21 October 2026
EMA/PRAC/225029/2026
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Minutes of PRAC meeting on 31 August-03 September 2026

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

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Of note, the minutes are a working document primarily designed for PRAC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes 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

The Chairperson opened the 31 August – 03 September 2026 meeting by welcoming all participants. The meeting was held remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and on the topics in the agenda of the meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics. Participants were asked to declare any changes, omissions or errors to their declared interests concerning the matters for discussion. No new or additional competing interests were declared. Restrictions applicable to this meeting are captured in the List of participants included in the minutes.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure (EMA/PRAC/567515/2012 Rev.3). All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified. The members of the EEA-EFTA states agreed with the recommendation of the PRAC, unless otherwise specified.

The Chair welcomed the new member(s) and alternate(s) and thanked the departing members/alternates for their contributions to the Committee.

The EMA Secretariat announced the names of the Committee members who delegated their vote via proxy and the Committee members who received such proxy.

1.2. Agenda of the meeting on 31 August-03 September 2026

The agenda was adopted with some modifications upon request from the members of the Committee and the EMA secretariat as applicable.

1.3. Minutes of the previous meeting on 06-09 July 2026

The minutes were adopted with some amendments received during the consultation phase and will be published on the EMA website.

Post-meeting note: the PRAC minutes of the meeting held on 06-09 July 2026 were published on the EMA website on 30 September 2026 (EMA/PRAC/203477/2026).

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. Ferric carboxymaltose, ferric derisomaltose, ferric gluconate, ferric hydroxide polymaltose complex, iron sucrose, iron dextran (NAP) - EMA/REF/0000369747

Applicant(s): various

PRAC Rapporteur: Zane Neikena; PRAC Co-rapporteur: Jan Neuhauser

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

Background

The Austrian Authority for Medicines and Medical Devices (BASG) sent a letter of notification dated 27 August 2026 triggering a referral under Article 31 of Directive 2001/83/EC for the review of parenteral iron-containing products following concerns regarding hypophosphataemic osteomalacia.

Discussion

- PRAC noted the notification letter from the BASG.
- PRAC appointed Zane Neikena as PRAC Rapporteur and Jan Neuhauser as Co-Rapporteur for the procedure.
- PRAC discussed the lists of questions (LoQ) to be addressed during the procedure together with a timetable for conducting the review. PRAC also discussed the need for a public hearing.

Summary of recommendation(s)/conclusions

- The Committee adopted a list of questions to the MAHs of parenteral iron-containing products and a timetable for the procedure.
- PRAC discussed the option to conduct a public hearing, according to the pre-defined criteria set out in the rules of procedure on the organisation and conduct of public hearings at PRAC (EMA/11523/2023 Rev.2). It was agreed by the Committee that at this stage in the assessment, in light of the currently available data, a public hearing would not be appropriate. PRAC can come back to reconsider this at a later stage of the procedure as needed.

For further details, please see https://www.ema.europa.eu/en/medicines/human/referrals/parenteral-iron-containing-medicinal-products.

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]

For further details, see also the adopted PRAC recommendations on signals under the corresponding month.

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

See also Annex I 14.1.

4.1.1. Fentanyl (transdermal patches) (NAP)

Applicant: various

PRAC Lead: Liana Martirosyan

Scope: Signal of accidental exposure

EPITT 17778 – New signal

Lead Member State(s): NL

Background

Fentanyl is an opioid indicated, as transdermal patches, in adults for the management of severe chronic pain that requires continuous long-term opioid administration and for long-term management of severe chronic pain in children from 2 years of age who are receiving opioid therapy, subject to certain conditions.

The Irish health products regulatory authority (HPRA) has received 1 fatal case report of a

[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

child accidentally exposed to fentanyl transdermal patch. A search conducted in EudraVigilance retrieved 3 cases of accidental exposure in association with fentanyl transdermal patches, while recent scientific publications (by *Mshari et al*[3]) highlights the same safety concern. The Netherlands confirmed that the signal needed initial analysis and prioritisation by PRAC.

Discussion

Having considered the available evidence from case reports in EudraVigilance and the published literature, PRAC agreed that further evaluation on the signal of accidental exposure is warranted.

PRAC appointed Liana Martirosyan as Rapporteur for the signal.

Summary of recommendation(s)

- The MAHs for fentanyl (transdermal patches) should provide a cumulative review of post-marketing accidental exposure data collected from 1 July 2021 to 30 June 2026 associated with fentanyl transdermal patch as suspect medicinal product. The review should include spontaneous reports and relevant published literature. The MAHs should also provide a cumulative review of spontaneous reports of patch, product, or device adhesion issues recorded in their safety databases (same reporting period). Based on the totality of the available evidence, the MAHs should assess whether the current routine risk minimisation measures remain adequate to minimise the risks of patch detachment and accidental exposure or whether further risk minimisation measures are needed.
- A 90-day timetable was recommended for the assessment of this review leading to a further PRAC recommendation.

4.1.2. Idarucizumab - PRAXBIND (CAP)

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Signal of disseminated intravascular coagulation

EPITT 20297 – New signal

Lead Member State(s): NL

Background

For background information on substance(s) and indication(s) of centrally authorised product(s) identified as 'CAP', see Human medicine European public assessment report (EPAR) on the EMA website.

During routine signal detection activities, a signal of disseminated intravascular coagulation was identified by EMA, based on 11 cases retrieved in the literature and 4 supportive cases retrieved from EudraVigilance.

Discussion

[3] Mshari E, Copeland CS, Richards GC. "Safety concerns reported by coroners following fentanyl patch fatalities in England, Wales and Northern Ireland between 1997 and 2024." Br J Clin Pharmacol. (2026):1-11.

Having considered the available evidence from case reports in EudraVigilance and the literature, PRAC has agreed that the signal should be addressed as part of the next PSUSA procedure.

Summary of recommendation(s)

- The MAH of Praxbind should submit within the PSUR with data lock point 15/10/2027, a cumulative review of all cases of disseminated intravascular coagulation associated with idarucizumab as suspect drug. This analysis should include a review of the published literature, data from spontaneous reports and reports from studies including all cases in EudraVigilance database, as well as a discussion on possible biological plausibility and mechanism of this association. The MAH should provide any evidence emerged after 6 June 2026 (date of the EudraVigilance search in this signal procedure) separately from the data identified before this date, to clearly distinguish newly emerged data. The MAH should also discuss the need for any potential amendment to the product information (PI) and/ or the risk management plan (RMP) and make accordingly a proposal for the changes to the relevant sections within this discussion.
- PRAC will assess the cumulative review within the PSUR procedure PSUSA/00010435/202710.

4.1.3. Infliximab - FLIXABI (CAP), REMICADE (CAP), REMSIMA (CAP), ZESSLY (CAP)

Applicants: Celltrion Healthcare Hungary Kft. (REMSIMA), Janssen Cilag International (REMICADE), Samsung Bioepis NL B.V. (FLIXABI), Sandoz GmbH (ZESSLY)

PRAC Rapporteur: Karin Bolin

Scope: Signal of IgA nephropathy

EPITT 18649 – New signal

Lead Member State(s): SE

Background

For background information on substance(s) and indication(s) of centrally authorised product(s) identified as 'CAP', see Human medicine European public assessment report (EPAR) on the EMA website.

During routine signal detection activities, a signal of IgA nephropathy was identified by EMA, based on a high literature count at PSUR finalisation (PSUSA/00010759/202508), as well as EudraVigilance and literature case reports, and the observational study by *Sumida et al*[4]*.* The Rapporteur confirmed that the signal needed initial analysis and prioritisation by PRAC.

Discussion

Having considered the available evidence from EudraVigilance, literature, including the study by Sumida et al. (2024), and the existing information on nephropathy and renal impairment in the product information of tumour necrosis factor alpha (TNFα) inhibitors, PRAC agreed that further evaluation of the signal is warranted and considered it appropriate to include all substances within the class in the review in order to ensure a comprehensive assessment of

[4] Sumida K, Shrestha P, Mallisetty Y, Thomas F, Gyamlani G, Streja E, et al. Anti-Tumor Necrosis Factor Therapy and Risk of Kidney Function Decline and Mortality in Inflammatory Bowel Disease. JAMA Netw Open. 2024 Apr 1;7(4): e246822.

the potential association between treatment with TNF inhibitors and the development of IgA nephropathy.

Summary of recommendation(s)

- The innovator MAHs for adalimumab, certolizumab, etanercept, golimumab and infliximab (AbbVie Deutschland GmbH & Co. KG; UCB Pharma SA; Pfizer Europe MA EEIG; and Janssen-Cilag International NV, respectively) should submit, by 11 November 2026, a cumulative review of IgA nephropathy reported in association with the TNFα inhibitors. Based on the outcome of the review, the MAHs should discuss the need for any changes to the product information and/or the RMP as appropriate.
- PRAC will assess the submitted review within a 90-day timetable.

4.1.4. Progestogens[5] (NAP)

Applicant: various

PRAC Rapporteur: Bianca Mulder

Scope: Signal of meningioma

EPITT 20300 – New signal

Lead Member State(s): NL, DE, DK, SE, FI, FR, IT, PL, HR

Background

Progestogens are a group of substances related to the female sex hormone, progesterone. The term progestogens includes both synthetic progestogens ("progestins") and endogenous progestogens such as progesterone and variants thereof. Progestogens are authorised for a wide variety of indications; some progestogens are only authorised for one indication, while other progestogens are authorised for more indications (typically with different posology). A non-exhaustive list of indications includes: contraception, gynaecological indications (e.g. endometriosis), postmenopausal hormone replacement therapy (HRT), advanced breast cancer and prostate cancer. Progestogens are also authorised in several formulations such as oral tablets, intrauterine devices, vaginal rings, subdermal implants, and intramuscular injections.

Based on the results of the epidemiological study[6] conducted by the Danish Medicines Agency (DKMA) to assess the risk of meningioma with all progestogens authorised for contraception and used in Denmark, a signal of meningioma was identified by DKMA. All Members States (NL, DE, DK, SE, FI, FR, IT, PL, HR) confirmed that the signal needed initial analysis and prioritisation by PRAC.

Discussion

[5] chlormadinone/ethinylestradiol, cyproterone acetate/estradiol valerate, cyproterone/ethinylestradiol, dienogest, dienogest/estradiol, dienogest/ethinylestradiol, drospirenone, drospirenone/estetrol, drospirenone/estradiol, drospirenone/ethinylestradiol, estradiol/levonorgestrel, estradiol/norethisterone, estradiol/progesterone, estradiol valerate/norgestrel, ethinylestradiol/gestodene, ethinylestradiol/levonorgestrel, ethinylestradiol/norelgestromin, ethinylestradiol/norethisterone, ethinylestradiol/norgestimate, levonorgestrel, lynestrenol, medroxyprogesterone <100 mg oral formulations, medroxyprogesterone acetate/estradiol, megestrol, nomegestrol acetate/estradiol, norethisterone, progesterone

[6] Hasselblad Lundstrøm N, Hjorslev Knudgaard M, Skaarup Pedersen M, Schougaard Christiansen ML, Wessel Skovlund C. Contraceptive Progestogens and Incident Meningioma. *JAMA Netw Open*. 2026;9(7):e2622603. Published 2026 Jul 1. doi:10.1001/jamanetworkopen.2026.22603

Having considered the available evidence from the literature PRAC considered that the potential association between progestogens and meningioma should be further evaluated.

PRAC appointed Bianca Mulder as Rapporteur for the signal.

Summary of recommendation(s)

- PRAC adopted a list of questions to the study authors. Based on the study authors' response, literature data and data from EudraVigilance, the PRAC Rapporteur will discuss the need for any potential amendment to the product information for each active substance and make a proposal accordingly.
- A 90-day timetable was recommended for the assessment of this review leading to a further PRAC recommendation.

