the potential effects of PEG accumulation in the choroid plexus of the brain and other tissues/organs.

Action: For adoption

7.5.26. Siponimod – MAYZENT (CAP) – EMA/PAM/0000280344

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Fourth interim study report of Study CBAF312A2411: Evaluation of pregnancy and infant outcomes in Mayzent patients using PRegnancy outcomes Intensive Monitoring (PRIM) data.

Action: For adoption

7.5.27. Solriamfetol – SUNOSI (CAP) – EMA/PAM/0000280836

Applicant: Atnahs Pharma Netherlands B.V.

PRAC Rapporteur: Julia Pallos

Scope: Submission of the sixth progress report (version 1.0) dated 9 May 2025 for JZP865-401 'A post-authorisation safety study (PASS) to evaluate cardiovascular events in adult patients with obstructive sleep apnoea (OSA) treated with solriamfetol'.

Action: For adoption

7.5.28. Sutimlimab – ENJAYMO (CAP) – EMA/PAM/0000273920

Applicant: Recordati Rare Diseases

Scope: 3rd Annual interim report for the sutimlimab Cold Agglutinin Disease Real World Evidence Registry (CADENCE, OBS16454) a multinational, multi-center, observational, prospective, longitudinal disease registry; former MEA 003.2

Action: For adoption

7.5.29. Upadacitinib – RINVOQ (CAP) – EMA/PAM/0000280404

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Annual progress report for PASS P20-199: Drug utilisation study of upadacitinib in Europe to evaluate the effectiveness of additional risk minimisation measures among patients with Rheumatoid Arthritis.

Action: For adoption

7.5.30. Velaglucerase alfa – VPRIV (CAP) – EMA/PAM/0000281221

Applicant: Takeda Pharmaceuticals International AG

PRAC Rapporteur: Martin Huber

Scope: Submission of the 14th Annual 2025 Study Results of Gaucher Disease Outcome Survey (GOS): An Observational, International, Multi-center, Long-term Registry of Patients with Gaucher Disease. GOS registry study discontinuation requested.

Action: For adoption

7.5.31. Venetoclax – VENCLYXTO (CAP) – EMA/PAM/0000255427

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

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

Action: For adoption

7.6. New Scientific Advice

7.7. Ongoing Scientific Advice

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

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Tofersen – QALSODY (CAP) – EMA/S/0000275049

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

8.2.1. Adagrasib – KRAZATI (CAP) – EMA/R/0000281723

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.2. Brexucabtagene autoleucel – TECARTUS (CAP) – EMA/R/0000278705

Applicant: Kite Pharma EU B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.3. Loncastuximab tesirine – ZYNLONTA (CAP) – EMA/R/0000281443

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Eva Jirsová

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

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

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.5. Sotorasib – LUMYKRAS (CAP) – EMA/R/0000285162

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.6. Spesolimab – SPEVIGO (CAP) – EMA/R/0000272399

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Zoubida Amimour

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.7. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/R/0000282648

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Atidarsagene autotemcel – LIBMELDY (CAP) – EMA/R/0000257479

Applicant: Orchard Therapeutics (Netherlands) B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.2. 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

8.3.3. Bevacizumab – OYAVAS (CAP) – EMA/R/0000278081

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.4. Bevacizumab – ALYMSYS (CAP) – EMA/R/0000276471

Applicant: Mabxience Research S.L.

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Cenobamate – ONTOZRY (CAP) – EMA/R/0000273504

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

PRAC Rapporteur: Jo Robays

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. 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

8.3.7. Fenfluramine – FINTEPLA (CAP) – EMA/R/0000256601

Applicant: UCB Pharma

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.8. Hepatitis B surface antigen – HEPLISAV B (CAP) – EMA/R/0000271891

Applicant: Dynavax GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.9. Icosapent ethyl – VAZKEPA (CAP) – EMA/R/0000275813

Applicant: Amarin Pharmaceuticals Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.10. Insulin aspart – KIRSTY (CAP) – EMA/R/0000276245

Applicant: Biosimilar Collaborations Ireland Limited

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

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

Applicant: KRKA tovarna zdravil d.d. Novo mesto

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.12. Ofatumumab – KESIMPTA (CAP) – EMA/R/0000276182

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.13. Remimazolam – BYFAVO (CAP) – EMA/R/0000278275

Applicant: Paion Pharma GmbH

PRAC Rapporteur: Eamon O Murchu

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.14. Risdiplam – EVRYSDI (CAP) – EMA/R/0000275338

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.15. Somapacitan – SOGROYA (CAP) – EMA/R/0000278080

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.16. Sunitinib – SUNITINIB ACCORD (CAP) – EMA/R/0000269316

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Amelia Cupelli

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. Carbamazepine (NAP) - DE/H/xxxx/WS/1998

Applicant: Novartis Pharma GmbH (Tegretal/Tegretol 100 mg/5 ml oral suspension)

PRAC Lead: Martin Huber

Scope: PRAC consultation on a worksharing variation to update the product information of Tegretal/Tegretol oral suspension to restrict its use in newborns below 4 weeks of age in line with the core data sheet (CDS) version 3.2, on request of Germany

Action: For adoption

11.1.2. Tofacitinib (NAP) - DE/H/8402/001-002/DC

PRAC Lead: Martin Huber

Scope: PRAC consultation on the evaluation of initial marketing authorisation applications under the decentralised procedure for a generic medicinal product on request of Germany

Action: For adoption

11.1.3. Valproate and related substances (NAP) - NL/H/xxxx/WS/988

Applicant: Sanofi B.V. (Depakine)

PRAC Lead: Liana Martirosyan

Scope: PRAC consultation on a worksharing variation to update the product information and the educational materials (healthcare professionals and patient guides) regarding the risk of being born small for gestational age after in utero exposure, on request of The Netherlands

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. PRAC working group - Best practice guide on using PRAC plenary time efficiently and effectively – update on the implementation of quantitative goals – Q2 2025

Action: For discussion

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

12.3.1. Healthcare Professionals Working Party (HCPWP) and Patients and Consumers Working Party (PCWP) - Nomination of PRAC representative(s)

PRAC lead: Ulla Wändel Liminga

Action: For adoption

12.4. Cooperation within the EU regulatory network

12.4.1. European Shortages Monitoring Platform overview for National Competent Authorities (NCAs)

Action: For discussion

12.5. Cooperation with International Regulators

None

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

None

12.7. PRAC work plan

12.7.1. PRAC work plan 2025 - update

PRAC lead: Ulla Wändel Liminga, Liana Martirosyan

Action: For discussion

12.8. Planning and reporting

12.8.1. PRAC workload statistics – Q2 2025

Action: For discussion

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. PSURs repository

None

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

Action: For adoption

12.11. Signal management

None

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. 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. Reflection Paper on Patient Experience Data (PED)

PRAC lead: Ulla Wändel Liminga, Carla Torre

Action: For adoption

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/