4.2. Signals follow-up and prioritisation

4.2.1. Oxacillin (NAP)

Applicant(s): various

PRAC Lead: Eva Jirsová

Scope: Signal of drug reaction with eosinophilia and systemic symptoms (DRESS)

EPITT 20223 - Follow-up to January 2026

Background

For background information, see PRAC minutes January 2026.

The MAH replied to the request for information on the signal of DRESS and the responses were assessed by the Rapporteur.

Discussion

Having considered the available evidence in EudraVigilance and published literature, including the cumulative review submitted by the MAH, PRAC has agreed that there is sufficient evidence to support a causal association between oxacillin and DRESS. Therefore, the product information of oxacillin-containing products should be updated to add DRESS as a warning and as an undesirable effect with a frequency 'not known'.

Summary of recommendation(s)

- The MAHs of oxacillin containing medicinal products should submit to the national competent authorities, within 60 days, a variation to amend the product information[7], taking into account the already existing wording in some nationally authorised products as the text needs to be adapted by MAHs to individual products.

4.3. Variation procedure(s) resulting from signal evaluation

None

[7] Update of sections 4.4 and 4.8 of the SmPC. The package leaflet is updated accordingly.

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

PRAC provided advice to CHMP on the proposed RMPs for a number of products (identified by active substance below) that are under evaluation for initial marketing authorisation. Information on the PRAC advice will be available in the European Public Assessment Reports (EPARs) to be published at the end of the evaluation procedure.

Please refer to the CHMP pages for upcoming information (http://www.ema.europa.eu/Committees>CHMP>Agendas, minutes and highlights).

See also Annex I 15.1.

5.1.1. Anselamimab - (CAP MAA) - EMEA/H/C/006422, Orphan

Scope (pre D-180 phase): Treatment of adult patients with kappa light chain amyloidosis

5.1.2. Baxdrostat - (CAP MAA) - EMEA/H/C/006597

Scope (pre D-180 phase): Treatment of hypertension in adults

5.1.3. Ensartinib - (CAP MAA) - EMEA/H/C/006757

Scope (pre D-180 phase): The treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).

5.1.4. Gadoquatrane - (CAP MAA) - EMEA/H/C/006443

Scope (pre D-180 phase): For contrast enhancement in magnetic resonance imaging (MRI) used for adults and paediatric patients of all ages.

5.1.5. Lunsotogene parvec - (CAP MAA) - EMEA/H/C/006802, Orphan

ATMP

Scope (pre D-120 phase, accelerated assessment): Treatment of biallelic OTOF variant-associated hearing loss in adults and children

5.1.6. Orforglipron - (CAP MAA) - EMEA/H/C/006632

Scope (pre D-180 phase): Treatment of obesity and type 2 diabetes mellitus in adults

5.1.7. Pimicotinib - (CAP MAA) - EMEA/H/C/006383, PRIME, Orphan

Scope (pre D-180 phase): Treatment of tenosynovial giant cell tumour in adults and adolescents from 12 years of age

5.1.8. Sintilimab - (CAP MAA) - EMEA/H/C/006743

Scope (pre D-180 phase): Treatment of non-squamous non-small cell lung cancer in adults

5.1.9. Zopapogene imadenovec - (CAP MAA) - EMEA/H/C/006508, Orphan

ATMP

Scope (pre D-180 phase): Treatment of respiratory papillomatosis in adults

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

See Annex 15.2

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

See Annex 15.3

6. Periodic safety update reports (PSURs)

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

For background information on substance(s) and indication(s) of centrally authorised product(s) identified as 'CAP', see Human medicine European public assessment report (EPAR) on the EMA website

See also Annex 16.1

6.1.1. Abatacept – ORENCIA (CAP) – EMA/PSUR/0000344377

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00000013/202512)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Orencia, a centrally authorised medicine containing abatacept and issued a recommendation on its marketing authorisation(s).

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of Orencia (abatacept) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to amend the conditions of the marketing authorisation by removing the infusion- and injection-related allergic reactions information from the patient card. Therefore, the current terms of the marketing authorisation(s) should be varied[8].
- In the next PSUR, the MAH should review all data regarding congenital anomalies and infections in infants exposed to abatacept in utero. Furthermore, the MAH should clarify

[8] Update of Annex II and Annex IIIA. The PRAC AR and PRAC recommendation are transmitted to CHMP for adoption of an opinion

whether reported autoimmune events are consistent with the patterns observed in patients with rheumatoid arthritis and assess the temporal relationship between vaccination and infections, including potential vaccine breakthrough cases.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC.

6.1.2. Belzutifan – WELIREG (CAP) – EMA/PSUR/0000344453

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011107/202602)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Welireg, a centrally authorised medicine containing belzutifan and issued a recommendation on its marketing authorisation(s).

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of Welireg (belzutifan) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include retinal oedema as an undesirable effect with a frequency 'uncommon'. Therefore, the current terms of the marketing authorisation(s) should be varied[9].
- In the next PSUR, the MAH should provide case reports for all fatal intracranial haemorrhages and assess whether the product information need to be updated.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC.

6.1.3. Daridorexant – QUVIVIQ (CAP) – EMA/PSUR/0000344443

Applicant: Idorsia Pharmaceuticals Deutschland GmbH

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010993/202601)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Quviviq, a centrally authorised medicine containing daridorexant and issued a recommendation on its marketing authorisation(s).

[9] Update of SmPC section 4.8. The package leaflet is updated accordingly. The PRAC AR and PRAC recommendation are transmitted to CHMP for adoption of an opinion

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of Quviviq (daridorexant) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to amend the warning regarding worsening of depression and suicidal ideation and to include angioedema among the symptoms of hypersensitivity reactions (frequency 'uncommon'). Therefore, the current terms of the marketing authorisation(s) should be varied[10].
- In the next PSUR, the MAH should provide a trend analysis regarding the reported medication errors 'product prescribing error' and 'wrong technique in product usage process', and also a detailed evaluation of all cases of sleep paralysis. Furthermore, the MAH should closely monitor cases of memory impairment in all patients (with and without concomitant use of CNS depressants). In addition, in the next PSUR, the important potential risk 'suicidal behaviour in high-risk patients (with a medical history of depression or other psychiatric disorders)' should be renamed 'suicidal behaviour' to encompass patients irrespective of depression or other psychiatric medical history.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC.

6.1.4. Ivacaftor – KALYDECO (CAP) – EMA/PSUR/0000344411

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00009204/202601)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Kalydeco, a centrally authorised medicine containing ivacaftor and issued a recommendation on its marketing authorisation(s).

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of Kalydeco (ivacaftor) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to amend the warning regarding elevated transaminases and hepatic injury. Therefore, the current terms of the marketing authorisation(s) should be varied[11].
- In the next PSUR, the MAH should conduct a cumulative review of ivacaftor (also its combinations) in relation to increased cholesterol, LDL, dyslipidaemia or other lipid-profile changes. The MAH should also conduct a cumulative review of cases of

[10] Update of SmPC sections 4.4 and 4.8. The package leaflet is updated accordingly. The PRAC AR and PRAC recommendation are transmitted to CHMP for adoption of an opinion
[11] Update of SmPC sections 4.4 and 4.8. The package leaflet is updated accordingly. The PRAC AR and PRAC recommendation are transmitted to CHMP for adoption of an opinion

behavioural changes in children under 6 years using data from clinical trials, the literature and post-marketing experience.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC.

6.1.5. Relugolix – ORGOVYX (CAP) – EMA/PSUR/0000344433

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00010994/202601)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Orgovyx, a centrally authorised medicine containing relugolix and issued a recommendation on its marketing authorisation(s).

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of Orgovyx (relugolix) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to amend information regarding breastfeeding and to include erectile dysfunction as an undesirable effect with a frequency 'common'. Therefore, the current terms of the marketing authorisation(s) should be varied[12].
- In the next PSUR, the MAH should provide a clear overview of the literature search process, and for each safety issue presented in the literature, to assess whether further regulatory or pharmacovigilance action is warranted and specify any proposed measures in accordance with GVP VII.B.5.11. The MAH should discuss the potential mechanisms underlying the interaction with levothyroxine and provide case narratives identified in the current and next reporting period, assessing whether there is a need for further regulatory action. Furthermore, the MAH should provide a cumulative review of cases of acute kidney injury and discuss the need for a product information update.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC.

6.1.6. Zuranolone – ZURZUVAE (CAP) – EMA/PSUR/0000344462

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Guðrún Stefánsdóttir

Scope: Evaluation of a PSUSA procedure (PSUSA/00011158/202602)

[12] Update of SmPC sections 4.6 and 4.8. The package leaflet is updated accordingly. The PRAC AR and PRAC recommendation are transmitted to CHMP for adoption of an opinion

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Zurzuvae, a centrally authorised medicine containing zuranolone and issued a recommendation on its marketing authorisation(s).

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of Zurzuvae (zuranolone) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to amend the warning regarding CNS depressant effect. Therefore, the current terms of the marketing authorisation(s) should be varied[13].
- In the next PSUR, the MAH should provide tabulated overviews of cases of off-label use and associated adverse events and of medication-error types, contributing factors, trends, patterns and affected populations. The MAH should also continue to monitor suicidal ideation, including a discussion on the disease severity at treatment initiation, disease progression while on treatment, time to onset, dosage, de-challenge and rechallenge following dose titration or zuranolone withdrawal, and whether the event resolved during treatment.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC.

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

See also Annex 16.2

6.2.1. Alendronic acid / Colecalciferol – ADROVANCE (CAP); FOSAVANCE (CAP); VANTAVO (CAP); NAP – EMA/PSUR/0000344382

Applicants: Organon N.V., various

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000079/202601)

Background

The fixed drug combination alendronic acid/colecalciferol is indicated for the treatment of postmenopausal osteoporosis in women at risk of vitamin D insufficiency and reduces the risk of vertebral and hip fractures.

Based on the assessment of the PSUR(s), PRAC reviewed the benefit-risk balance of Adrovance, Fosavance and Vantavo, centrally authorised medicines containing alendronic

[13] Update of SmPC section 4.4. The PRAC AR and PRAC recommendation are transmitted to CHMP for adoption of an opinion

acid/colecalciferol, and nationally authorised medicines containing alendronic acid/colecalciferol and issued a recommendation on their marketing authorisations.

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of alendronic acid/colecalciferol-containing product(s) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include atypical fractures of other bones as a warning and as an undesirable effect with a frequency 'not known'. Therefore, the current terms of the marketing authorisations should be varied[14].

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC.

6.2.2. Lenalidomide – LENALIDOMIDE ACCORD (CAP); LENALIDOMIDE KRKA (CAP); LENALIDOMIDE MYLAN (CAP); REVLIMID (CAP); NAP – EMA/PSUR/0000344392

Applicants: Bristol-Myers Squibb Pharma EEIG, Accord Healthcare S.L.U., Mylan Pharmaceuticals Limited, KRKA tovarna zdravil d.d. Novo mesto, various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00001838/202512)

Background

Lenalidomide is an immunomodulating agent indicated for the treatment of multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma and follicular lymphoma.

Based on the assessment of the PSUR(s), PRAC reviewed the benefit-risk balance of Lenalidomide Accord, Lenalidomide Krka, Lenalidomide Mylan, and Revlimid, centrally authorised medicines containing lenalidomide, and nationally authorised medicines containing lenalidomide and issued a recommendation on their marketing authorisations.

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of lenalidomide-containing product(s) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to add a warning regarding the risk of haemophagocytic lymphohistiocytosis (HLH), and to include progressive multifocal leukoencephalopathy (PML) as an undesirable effect with a frequency 'rare'.
- In the next PSUR, the MAHs should use the following list of safety concerns as basis: important identified risks of teratogenicity, serious infections, thromboembolic events, second primary malignancies, cardiac failure, cardiac arrhythmias, ischaemic heart disease including myocardial infarction, and tumour flare reaction; the important potential risk of off-label use.

[14] Update of SmPC sections 4.4 and 4.8. The package leaflet is updated accordingly. The PRAC AR and PRAC recommendation are transmitted to CHMP for adoption of an opinion

- The MAHs should closely monitor and fully document fatal cases, particularly those with an unreported cause of death, as well as HLH, non-infectious myocarditis, stress cardiomyopathy under ischaemic heart disease, and PML under serious infections.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC.

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

See also Annex 16.3

6.3.1. Alendronate – EMA/PSUR/0000344376

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000078/202601)

Background

Alendronate is a bisphosphonate indicated in postmenopausal women with osteoporosis to prevent fractures, including those of the hip and spine (vertebral compression fractures), for prevention of osteoporosis to reduce the risk of future fracture in postmenopausal women who are at risk of developing osteoporosis, for prevention of glucocorticoid-induced osteoporosis in men and women and for the treatment of Paget's disease of bone in men and women.

Based on the assessment of the PSUR(s), PRAC reviewed the benefit-risk balance of nationally authorised medicine(s) containing alendronate and issued a recommendation on their marketing authorisation(s).

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of alendronate-containing medicinal products in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include atypical fractures of other bones as a warning and as an undesirable effect with a frequency 'not known'. Therefore, the current terms of the marketing authorisation(s) should be varied[15].
- In the next PSUR, the MAH(s) should include atypical fractures (excluding atypical femur fractures) as an important identified risk in the PSUR summary of safety concerns. The MAHs of alendronate tablets or filmcoated tablets should provide a cumulative review on adverse effects on the airways following aspiration, with emphasis on erosion and ulceration and related complications, from all available sources and discuss the need to update the product information and/or the RMP. In addition, all MAHs should provide a

[15] Update of SmPC sections 4.4 and 4.8. The package leaflet is updated accordingly. The PRAC AR and PRAC recommendation are transmitted to CMDh for adoption of a position

cumulative review of cases of drug-induced liver injury from all available sources and discuss the need for update of the product information and/or the RMP.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC.

6.3.2. Diacerein – EMA/PSUR/0000344398

Applicants: various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00001026/202512)

Background

Diacerein is an anthraquinone derivative indicated for the symptomatic treatment of osteoarthritis of the hip or knee.

Based on the assessment of the PSUR(s), PRAC reviewed the benefit-risk balance of nationally authorised medicine(s) containing diacerein and issued a recommendation on their marketing authorisation(s).

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of diacerein-containing medicinal products in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to add nausea and vomiting as undesirable effects with a frequency 'not known'. Therefore, the current terms of the marketing authorisation(s) should be varied[16].

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC.

6.4. Follow-up to PSUR/PSUSA procedures

None

6.5. Variation procedure(s) resulting from PSUSA evaluation

None

6.6. Expedited summary safety reviews[17]

None

[16] Update of SmPC section 4.8. The package leaflet is updated accordingly. The PRAC AR and PRAC recommendation are transmitted to CMDh for adoption of a position

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

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[18]

See Annex 17.1

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[19]

See Annex 17.2

7.3. Results of PASS imposed in the marketing authorisation(s)[20]

None

7.4. Results of PASS imposed and non-imposed in the marketing authorisation(s)[21]

See also Annex 17.4

7.4.1. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/VR/0000334558

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final clinical study report for the non-interventional study C4591022, listed as a category 3 study in the RMP. This is a non-interventional post-approval safety study of pregnancy and infant outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.

Background

For background information on substance(s) and indication(s) of centrally authorised product(s) identified as 'CAP', see Human medicine European public assessment report (EPAR) on the EMA website.

As stated in the RMP of Comirnaty (COVID-19 mRNA vaccine), the MAH conducted a non-interventional post-approval safety study of pregnancy and infant outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry (US/Canada). The Rapporteur assessed the MAH's final study report in addition to the MAH's answers to the request for supplementary information (RSI).

Summary of advice

- Based on the available data, the MAH's responses to the RSI and the Rapporteur's review, PRAC considered that the ongoing variation assessing the final study report

[18] In accordance with Article 107n of Directive 2001/83/EC
[19] 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
[20] In accordance with Article 107p-q of Directive 2001/83/EC
[21] 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

could be recommended for approval.

- Based on the final results of the PASS study C4591022 as well as the totality of evidence from published literature and completed PASS studies, PRAC concluded that there is no increased risk of adverse pregnancy outcomes, including spontaneous abortion and major congenital malformations, following exposure to Comirnaty during pregnancy. Therefore, PRAC considered that an update of the product information (SmPC section 4.6 and package leaflet) is needed.

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

See also Annex 17.5

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

Applicant: Cassiopea S.p.A.

PRAC Rapporteur: Zane Neikena

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

Background

For background information on substance(s) and indication(s) of centrally authorised product(s) identified as 'CAP', see Human medicine European public assessment report (EPAR) on the EMA website.

According to the RMP for Winlevi (clascoterone), the MAH had committed to submit the feasibility assessment for a PASS to characterise the potential risk of HPA axis suppression with long-term use of Winlevi in adolescents.

Summary of advice

- PRAC considered that the category 3 PASS aimed to address the important potential risk of hypothalamic-pituitary-adrenal axis (HPA) suppression is not feasible. Therefore, the study should be removed from the additional pharmacovigilance activities of the RMP. The important potential risk of hypothalamic-pituitary-adrenal axis (HPA) suppression should be further monitored in the PSUR.

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

8.1. Annual reassessments of the marketing authorisation

See Annex 18.1

8.2. Conditional renewals of the marketing authorisation

See Annex 18.2

8.3. Renewals of the marketing authorisation

See Annex 18.3

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 minutes.

None

9.3. Others

None

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

None

11. Scientific advice procedures

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

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of PRAC

12.1.1. PRAC membership

The Chair thanked Magdalena Wielowieyska, alternate for Luxembourg, for her commitment during her mandate.

12.1.2. Nominated proxy

Anne-Cecile Vuillemin gave a proxy right to Tiphaine Vaillant and Hedvig Nordeng to Annete Kirstine Stark for the entire meeting.

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. Areas of collaboration between PRAC and Methodology Working Party (MWP)

PRAC lead: Ulla Wändel Liminga, Liana Martirosyan, Carla Torre

In order to increase awareness on the methodology domain activities and opportunities for collaboration with PRAC, the EMA Secretariat presented to PRAC an overview of the Methodological Working Party, including the scope, structure and the ongoing/planned activities, as well as relevant specialised interest areas. PRAC noted the information.

12.4. Cooperation within the EU regulatory network

None

12.5. Cooperation with International Regulators

None

12.6. Contacts of 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 2026 - update

PRAC lead: Ulla Wändel Liminga, Liana Martirosyan

The EMA Secretariat presented to PRAC a mid-year status update on the activities described in the PRAC work plan 2026. PRAC will initiate its work plan for 2027 taking into account the activities completed, progress made, priorities identified at the level of the Committee, EMA, Heads of Medicines Agencies (HMA) and the EU network.

12.8. Planning and reporting

None

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

None

12.10.3. PSURs repository

None

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

In line with the criteria for plenary presentation of updates to the EURD List adopted by PRAC in December 2021[22], PRAC endorsed the draft revised EURD list, version *September 2-2026*, reflecting the PRAC's comments impacting on the data lock point (DLP) and PSUR submission frequencies of the substances/combinations. PRAC endorsed the newly allocated Rapporteurs for upcoming PSUSAs in accordance with the principles previously endorsed by PRAC (see PRAC minutes April 2013).

Post-meeting note: following the PRAC meeting of September 2026[23], the updated EURD list was adopted by CHMP and CMDh at their September 2026 meetings and published on the EMA website, see: Home> Human Regulatory>Post-authorisation>Pharmacovigilance>Periodic safety update reports>> List of Union reference dates and frequency of submission of periodic safety update reports (PSURs)

12.11. Signal management

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

PRAC lead: Dennis Lex

The EMA Secretariat provided PRAC with an update on the activities of the SMART Methods group, including activity progress of the pregnancy focus group, collaborative activities between EMA and the Uppsala Monitoring Center, and activities undertaken by the EMA Health DataLab. PRAC noted the information.

[22] Held on 29 November – 02 December 2026.
[23] Held on 31 August – 03 September 2026.

12.12. Adverse drug reactions reporting and additional monitoring

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

PRAC was informed on the updates made to the list of products under additional monitoring.

Post-meeting note: The updated additional monitoring list was published on the EMA website, see: Home>Human Regulatory>Post-authorisation>Pharmacovigilance>Medicines under additional monitoring>List of medicines under additional monitoring

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

12.20.1. Strategy on measuring the impact of pharmacovigilance: draft technical specifications for a quantitative impact study on healthcare professionals' preferences for additional risk minimisation measures (under EMA/2024/OP/0016)

PRAC leads: The PRAC Sponsor presented the draft technical specifications for tender under framework contract EMA/2024/OP/0016 for an impact study on healthcare professionals' preferences for additional risk minimisation measures. The rationale, proposed research question, study objectives and methodology (discreet choice experiment) were supported by PRAC with some modifications to the study objectives. PRAC members were invited to provide written comments.

Post-meeting note: PRAC endorsed, by written procedure on 18 September 2026 the draft technical specifications for the impact study on healthcare professionals' preferences for additional risk minimisation measures.

12.21. Others

12.21.1. Guideline on good pharmacovigilance practices (GVP) – Annex I Definitions

The EMA Secretariat circulated to PRAC the GVP Annex I Definitions for adoption via written procedure.

Post-meeting note: PRAC endorsed the GVP Annex I Definitions on 06 October 2026.

12.21.2. Extension application timetable alignment with MAA timetable

The EMA Secretariat presented to PRAC the proposal to align the extension application timetable with the initial marketing authorization application timetable. PRAC endorsed the proposal. As a next step, this topic will be brought to CHMP for endorsement at their

September 2026 plenary meeting.

13. Any other business

None

14. Annex I – Signals assessment and prioritisation[24]

As per the agreed criteria for new signal(s), PRAC adopted without further plenary discussion the recommendation of the Rapporteur to request MAH(s) to submit a cumulative review following standard timetables[25].

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

14.1.1. Acitretin (NAP)

Applicant: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Signal of erectile dysfunction

EPITT 20310 – New signal

Lead Member State(s): DK

14.1.2. Anakinra - KINERET (CAP)

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Karin Erneholm

Scope: Signal of fulminant hepatitis

EPITT 20308 – New signal

Lead Member State(s): DK

14.1.3. Deucravacitinib – SOTYKTU (CAP)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Signal of pemphigoid

EPITT 20304 – New signal

[24] 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

[25] Either MAH(s)'s submission within 60 days followed by a 60 day-timetable assessment or MAH's submission cumulative review within an ongoing or upcoming PSUR/PSUSA procedure (if the DLP is within 90 days), and no disagreement has been raised before the meeting

Lead Member State(s): NL

14.1.4. Gefitinib - IRESSA (CAP)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Signal of pulmonary alveolar haemorrhage

EPITT 20307 – New signal

Lead Member State: SE

14.1.5. Lazertinib - LAZCLUZE (CAP)

Applicant: Janssen Cilag International

PRAC Lead: Petar Mas

Scope: Signal of colitis

EPITT 20296 – New signal

Lead Member State(s): HR

14.2. Signals follow-up and prioritisation

None

14.3. Variation procedure(s) resulting from signal evaluation

None

15. Annex I – Risk management plans

15.1. Medicines in the pre-authorisation phase

As per the agreed criteria, PRAC endorsed without further plenary discussion the conclusions of the Rapporteur on the assessment of the RMP for the medicine(s) mentioned below under evaluation for initial marketing authorisation application. Information on the medicines containing the active substance(s) listed below will be made available following the CHMP opinion on their marketing authorisation(s).

15.1.1. Apixaban - (CAP MAA) - EMEA/H/C/006752

Scope (pre D-180 phase): Prevention of venous thromboembolic events (VTE), stroke and systemic embolism; treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) in adults. Treatment of VTE in children from 28 days to < 18 years of age.

15.1.2. Bevacizumab - (CAP MAA) - EMEA/H/C/005995

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

15.1.3. Filgrastim - (CAP MAA) - EMEA/H/C/007009

Scope (pre D-60 phase): Reduction in the duration of neutropenia and the incidence of febrile neutropenia; mobilisation of peripheral blood progenitor cells (PBPCs); increase in the neutrophil counts and reduction in the incidence and duration of infection-related events; treatment of persistent neutropenia

15.1.4. Fondaparinux sodium - (CAP MAA) - EMEA/H/C/006824

Scope (pre D-180 phase): Prevention of venous thromboembolic events (VTE), treatment of deep vein thrombosis (DVT), treatment of pulmonary embolism, treatment of unstable angina and myocardial infarction in adults

15.1.5. Insulin aspart - (CAP MAA) - EMEA/H/C/006677

Scope (pre D-180 phase): Treatment of diabetes mellitus from 1 year of age

15.1.6. Insulin aspart - (CAP MAA) - EMEA/H/C/006864

Scope (pre D-180 phase): Treatment of diabetes mellitus from 1 year of age

15.1.7. Ruxolitinib - (CAP MAA) - EMEA/H/C/006793

Scope (pre D-180 phase): Treatment of myelofibrosis (MF) and polycythaemia vera (PV) in adults, and treatment of Graft versus host disease (GvHD) in adults and children

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

As per the agreed criteria, PRAC endorsed without further plenary discussion the conclusions of the Rapporteur on the assessment of the variation procedure for the medicine(s) mentioned below., unless otherwise specified.

15.2.1. Dimethyl fumarate – DIMETHYL FUMARATE MYLAN (CAP); NAP – EMA/VR/0000344712

Applicants: Mylan Pharmaceuticals Limited, various

PRAC Rapporteur: Dennis Lex

Scope: Type IB, C.9.b - the MAH updated the proposed RMP in line with the reference product Tecfidera RMP version 17.0, dated 2024, published by EMA on 11 July 2024.
The following significant changes were made in the current RMP:
List of important risks and missing information were deleted
• Important identified risk- Decreased in leukocyte and lymphocyte counts and drug induced liver injury has been deleted
• Important potential risk-Serious and opportunistic infections (other than PML and herpes zoster) and Interaction with nephrotoxic medications leading to renal toxicity has been deleted.
• Missing information- Safety profile in patients over the age of 55 years, Safety profile in patients with hepatic impairment, Safety profile in patients with severe active GI disease and Increased risk of infection in patients concomitantly taking anti-neoplastic or

immunosuppressive therapies has been deleted.
Part II (SVII and SVIII), Part III and Part VI were updated accordingly.

15.2.2. Emtricitabine / Tenofovir disoproxil – EMTRICITABINE/TENOFOVIR DISOPROXIL ZENTIVA (CAP); NAP – EMA/VR/0000335678

Applicants: Zentiva k.s., various

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: To update the RMP in line with the reference medicinal product:
To remove missing Information Safety in pregnancy and lactation. To add Annex 4: Specific Adverse Reaction Follow-up Questionnaire for Lack of efficacy in pre-exposure prophylaxis. And to remove Follow-up form for renal toxicity, Follow-up form for renal tubulopathy, Follow-up form for bone events, Pregnancy report form (to report pregnancy before outcome is known) and Pregnancy outcome report (to be used when pregnancy outcome is known).

15.2.3. Fosdenopterin – NULIBRY (CAP) – EMA/VR/0000347997

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Dennis Lex

Scope: Submission of an updated RMP version 3.0 following PSUSA procedure EMEA/H/C/PSUSA/00011017/202508. The Annex II is updated accordingly.

15.2.4. Pomalidomide – POMALIDOMIDE KRKA (CAP); NAP – EMA/VR/0000361252

Applicants: KRKA tovarna zdravil d.d. Novo mesto, various

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Type IB, C.9.b -to align the RMP with the RMP version 18.0 of reference product Imnovid published on 20 January 2026. To remove the reference to the questionnaire for male patients of pregnant partners from the follow-up questionnaire.

15.2.5. Sonidegib – ODOMZO (CAP); NAP – EMA/VR/0000357142

Applicants: Sun Pharmaceutical Industries (Europe) B.V., various

PRAC Rapporteur: Petar Mas

Scope: Submission of the final report from study NISSO (CLDE225A2404) listed as a category 3 study in the RMP. This is a non-imposed, non-interventional, multi-national, multi-center post-authorization safety study) to assess the long-term safety and tolerability of Odomzo (sonidegib) administered in patients with locally advanced basal cell carcinoma (laBCC). The RMP version 9.2 has also been submitted.

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

15.3.1. Abiraterone acetate – ABIRATERONE MYLAN (CAP); NAP – EMA/VR/0000291298

Applicants: Mylan Pharmaceuticals Limited, various

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Grouped application comprising of 3 Extension of indication variations for ABIRATERONE MYLAN, as follows:

C.I.6: to update the currently approved indication for metastatic hormone sensitive prostate cancer (mHSPC) patients to also include non-high risk mHSPC

C.I.6: to include the treatment of newly diagnosed mHSPC in adult men in combination with androgen deprivation therapy (ADT) and docetaxel in patients who are fit for chemotherapy

C.I.6: to include the treatment of newly diagnosed high risk non-metastatic hormone sensitive prostate cancer (HSPC) in adult men in combination with ADT and radiotherapy

The variations are based on literature data. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted.

15.3.2. Abrocitinib – CIBINQO (CAP) – EMA/VR/0000350662

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: Update of section 4.4 and 4.8 of the SmPC in order to update long-term safety information based on results from study B7451015, listed as a category 3 study in the RMP. This is a Phase 3 Multicenter, Long-Term Extension Study Investigating the Efficacy and Safety of Abrocitinib, With or Without Topical Medications Administered to Subjects Aged 12 Years and Older With Moderate to Severe Atopic Dermatitis. The RMP version 5.1 has also been submitted.

15.3.3. Afamelanotide – SCENESSE (CAP) – EMA/VR/0000325360

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Dennis Lex

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

15.3.4. Aflibercept – OPUVIZ (CAP) – EMA/VR/0000357444

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Quality

15.3.5. Apixaban – ELIQUIS (CAP) – EMA/VR/0000327005

Applicant: Bristol-Myers Squibb Pfizer EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include neonates in the currently approved indication treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age for ELIQUIS, based on final results from pivotal study CV185325. This is an open-label, multi-centre, randomized, active controlled trial to provide PK data and data on anti-Xa activity to support the extrapolation of efficacy to children, to evaluate safety and efficacy of apixaban in children (full term neonates to less than 18 years of age) who require anticoagulation for venous thromboembolism, and Study 2, modelling and simulation study to derive dosing of apixaban for use in neonates for treatment of venous thromboembolism; As a consequence, section 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 24.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the Patient Card to mention Eliquis only once on the title page and refer to apixaban throughout the rest of the card.

15.3.6. Asciminib – SCEMBLIX (CAP) – EMA/VR/0000342126

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Eva Jirsová

Scope: Update of section 4.4 of the SmPC in order to add a new warning on arterial occlusive events, based on a safety review. The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted.

15.3.7. Atidarsagene autotemcel – LIBMELDY (CAP) – EMA/VR/0000334917

Applicant: Orchard Therapeutics (Netherlands) B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: A grouped application consisting of:

C.12: Submission of the final report from study 201222 listed as a category 3 study in the RMP. This is a Phase I/II clinical trial of haematopoietic stem cell gene therapy for the treatment of metachromatic leukodystrophy (MLD).

C.12: Submission of the final report from study CUP 207394 listed as a category 3 study in the RMP. This is a gene therapy protocol using autologous haematopoietic stem cells for a patient with metachromatic leukodystrophy (MLD).

C.12: Submission of the final report from studies CUP 206258 and HE 205029 listed as category 3 studies in the RMP. These are Expanded Access Programs (EAP) for hematopoietic stem cell gene therapy OTL-200 in subjects with early-onset metachromatic leukodystrophy (MLD).

The RMP version 4.1 has also been submitted.

15.3.8. Atropine sulfate – RYJUNEA (CAP); NAP – EMA/VR/0000357137

Applicants: Santen Oy, various

PRAC Rapporteur: Dennis Lex

Scope: Update of section 5.1 of the SmPC in order to update efficacy information based on results from study SYD-101-001. This is a Phase 3, Randomized, Double Masked, Vehicle Controlled Study to Assess the Safety and Efficacy of SYD-101 Ophthalmic Solution for the Treatment of Myopia in Children. The RMP version 2 has also been submitted.

15.3.9. Cabotegravir – VOCABRIA (CAP) – EMA/VR/0000332087

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Update of sections 4.4, 4.6 and 5.2 of the SmPC in order to update information on pregnancy based on interim results from study HPTN 084/084-01; this is phase 3 double blind safety and efficacy study of long-acting injectable cabotegravir compared to daily oral TDF/FTC for pre-exposure prophylaxis in HIV-uninfected women – Pregnancy Safety and PK Interim Analysis; the Package Leaflet is updated accordingly. The RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template and to make typographical edits.

15.3.10. Cabotegravir – APRETUDE (CAP) – EMA/VR/0000331993

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Update of sections 4.6 and 5.2 of the SmPC in order to update information and recommendations on pregnancy, based on interim results from the open label extension (OLE) phase of the Phase 3 study HPTN 084 (study 201739) on the use of cabotegravir (CAB) for HIV-1 pre-exposure prophylaxis (PrEP) during pregnancy. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce updates to the information on excipients in alignment with the excipient guideline and to introduce minor editorial and formatting changes to the PI.

15.3.11. Capivasertib – TRUQAP (CAP) – EMA/VR/0000293735

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Extension of indication to include include Truqap in combination with abiraterone for the treatment of metastatic castration-sensitive prostate cancer characterized by PTEN deficient tumours based on non-clinical and clinical dataset, including interim results from the pivotal study D361BC00001 (CAPItello-281); this is a Phase III double-blind, randomised, placebo-controlled study assessing the efficacy and safety of capivasertib + abiraterone versus placebo + abiraterone as treatment for patients with de novo metastatic hormone-sensitive prostate cancer (mHSPC) characterised by PTEN deficiency; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

15.3.12. Dabigatran etexilate – PRADAXA (CAP) – EMA/VR/0000347421

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: A grouped application consisting of:

Type II (C.4): Update sections 4.1 and 4.2 of the SmPC following the deletion of pharmaceutical form "coated granules"; the Package Leaflet, Annex II, and Labelling are updated accordingly. An updated RMP version 43.0 has also been submitted. In addition, the Applicant took the opportunity to bring the PI in line with the latest QRD template (version 10.4), and to introduce editorial and linguistic changes to the translated PI for Sweden, Spain, Denmark, Norway, Netherland and France.

Type IB (C.7.a): Delete the pharmaceutical form "coated granules" from the Pradaxa marketing authorisation (EU/1/08/442/025-030).

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

Applicant: International Partnership For Microbicides

PRAC Rapporteur: Jan Neuhauser

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

15.3.14. Dasatinib – SPRYCEL (CAP); NAP – EMA/VR/0000356665

Applicants: Bristol-Myers Squibb Pharma EEIG, various

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Update of section 4.8 of the SmPC in order to remove the wording referring to the absence of pleural effusion and pulmonary arterial hypertension in paediatric patients following the update in Company Core Data Sheet and based on results from study CA180226; this is an open label, multi-center, Phase 2 study of dasatinib therapy in children and adolescents with newly diagnosed CP-CML or with Ph+ leukaemias resistant or intolerant to imatinib. The RMP version 19.0 has also been submitted.

15.3.15. Deferasirox – EXJADE (CAP) – EMA/VR/0000333352

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of sections 4.3 and 4.5 of the SmPC in order to remove the existing contraindication for the combination of deferasirox with other iron chelator therapies, based on a cumulative review of the available data. The Package Leaflet is updated accordingly. The RMP version 24.0 has also been submitted.

15.3.16. Delgocitinib – ANZUPGO (CAP) – EMA/VR/0000315280

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include treatment of adolescents 12 years and older with moderate to severe chronic hand eczema (CHE) for whom topical corticosteroids are inadequate or inappropriate for ANZUPGO, based on final results from study LP0133-1426 (DELTA TEEN); this is a phase 3 pivotal clinical trial to evaluate efficacy and safety of twice-daily applications of delgocitinib cream compared with cream vehicle for a 16-week treatment period in adolescents 12-17 years of age with moderate to severe chronic hand eczema. The trial is a randomized, double-blind, vehicle-controlled study. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

15.3.17. Dolutegravir – TIVICAY (CAP) – EMA/VR/0000351003

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include, in combination with other anti-retroviral medicinal products, the treatment of Human Immunodeficiency Virus (HIV) infected neonates from birth to less than 4 weeks and weighing at least 2 kg for TIVICAY, based on safety, tolerability, and PK data from the study 212161 (IMPAACT 2023) conducted in term (gestational age >=37 weeks) neonates exposed to HIV-1 weighing at least 2 kg and enrolled within 5 days of birth who received dolutegravir (DTG) in addition to standard of care prophylaxis. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 23.0 of the RMP has also been submitted. In addition, the MAH is taking the opportunity to introduce minor amendments to the PI.

15.3.18. Enfortumab vedotin – PADCEV (CAP) – EMA/VR/0000336191

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include Padcev, in combination with pembrolizumab, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment, is indicated for the treatment of adults with muscle invasive bladder cancer (MIBC) who are eligible for cisplatin-containing chemotherapy, based on the results from Interim Analysis 1 of the pivotal Study KN-B15 (EV-304); this is a phase 3, randomized, open-label study to evaluate perioperative enfortumab vedotin plus pembrolizumab (MK-3475) versus neoadjuvant gemcitabine and cisplatin in cisplatin-eligible participants with Muscle-Invasive Bladder Cancer. As consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC have been updated; the Package Leaflet is updated accordingly. Version 6.1 of the RMP is submitted, to reflect the updated data. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

15.3.19. Epcoritamab – TEPKINLY (CAP); NAP – EMA/VR/0000358245

Applicants: Abbvie Deutschland GmbH & Co. KG, various

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Update of sections 4.8, 5.1, and 5.2 of the SmPC in order to update the efficacy and safety information based on results from study GCT3013-05 listed as a specific obligation (category 2) in the Annex II; this is a randomized, open-label, phase 3 trial of epcoritamab vs investigator's choice chemotherapy in relapsed/refractory diffuse large B-cell lymphoma. The Package Leaflet and Annex II are updated accordingly. The RMP version 4.1.0 has also been submitted.

15.3.20. Exagamglogene autotemcel – CASGEVY (CAP); NAP – EMA/VR/0000356719

Applicants: Vertex Pharmaceuticals (Ireland) Limited, various

PRAC Rapporteur: Bianca Mulder

Scope: Update of sections 4.8 and 5.1 of the SmPC in order to update clinical safety and efficacy information based on final results from study CTX001-111 (in subjects with transfusion-dependent β-thalassemia (TDT)) and study CTX001-121 (in subjects with severe sickle cell disease (SCD)) as well as interim results from study CTX001-131 (long-term follow-up in subjects with either TDT or severe SCD), listed as specific obligations in the Annex II. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce additional changes to the PI.

15.3.21. Fenfluramine – FINTEPLA (CAP) – EMA/VR/0000350597

Applicant: UCB Pharma

PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include treatment of seizures associated with cyclin-dependant kinase-like 5 (CDKL5) deficiency disorder (CDD) for patients aged 1 year and older as adjunctive therapy in patients inadequately controlled with anti-seizure medicines, for FINTEPLA, based on results from study ZX008-2103 (EP0216). This is a Phase 3, randomized, double-blind, placebo-controlled, fixed-dose, multicenter study to assess the efficacy and safety of fenfluramine HCl when used as adjunctive therapy for seizures in participants with CDD. 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 5.4 of the RMP has also been submitted.

15.3.22. Fenfluramine – FINTEPLA (CAP) – EMA/VR/0000350494

Applicant: UCB Pharma

PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include treatment of seizures associated with Dravet syndrome in patients aged 1 to <2 years for FINTEPLA based on results from EP0213 study. EP0213 is an open- label, single-arm, phase 3 study to evaluate safety, tolerability, and

pharmacokinetics of fenfluramine HCl (Hydrochloride) in infants 1 year to less than 2 years of age with Dravet syndrome. As 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 5.3 of the RMP has also been submitted. The PI is brought in line with the latest QRD template version 10.4. In addition, the MAH took the opportunity to implement editorial changes to the PI.

15.3.23. Filgotinib – JYSELECA (CAP) – EMA/VR/0000350853

Applicant: Alfasigma S.p.A.

PRAC Rapporteur: Petar Mas

Scope: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update long term efficacy and safety information following final results from study GS-US-417-0304 (FINCH 4), listed as a category 3 study in the RMP, and based on the pooled safety data from the Phase 2 and Phase 3 clinical studies conducted with figotinib in rheumatoid arthritis patients. FINCH 4 is a Phase 3 multicenter, open-label, long-term extension (LTE) study to assess the safety and efficacy of filgotinib in subjects with rheumatoid arthritis. The RMP version 7.2 and Annex II have also been updated.

15.3.24. Florbetapir (18F) – AMYVID (CAP) – EMA/VR/0000333287

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Dennis Lex

Scope: Update of section 4.8 of the SmPC in order to revise the frequency category of ADRs and include additional adverse reaction terms related to injection site reactions based on a pooled safety analysis incorporating cumulative florbetapir (18F) exposure data from 26 979 subjects from 48 clinical trials; the Package Leaflet is updated accordingly. The RMP version 6.1 has also been submitted. In addition, the MAH took the opportunity update Annex II.D of the SmPC to align with proposed RMP changes.

15.3.25. Givinostat – DUVYZAT (CAP) – EMA/VR/0000343703

Applicant: Italfarmaco S.p.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Update of section 5.3 of the SmPC based on results from carcinogenicity studies in mice and rat. The RMP version 1.1 has also been submitted.

15.3.26. Givinostat – DUVYZAT (CAP) – EMA/VR/0000343737

Applicant: Italfarmaco S.p.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.2 and 5.2 of the SmPC based on final results from study ITF/2357/60. This is a Phase I, open-label, non-randomized study to evaluate the pharmacokinetic, safety and tolerability of ITF2357 given as an oral single 50 mg dose in participants with chronic hepatic impairment relative to matched participants with normal hepatic function. The RMP version 1.1 has also been submitted.

15.3.27. Glofitamab – COLUMVI (CAP) – EMA/VR/0000327100

Applicant: Roche Registration GmbH

PRAC Rapporteur: Veronika Macurova

Scope: Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add a new warning on 'haemophagocytic lymphohistiocytosis' and to add it to the list of adverse drug reactions (ADRs) with frequency not known, based on a drug safety report. The Package Leaflet is updated accordingly. The RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and administrative changes to the PI.

15.3.28. Glofitamab – COLUMVI (CAP) – EMA/VR/0000348695

Applicant: Roche Registration GmbH

PRAC Rapporteur: Veronika Macurova

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add 'Progressive multifocal leukoencephalopathy (PML)' to the list of adverse drug reactions (ADRs) with frequency 'not known' based on post-marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 7 has also been submitted.

15.3.29. Ivacaftor – KALYDECO (CAP) – EMA/VR/0000343903

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: A grouped application consisting of:

Type II variation (C.6.a) Extension of indication in combination with ivacaftor/tezacaftor/elexacaftor for existing treatment of cystic fibrosis (CF) to paediatric patients aged 1 to less than 6 years who have at least one non Class I mutation in the CFTR gene, for KALYDECO granules, based on interim results from study VX22-445-122; this is a phase 3, open-label study evaluating the pharmacokinetics, safety, and tolerability of elexacaftor/tezacaftor/ivacaftor in cystic fibrosis subjects 12 to less than 24 months of age; As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 16.1 of the RMP has also been submitted.

15.3.30. Procedure withdrawn by the MAH.Ivacaftor / Tezacaftor / Elexacaftor – KAFTRIO (CAP) – EMA/X/0000343848

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Dennis Lex

Scope: Extension application to add a new strength, 45 mg/30 mg/60 mg granules, grouped with a type II variation (C.6.a) to extend the existing indication of cystic fibrosis (CF) to paediatric patients aged 1 to less than 6 years who have at least one non-Class I mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, for the granules strengths (60mg/40mg/80mg and 75mg/50mg/100mg). The RMP (version 10.4) is updated in accordance.

15.3.31. Procedure withdrawn by the MAH.Levacetylleucine – AQNEURSA (CAP) – EMA/VR/0000354947

Applicant: Intrabio Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: A grouped application consisting of:

C.6: Extension of indication to include treatment of Ataxia-telangiectasia for AQNEURSA based on results from study IB1001-303. This is a Phase 3 study to investigate the effects of N-Acetyl-L-Leucine on Ataxia-Telangiectasia (A-T). As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

C.6: Modification of the approved indication for Niemann-Pick type C disease to include treatment of the neurological manifestations in patients aged 4 years and older and weighing at least 15 kg based on results from study IB1001-301. This is a Phase III study to assess the safety and efficacy of N-Acetyl-L-Leucine versus Placebo for the treatment of Niemann-Pick type C disease (NPC). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted.

C.4: Update of sections 4.2 and 6.6 of the SmPC in order to add the use of smaller feeding tubes for enteral administration and to add yoghurt as an alternative administration method for young children based on results from studies IB1001-201, IB1001-202, IB1001 203, and IB1001-301. The Package Leaflet is updated accordingly.

15.3.32. Maralixibat – LIVMARLI (CAP) – EMA/VR/0000320544

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application consisting of:
C.I.13: Submission of the final report from study MRX- 503 listed as category 3 study in the RMP. This is a phase 3 study to Evaluate the Long-Term Safety and Efficacy of Maralixibat in the Treatment of Subjects with Progressive Familial Intrahepatic Cholestasis (PFIC). The RMP version 7.2 has also been submitted.
C.I.13: Submission of the final report for a retrospective study titled ''Analysis of Clinical Outcomes in PFIC: Comparison of Maralixibat from Studies MRX-502/503 and MRX-801 versus Natural History (NAtural course and Prognosis of PFIC and Effect of biliary Diversion [NAPPED])''.

15.3.33. Melphalan flufenamide – PEPAXTI (CAP) – EMA/VR/0000350278

Applicant: Oncopeptides AB

PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include, in combination with dexamethasone, the treatment of adult patients with multiple myeloma who have received at least two prior lines of therapies, whose disease is refractory to lenalidomide and the last line of therapy, for

PEPAXTI, based on final results from study OP-103 (OCEAN); this is a randomized, open-label phase 3 study in patients with relapsed or refractory multiple myeloma following 2 to 4 lines of prior therapies and who were refractory to lenalidomide and the last line of therapy. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.4 of the RMP has also been submitted.

15.3.34. Metreleptin – MYALEPTA (CAP); NAP – EMA/VR/0000356904

Applicants: Chiesi Farmaceutici S.p.A., various

PRAC Rapporteur: Adam Przybylkowski

Scope: Update of sections 4.4, and 4.8 of the SmPC in order to amend existing safety information on T cell lymphoma based on cumulative safety evidence from the clinical studies, post-marketing data, and literature; the Annex II and the Package Leaflet are updated accordingly. The RMP version 2.4 to remove Lymphoma from the list of Important Potential Risks has also been submitted. In addition, the MAH took the opportunity to update the information on polysorbates.

15.3.35. Mirabegron – BETMIGA (CAP) – EMA/VR/0000349861

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Update of section 4.4 of the SmPC in order to add a new warning on ANCA Associated Vasculitis based on clinical, post-marketing, literature, and nonclinical evidence. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

15.3.36. Naloxone – NYXOID (CAP) – EMA/VR/0000325329

Applicant: Mundipharma Corporation (Ireland) Limited

PRAC Rapporteur: Liana Martirosyan

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

15.3.37. Obinutuzumab – GAZYVARO (CAP) – EMA/VR/0000350995

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Extension of indication to include treatment of adult patients with primary membranous nephropathy (pMN) for GAZYVARO, based on the results from study WA41937 (MAJESTY); this is a Phase III, randomized, open-label active comparator-controlled multicenter study to evaluate efficacy and safety of obinutuzumab in patients with pMN. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor edits to the PI.

15.3.38. Obinutuzumab – GAZYVARO (CAP) – EMA/VR/0000327013

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jenny-Maria Jönsson

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

C.6.a: Extension of indication to include treatment of adult patients with active systemic lupus erythematosus (SLE) who are receiving standard therapy, for GAZYVARO, based on the results from study CA42750 (ALLEGORY); this is a Phase III, randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy and safety of obinutuzumab in patients with SLE treated with standard-of-care therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the SmPC with minor edits. Version 12 of the RMP has also been submitted.

C.4: Update of section 4.2 of the SmPC to introduce short duration infusion (SDI) as method of administration for SLE patients, supported by previously submitted data in patients with Follicular Lymphoma and by simulations conducted using an integrated population PK model to estimate exposures following administration as an SDI to SLE patients.

15.3.39. Obinutuzumab – GAZYVARO (CAP) – EMA/VR/0000349826

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Extension of indication to include treatment of patients 2 years of age and older with idiopathic nephrotic syndrome (INS) for GAZYVARO, based on final results from Phase 3 INShore (WA43380) study; this is a Phase 3, international, multicenter, randomised open label study to evaluate the efficacy and safety of Gazyvaro versus mycophenolate mofetil (MMF) in patients with childhood onset idiopathic nephrotic syndrome. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

15.3.40. Ocrelizumab – OCREVUS (CAP) – EMA/VR/0000313041

Applicant: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Liver Injury' and to add it to the list of adverse drug reactions (ADRs) with frequency 'rare', based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to submit a DHPC Letter and to introduce minor changes to the PI, including the Labelling section.

15.3.41. Ocrelizumab – OCREVUS (CAP); NAP – EMA/VR/0000357152

Applicants: Roche Registration GmbH, various

PRAC Rapporteur: Dirk Mentzer

Scope: Update of sections 4.4 and 4.6 of the SmPC in order to update information on the use of ocrelizumab therapy pre-conception and up to the first trimester of pregnancy, and on infants potentially exposed to ocrelizumab during pregnancy or via breastfeeding, based on the final analyses of 2 clinical studies - MN42988 (MINORE) and MN42989 (SOPRANINO) and other supportive data (the final CSR from an observational pregnancy registry (WA40063) and a cumulative review of pregnancy, lactation and infant data from women with multiple sclerosis (MS) treated with ocrelizumab from the Company Global Safety Database). The Package Leaflet is updated accordingly. The RMP version 17.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial updates and clarifications to the PI.

15.3.42. Pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) – VAXNEUVANCE (CAP); NAP – EMA/VR/0000356991

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

PRAC Rapporteur: Dirk Mentzer

Scope: Update of section 5.1 of the SmPC in order to introduce efficacy information against acute otitis media in infants and children based on final results from post authorisation efficacy study V114-032 listed as obligation in the Annex II; this is a phase 3, randomized, double-blind, parallel-group, multicenter, efficacy study to evaluate V114 in the prevention of VT-AOM in healthy infants enrolled at approximately 2 months of age. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI.

15.3.43. Radium-223 – XOFIGO (CAP) – EMA/VR/0000350998

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Submission of the final report from study 20510 RADIANT listed as an obligation in the Annex II of the Product Information. The Annex II and the RMP (version 9.1) are updated accordingly.

15.3.44. Radium-223 – XOFIGO (CAP) – EMA/VR/0000351078

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Extension of indication to include the combination treatment with enzalutamide for mCRPC with bone metastases for XOFIGO and modifications of existing indication, based on final results from study PEACE-3; this is a randomized multicenter phase III trial comparing enzalutamide vs. a combination of Ra223 and enzalutamide in asymptomatic or mildly symptomatic castration resistant prostate cancer patients metastatic to bone; As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet ise updated in accordance. Version 8.2 of the RMP has also been submitted.

15.3.45. Respiratory syncytial virus mRNA vaccine (nucleoside modified) – MRESVIA (CAP) – EMA/VR/0000320244

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

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 mRESVIA in immunocompromised individuals 18 years of age and older, based on interim results from study mRNA-1345-P303 Part B; this is a Phase 3 study to evaluate the immunogenicity and safety of mRNA-1345, an mRNA vaccine targeting respiratory syncytial virus, in high-risk adults. The updated RMP version 6.0 has also been submitted.

15.3.46. Rilzabrutinib – WAYRILZ (CAP); NAP – EMA/VR/0000357430

Applicants: Sanofi B.V., various

PRAC Rapporteur: Dennis Lex

Scope: A grouped application consisting of:
C.12: Submission of the final report from study LUNA-2 (PRN1008 010), listed as a category 3 study in the RMP. This is a Phase 1/2 Study Investigating the Safety, Pharmacokinetics, and Clinical Activity of Rilzabrutinib, an Oral Bruton tyrosine kinase (BTK) Inhibitor, in Patients with Relapsed Immune Thrombocytopenia. The RMP version 2 has also been submitted.

C.12: Submission of the final report from study LUNA-3 (PRN1008 018), listed as a category 3 study in the RMP. This is a Phase 3, Multicenter, Randomized, Double-Blind, Placebo Controlled, Parallel-Group Study with an Open-Label Extension to Evaluate the Efficacy and Safety of Oral Rilzabrutinib in Adults and Adolescents with Persistent or Chronic Immune Thrombocytopenia. The RMP version 2 has also been submitted.

15.3.47. Selumetinib – KOSELUGO (CAP) – EMA/VR/0000347385

Applicant: AstraZeneca AB

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: A grouped application consisting of:
C.4: Update of sections 4.4, and 4.8 of the SmPC in order to include revised information on the retinal disorders based on review of all available safety data. The RMP version 5.2 has also been submitted.
C.4: Update of sections 4.4, and 4.8 of the SmPC in order to revise time-to-onset data following correction of programming error in the KOMET study, describing the median time to onset at maximum Common Terminology Criteria for Adverse Event (CTCAE) grade.

15.3.48. Somapacitan – SOGROYA (CAP) – EMA/VR/0000350795

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Dennis Lex

Scope: Extension of indication for SOGROYA to include treatment of growth failure in children and adolescents with Turner Syndrome (TS) based on final results from three clinical studies, two phase 3 studies (4467 and 4469) and a phase 2 study (4245). 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 5.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the QRD template version 10.4.

15.3.49. Sulfur hexafluoride – SONOVUE (CAP) – EMA/VR/0000355106

Applicant: Bracco International B.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of section 4.3 of the SmPC in order to remove an existing contraindication based on post-marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 11.0 has also been submitted.

15.3.50. Talazoparib – TALZENNA (CAP) – EMA/VR/0000350865

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include TALZENNA in combination with enzalutamide for the treatment of homologous recombination repair (HRR) gene-mutated metastatic hormone-sensitive prostate cancer (mHSPC), based on interim results from study C3441052 (TALAPRO-3); this is a pivotal multinational, randomised, double-blind Phase 3 study of talazoparib + enzalutamide versus placebo + enzalutamide in men with HRRm mHSPC. 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 3.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

15.3.51. Trastuzumab – HERZUMA (CAP) – EMA/X/0000343856

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Dirk Mentzer

Scope: Extension application to introduce addition of a new pharmaceutical form, new strength and new route of admin (600 mg solution for injection, subcutaneous use). Due to the introduction of the subcutaneous formulation, the Product Information of the IV formulations (150mg + 420mg powder for concentrate for solution for infusion) were also updated in addition to editorial changes according to the last version of the QRD guidance.

15.3.52. Ustekinumab – IMULDOSA (CAP) – EMA/VR/0000347840

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Quality

16. Annex I - Periodic safety update reports (PSURs)

Based on the assessment of the following PSURs, PRAC concluded that the benefit-risk balance of the medicine(s) mentioned below remains favourable in the approved indication(s) and adopted a recommendation to maintain the current terms of the marketing authorisation(s) together with the assessment report. As per the agreed criteria, the procedures listed below were finalised at the PRAC level without further plenary discussion.

The next PSURs should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal, unless changes apply as stated in the outcome of the relevant PSUR/PSUSA procedure(s).

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

16.1.1. Abacavir – ZIAGEN (CAP) – EMA/PSUR/0000344374

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00000010/202512)

16.1.2. Adalimumab – AMGEVITA (CAP); AMSPARITY (CAP); HEFIYA (CAP); HUKYNDRA (CAP); HULIO (CAP); HUMIRA (CAP); HYRIMOZ (CAP); IDACIO (CAP); IMRALDI (CAP); LIBMYRIS (CAP); YUFLYMA (CAP); NAP – EMA/PSUR/0000344425

Applicants: Abbvie Deutschland GmbH & Co. KG, Amgen Europe B.V., Samsung Bioepis NL B.V., Sandoz GmbH, Biosimilar Collaborations Ireland Limited, Fresenius Kabi Deutschland GmbH, Pfizer Europe MA EEIG, Celltrion Healthcare Hungary Kft., STADA Arzneimittel AG, various

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010783/202512)

16.1.3. Amino acids – MAAPLIV (CAP) – EMA/PSUR/0000344441

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00011149/202601)

16.1.4. Angiotensin II – GIAPREZA (CAP) – EMA/PSUR/0000344429

Applicant: Paion Deutschland GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010785/202512)

16.1.5. Avapritinib – AYVAKYT (CAP) – EMA/PSUR/0000344431

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010878/202601)

16.1.6. Birch bark extract – FILSUVEZ (CAP) – EMA/PSUR/0000344404

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00010446/202601)

16.1.7. Brensocatib – BRINSUPRI (CAP) – EMA/PSUR/0000344438

Applicant: Insmed Netherlands B.V.

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00011170/202602)

16.1.8. Brexucabtagene autoleucel – TECARTUS (CAP) – EMA/PSUR/0000344416

Applicant: Kite Pharma EU B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010903/202601)

16.1.9. Catumaxomab – KORJUNY (CAP) – EMA/PSUR/0000344454

Applicant: Atnahs Pharma Netherlands B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011108/202602)

16.1.10. Crovalimab – PIASKY (CAP) – EMA/PSUR/0000344450

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011071/202602)

16.1.11. Danicopan – VOYDEYA (CAP) – EMA/PSUR/0000344446

Applicant: Alexion Europe

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011056/202601)

16.1.12. Dapivirine – DAPIVIRINE VAGINAL RING 25 MG (Art 58) – EMA/PSUR/0000339021

Applicant: International Partnership For Microbicides

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUV Dapivirine)

16.1.13. Delgocitinib – ANZUPGO (CAP) – EMA/PSUR/0000344461

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011091/202601)

16.1.14. Donanemab – KISUNLA (CAP) – EMA/PSUR/0000344439

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00011165/202601)

16.1.15. Elinzanetant – LYNKUET (CAP) – EMA/PSUR/0000344463

Applicant: Bayer AG

PRAC Rapporteur: Guðrún Stefánsdóttir

Scope: Evaluation of a PSUSA procedure (PSUSA/00011171/202601)

16.1.16. Epinephrine – EURNEFFY (CAP) – EMA/PSUR/0000344451

Applicant: Alk-Abello A/S

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011081/202602)

16.1.17. Eptacog alfa (activated) – NOVOSEVEN (CAP) – EMA/PSUR/0000344447

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001245/202512)

16.1.18. Ertugliflozin – STEGLATRO (CAP); Ertugliflozin / Metformin hydrochloride – SEGLUROMET (CAP); Ertugliflozin / Sitagliptin – STEGLUJAN (CAP) – EMA/PSUR/0000344430

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010784/202512)

16.1.19. Evinacumab – EVKEEZA (CAP) – EMA/PSUR/0000344420

Applicant: Ultragenyx Germany GmbH

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010945/202602)

16.1.20. Faricimab – VABYSMO (CAP) – EMA/PSUR/0000344426

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00011016/202601)

16.1.21. Garadacimab – ANDEMBRY (CAP) – EMA/PSUR/0000344455

Applicant: CSL Behring GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011109/202601)

16.1.22. Gefapixant – LYFNUA (CAP) – EMA/PSUR/0000344383

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000132/202601)

16.1.23. Lamivudine / Abacavir – KIVEXA (CAP) – EMA/PSUR/0000344375

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00000011/202512)

16.1.24. Lecanemab – LEQEMBI (CAP) – EMA/PSUR/0000344458

Applicant: Eisai GmbH

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00011132/202601)

16.1.25. Lisocabtagene maraleucel / Lisocabtagene maraleucel – BREYANZI (CAP) – EMA/PSUR/0000344421

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010990/202602)

16.1.26. Lonoctocog alfa – AFSTYLA (CAP) – EMA/PSUR/0000344406

Applicant: CSL Behring GmbH

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010559/202601)

16.1.27. Lutetium (177Lu) oxodotreotide – LUTATHERA (CAP) – EMA/PSUR/0000344414

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010643/202512)

16.1.28. Metreleptin – MYALEPTA (CAP) – EMA/PSUR/0000344434

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010700/202601)

16.1.29. Mexiletine – NAMUSCLA (CAP) – EMA/PSUR/0000344427

Applicant: Lupin Europe GmbH

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00010738/202512)

16.1.30. Mirdametinib – EZMEKLY (CAP) – EMA/PSUR/0000344444

Applicant: Merck Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011161/202602)

16.1.31. Omalizumab – OMLYCLO (CAP); XOLAIR (CAP); NAP – EMA/PSUR/0000344391

Applicants: Novartis Europharm Limited, Celltrion Healthcare Hungary Kft., various

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00002214/202512)

16.1.32. 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/0000344449

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00011057/202601)

16.1.33. Pirtobrutinib – JAYPIRCA (CAP) – EMA/PSUR/0000344380

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000155/202601)

16.1.34. Plerixafor – MOZOBIL (CAP) – EMA/PSUR/0000344390

Applicant: Sanofi B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00002451/202512)

16.1.35. Pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) – VAXNEUVANCE (CAP) – EMA/PSUR/0000344419

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010975/202601)

16.1.36. Quadrivalent influenza vaccine (recombinant, prepared in cell culture) – SUPEMTEK TETRA (CAP); Trivalent influenza vaccine (recombinant, prepared in cell culture) – SUPEMTEK (CAP) – EMA/PSUR/0000344432

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00010886/202601)

16.1.37. Romosozumab – EVENITY (CAP) – EMA/PSUR/0000344428

Applicant: UCB Pharma

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00010824/202601)

16.1.38. Rucaparib – RUBRACA (CAP) – EMA/PSUR/0000344413

Applicant: pharmaand GmbH

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00010694/202512)

16.1.39. Sarilumab – KEVZARA (CAP) – EMA/PSUR/0000344412

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00010609/202601)

16.1.40. Sebetralstat – EKTERLY (CAP) – EMA/PSUR/0000344437

Applicant: Kalvista Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00011154/202601)

16.1.41. Sutimlimab – ENJAYMO (CAP) – EMA/PSUR/0000344445

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011023/202602)

16.1.42. Tafasitamab – MINJUVI (CAP) – EMA/PSUR/0000344435

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00010951/202601)

16.1.43. Tagraxofusp – ELZONRIS (CAP) – EMA/PSUR/0000344436

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010896/202512)

16.1.44. Talquetamab – TALVEY (CAP) – EMA/PSUR/0000344393

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00000099/202602)

16.1.45. Tebentafusp – KIMMTRAK (CAP) – EMA/PSUR/0000344442

Applicant: Immunocore Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010991/202601)

16.1.46. Tecovirimat – TECOVIRIMAT SIGA (CAP) – EMA/PSUR/0000344448

Applicant: Siga Technologies Netherlands B.V.

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010971/202601)

16.1.47. Teprotumumab – TEPEZZA (CAP) – EMA/PSUR/0000344456

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011148/202601)

16.1.48. Tezacaftor / Ivacaftor – SYMKEVI (CAP) – EMA/PSUR/0000344423

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00010730/202602)

16.1.49. Tiratricol – EMCITATE (CAP) – EMA/PSUR/0000344457

Applicant: Rare Thyroid Therapeutics International AB

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00011114/202602)

16.1.50. Ustekinumab – FYMSKINA (CAP); IMULDOSA (CAP); OTULFI (CAP); PYZCHIVA (CAP); QOYVOLMA (SRD) (CAP); STELARA (CAP); STEQEYMA (CAP); USGENA (CAP); USRENTY (CAP); USYMRO (CAP); UZPRUVO (CAP); WEZENLA (CAP); YESINTEK (CAP) – EMA/PSUR/0000344407

Applicants: Celltrion Healthcare Hungary Kft., Janssen Cilag International, STADA Arzneimittel AG, Biosimilar Collaborations Ireland Limited, Fresenius Kabi Deutschland GmbH, Amgen Technology (Ireland) Unlimited Company, Samsung Bioepis NL B.V., Accord Healthcare S.L.U., Formycon AG, Gedeon Richter Plc.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00003085/202512)

16.1.51. Vericiguat – VERQUVO (CAP) – EMA/PSUR/0000344417

Applicant: Bayer AG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010950/202601)

16.1.52. Voclosporin – LUPKYNIS (CAP) – EMA/PSUR/0000344422

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011020/202601)

16.1.53. Vorasidenib – VORANIGO (CAP) – EMA/PSUR/0000344440

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00011157/202602)

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

16.2.1. Lamivudine / Abacavir / Zidovudine – TRIZIVIR (CAP); NAP – EMA/PSUR/0000344408

Applicants: ViiV Healthcare B.V., various

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00003144/202512)

16.2.2. Repaglinide – NOVONORM (CAP); PRANDIN (CAP); NAP – EMA/PSUR/0000344399

Applicants: Novo Nordisk A/S, various

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00002618/202512)

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

16.3.1. 5 fluorouracil (topical application) – EMA/PSUR/0000344410

Applicants: various

PRAC Lead: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010000/202601)

16.3.2. Alitretinoin (oral use) – EMA/PSUR/0000344424

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010710/202601)

16.3.3. Alizapride – EMA/PSUR/0000344378

Applicants: various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00000091/202601)

16.3.4. Allergen for therapy: Dactylis Glomerata L., Phleum Pratense L., Anthoxanthum Odoratum L., Lolium Perenne L., Poa Pratensis L. (sublingual tablet) – EMA/PSUR/0000344403

Applicants: various

PRAC Lead: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010465/202512)

16.3.5. Amino acid combinations (only combinations of pure amino acids or combination of amino acids with mineral compounds/electrolytes, i.v. application) – EMA/PSUR/0000344409

Applicants: various

PRAC Lead: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010187/202601)

16.3.6. Aminophylline – EMA/PSUR/0000344384

Applicants: various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00000164/202601)

16.3.7. Amisulpride – EMA/PSUR/0000344386

Applicants: various

PRAC Lead: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00000167/202601)

16.3.8. Antithrombin III – EMA/PSUR/0000344418

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00003159/202512)

16.3.9. Atropine / diphenoxylate – EMA/PSUR/0000344381

Applicants: various

PRAC Lead: Jana Pecherova

Scope: Evaluation of a PSUSA procedure (PSUSA/00000269/202601)

16.3.10. Benzydamine / cetylpyridine – EMA/PSUR/0000344385

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000378/202601)

16.3.11. Beta-alanine – EMA/PSUR/0000344401

Applicants: various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00010510/202601)

16.3.12. Bezafibrate – EMA/PSUR/0000344389

Applicants: various

PRAC Lead: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00000405/202601)

16.3.13. Biotin – EMA/PSUR/0000344397

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000414/202601)

16.3.14. Calcitriol – EMA/PSUR/0000344379

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000495/202601)

16.3.15. Carboprost – EMA/PSUR/0000344396

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00000560/202601)

16.3.16. Cilostazol – EMA/PSUR/0000344415

Applicants: various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010209/202601)

16.3.17. Estriol – EMA/PSUR/0000344405

Applicants: various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001282/202512)

16.3.18. Exemestane – EMA/PSUR/0000344395

Applicants: various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00001345/202512)

16.3.19. Famciclovir – EMA/PSUR/0000344387

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00001349/202512)

16.3.20. Nifurtimox – EMA/PSUR/0000344452

Applicants: various

PRAC Lead: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00011088/202601)

16.3.21. Sertindole – EMA/PSUR/0000344394

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00002695/202601)

16.4. Follow-up to PSUR/PSUSA procedures

None

16.5. Variation procedure(s) resulting from PSUSA evaluation

None

16.6. Expedited summary safety reviews[26]

None

17. Annex I – Post-authorisation safety studies (PASS)

Based on the assessment of the following PASS protocol(s), result(s), interim result(s) or feasibility study(ies), and following endorsement of the comments received, PRAC adopted the conclusion of the Rapporteurs on their assessment for the medicines listed below without further plenary discussion.

[26] 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

17.1. Protocols of PASS imposed in the marketing authorisation(s)[27]

17.1.1. Cabotegravir – VOCABRIA (CAP); Rilpivirine – REKAMBYS (CAP) – EMA/PASS/0000358848

Applicants: ViiV Healthcare B.V., Janssen Cilag International

PRAC Rapporteur: Liana Martirosyan

Scope: PASS 107o [PASS protocol amendment]: Drug Utilization, Adherence, Effectiveness and Resistance: A Prospective Observational Cohort Study in People living with HIV (PLWH) initiating ARV regimen of CAB+RPV LA in Collaboration with EuroSIDA

17.1.2. Lonafarnib – ZOKINVY (CAP) – EMA/PASS/0000357585

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: PASS amendment [107o]: Prospective Non-Interventional observational study to evaluate the long-term safety and effectiveness of lonafarnib treatment among patients with Hutchinson-Gilford Progeria Syndrome (HGPS) or a processing deficient progeroid laminopathy (PDPL) in real-world clinical care settings (STI-LNF-400).

17.1.3. Mirdametinib – EZMEKLY (CAP) – EMA/PASS/0000340654

Applicant: Merck Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: PASS protocol [107n]: Non-interventional PASS to confirm the long-term safety of mirdametnib, in the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric and adult patients with neurofibromatosis type 1 (NF1) aged 2 years and above.

17.1.4. Sodium valproate (NAP) – EMA/PASS/0000328174

Applicants: various

PRAC Rapporteur: Liana Martirosyan

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

17.2. Protocols of PASS non-imposed in the marketing authorisation(s)[28]

17.2.1. Aficamten – MYQORZO (CAP) – EMA/PAM/0000347918

Applicant: Cytokinetics (Ireland) Limited

[27] In accordance with Article 107n of Directive 2001/83/EC
[28] 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

PRAC Rapporteur: Eva Jirsová

Scope: Protocol for cat 3 study in the RMP CY 6044: Meta-analysis of two Phase 3 studies (CY 6031 and CY 6032) and one Phase 2 study (CY 6021, Cohorts 1 and 2) to evaluate the cardiovascular safety profile of aficamten (MYQORZO) in patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM), focusing on time to first occurrence of major adverse cardiovascular events (MACE). This study constitutes an additional pharmacovigilance activity as described in the EU Risk Management Plan (RMP). To assess aficamten cardiovascular safety based on endpoints of time to first occurrence of MACE (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, and cardiovascular hospitalization) from randomization up to the end of study follow-up visit.

17.2.2. Cladribine – MAVENCLAD (CAP) – EMA/PAM/0000357455

Applicant: Merck Europe B.V.

PRAC Rapporteur: Carla Torre

Scope: Revised protocol version 3.0 for the non-imposed non-interventional PASS cat.3 Pregnancy outcomes in women exposed to oral cladribine: a multi-country cohort database study – CLEAR Study.

17.2.3. Delgocitinib – ANZUPGO (CAP) – EMA/PAM/0000291999

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of a revised protocol for the non-imposed non-interventional PASS "Delgocitinib cream 20 mg/g in moderate to severe chronic hand eczema and risk of non-melanoma skin cancer: a nationwide registry based long-term post-authorisation safety study", as requested as part of MEA 003.

17.2.4. Deucravacitinib – SOTYKTU (CAP) – EMA/PAM/0000357688

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

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

17.2.5. Efgartigimod alfa – VYVGART (CAP) – EMA/PAM/0000358653

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Amendment of the protocol for RMP category 3 study ARGX-113-PASS-2208: A non-interventional, post-authorisation safety study of patients treated with efgartigimod alfa

17.2.6. Efgartigimod alfa – VYVGART (CAP) – EMA/PAM/0000358063

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Protocol Amendment for the RMP category 3 study ARGX-113-2316: Post-Authorisation Safety Study (PASS) to Evaluate the Risk of Malignancies in Patients with Myasthenia Gravis (MG) Treated with Efgartigimod

17.2.7. Efgartigimod alfa – VYVGART (CAP) – EMA/PAM/0000358689

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Second interim report for the RMP category 3 study ARGX-113-PASS-2208: A Noninterventional Post-Authorisation Safety Study of Patients Treated with Efgartigimod Alfa

17.2.8. Etrasimod – VELSIPITY (CAP) – EMA/PAM/0000357465

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Bolin

Scope: Post-Authorisation Measure (PAM) [MEA] – Submission of Substantial Amendment 3 (version 4) to Protocol C5041046: "An Active Surveillance, Post-Authorization Safety Study to Characterize the Safety of Etrasimod in Patients with Ulcerative Colitis Using Real-World Data in the European Union" (as listed in PART III of RMP)

17.2.9. Inebilizumab – UPLIZNA (CAP) – EMA/PAM/0000357209

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Protocol amendment for PASS "An Observational Pregnancy Safety Study in Women with Neuromyelitis Optica Spectrum Disorder (NMOSD) or Generalized Myasthenia Gravis (gMG) Exposed to UPLIZNA® (inebilizumab-cdon) During Pregnancy

17.2.10. Inebilizumab – UPLIZNA (CAP) – EMA/PAM/0000357017

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

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

17.2.11. Mavacamten – CAMZYOS (CAP) – EMA/PAM/0000343701

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Protocol amendment of CV027013: a post-authorisation, multi-national, long-term, observational study in patients with obstructive Hypertrophic Cardiomyopathy in the real-world setting in Europe

17.2.12. Naltrexone hydrochloride / Bupropion hydrochloride – MYSIMBA (CAP) – EMA/PAM/0000349763

Applicant: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: Protocol of study (PASS) NB-454 - A Cross-Sectional Survey to Evaluate the Effectiveness of the Revised Mysimba Physician Prescribing Checklist (PPC) in Europe.

17.2.13. Nipocalimab – IMAAVY (CAP) – EMA/PAM/0000358639

Applicant: Janssen Cilag International

PRAC Rapporteur: Dirk Mentzer

Scope: Protocol for RMP category 3 study PCSNSPA0210: A Non-Interventional, Post-Authorization Safety Study (PASS) of Patients Treated with Nipocalimab for Generalized Myasthenia Gravis (gMG) in Routine Clinical Practice in the United States

17.2.14. Nipocalimab – IMAAVY (CAP) – EMA/PAM/0000357528

Applicant: Janssen Cilag International

PRAC Rapporteur: Dirk Mentzer

Scope: Protocol for RMP category 3 study PCSNSPA0211: A Post-authorization Safety Study Using US Administrative Health Insurance Claims Databases to Assess Pregnancy, Maternal, and Infant Outcomes in Women with Generalized Myasthenia Gravis Who Were Exposed to Nipocalimab During Pregnancy

17.3. Results of PASS imposed in the marketing authorisation(s)[29]

None

17.4. Results of PASS non-imposed in the marketing authorisation(s)[30]

17.4.1. Baricitinib – OLUMIANT (CAP) – EMA/VR/0000345885

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Submission of the final report of the Category 3 European Union Post-Authorisation Safety Study (EU PASS) I4V-MC-B011, Objective 4, atopic dermatitis (AD) cohort (Study B011). This is an Observational Cohort Study to Assess the Safety of Baricitinib Compared

[29] In accordance with Article 107p-q of Directive 2001/83/EC
[30] 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

with Other Therapies used in the Treatment of Atopic Dermatitis in Nordic Countries – Objective 4: Assessment of Risk Minimisation Measures. The RMP version 30.1 has also been submitted.

17.4.2. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/VR/0000343925

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

Type II (C.12): Submission of final report from study C4591052 listed as a category 3 study in the RMP. This is a non-interventional Post-Authorization Safety Study of Comirnaty Original/Omicron BA.1 and Comirnaty Original/Omicron BA.4-5 in Europe. The RMP version 17.1 has also been submitted.
Type IB (C.9.b): Submission of an updated RMP version 17.1 in order to propose to change the final results due date and a consequential change of 12-month progress reports for study C4591036, listed as a category 3 study in the RMP.

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

Applicant: Biomarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

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

17.4.4. Fexinidazole – FEXINIDAZOLE WINTHROP (CAP); NAP – EMA/VR/0000356314

Applicants: Sanofi Winthrop Industrie, various

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final report for study FEXINC09395: a Post Authorization Safety Study (PASS) of Fexinidazole for Human African Trypanosomiasis: Analysis of Real-Life Safety and Effectiveness Data on Fexinidazole, listed as a category 3 study in the RMP. The RMP version 4.0 has also been submitted.

17.4.5. Ponesimod – PONVORY (CAP) – EMA/VR/0000320506

Applicant: Laboratoires Juvise Pharmaceuticals

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the final report from non-interventional post authosiration safety study PCSNSP003693 listed as a category 3 study in the RMP. This is a Survey to Assess the Effectiveness of Ponvory Educational Materials for Additional Risk Minimization Measures in the European Union.

17.4.6. Tacrolimus – ADVAGRAF (CAP); MODIGRAF (CAP); NAP – EMA/VR/0000315125

Applicants: Astellas Pharma Europe B.V., various

PRAC Rapporteur: Eamon O Murchu

Scope: Submission of the final report from noninterventional post-authorization safety study (NIPASS) listed as a category 3 study in the RMP. This is a feasibility assessment of conducting a NIPASS of outcomes associated with the use of tacrolimus around conception, or during pregnancy or lactation using data from available secondary use data sources to replicate the Transplant Pregnancy Registry International (TPRI) study. The RMP version 6.0 has also been submitted.

17.4.7. Voretigene neparvovec – LUXTURNA (CAP); NAP – EMA/VR/0000357435

Applicants: Novartis Europharm Limited, various

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of the final report from study SPKRPE-PASS, following the request from PRAC in PSUSA/00010742/202507. This is a post-authorization, multicenter, longitudinal, observational safety registry study for patients treated with voretigene neparvovec in US.

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

17.5.1. Abaloparatide – ELADYNOS (CAP) – EMA/PAM/0000357990

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Karin Erneholm

Scope: 1st interim report for European and US non-interventional PASS to evaluate cardiovascular events in patients newly exposed to abaloparatide or teriparatide.

17.5.2. Beclometasone / Formoterol / Glycopyrronium bromide – TRYDONIS (CAP) – EMA/PAM/0000350569

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Interim study results. 3rd interim report. PASS CLI-05993BA1-05 (TRIBE): 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) (MEA/01098/3).

17.5.3. Beclometasone / Formoterol / Glycopyrronium bromide – TRIMBOW (CAP) – EMA/PAM/0000350566

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Interim study results. 3rd interim report. PASS CLI-05993BA1-05 (TRIBE): 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) (MEA/01097/3).

17.5.4. Cabotegravir – VOCABRIA (CAP) – EMA/PAM/0000348704

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Interim study results. Pregnancy and Neonatal Outcomes Following Prenatal Exposure to Cabotegravir: Data from the Antiretroviral Pregnancy Registry (APR) (MEA/02050/1).

17.5.5. Cabotegravir – APRETUDE (CAP) – EMA/PAM/0000348786

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: The interim report for Category 3 MEA Antiretroviral Pregnancy Registry, as a standalone post-approval measure, for cabotegravir sodium 30mg film-coated tablets and cabotegravir prolonged- release suspension for injection (600mg/3ml) (Apretude) to monitor prenatal exposures to ARV drugs to detect a potential increase in the risk of birth defects through a prospective exposure-registration cohort and to assess maternal and foetal outcomes following cabotegravir use during pregnancy.

17.5.6. Danicopan – VOYDEYA (CAP) – EMA/PAM/0000357946

Applicant: Alexion Europe

PRAC Rapporteur: Dennis Lex

Scope: PAM [MEA]: Category 3 Study - Additional Pharmacovigilance Activity in the Risk Management Plan Submission of Paroxysmal Nocturnal Hemoglobinuria (PNH) IPIG-Registry Biennial Interim Report, Protocol ALX-PNH-502. This is the first biennial interim report for Voydeya (danicopan).

17.5.7. Dimethyl fumarate – SKILARENCE (CAP) – EMA/PAM/0000357021

Applicant: Almirall S.A.

PRAC Rapporteur: Karin Bolin

Scope: 8th Study Progress Report (2026 Annual Progress Report): "An observational Post-Authorisation Safety Study of Skilarence in European Psoriasis Registers" M-41008-40; follow on from EMA/PAM/0000280759

17.5.8. Estetrol – FYLREVY (CAP) – EMA/PAM/0000357663

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Sonja Radowan

Scope: Submission of feasibility report on potential real-world data study as additional pharmacovigilance activity in the RMP

17.5.9. Etuvetidigene autotemcel – WASKYRA (CAP) – EMA/PAM/0000357590

Applicant: Fondazione Telethon Ets

PRAC Rapporteur: Jo Robays

Scope: Updated PASS protocol (version 4.0) for the imposed interventional Post-Approval Safety Study (PASS) WAS-TLT003-01, a Category 1- Required additional pharmacovigilance activity, a Phase III/IV low-interventional study, with primary objective being the assessment of long-term safety across multiple endpoints.
The updated protocol includes the changes recommended by CAT and PRAC in their assessment of v3.0 (EMA/PAM/0000334844), as well as other changes required by the FDA and other changes introduced by the Applicant, with the aim of maintaining a globally aligned protocol.

17.5.10. Fingolimod – GILENYA (CAP) – EMA/PAM/0000320326

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: 6th Annual Interim Report of Study CFTY720D2311: A two-year, double-blind, randomized, multicenter, active-controlled Core Phase study to evaluate the safety and efficacy of fingolimod administered orally once daily versus interferon β-1a i.m. once weekly in pediatric patients with multiple sclerosis with five-year fingolimod Extension Phase.

17.5.11. Hydroxycarbamide – XROMI (CAP) – EMA/PAM/0000350555

Applicant: Lipomed GmbH

PRAC Rapporteur: Jo Robays

Scope: Submission of the interim progress report related to the protocol NOVDD-001 related to the Category 3 MEA – Required additional pharmacovigilance activities (Planned Additional Pharmacovigilance Studies) in the approved Risk Management Plan: 'A comparative observational study to evaluate the safety and effectiveness of Xromi (hydroxycarbamide oral solution 100mg/ml) for the prevention of vasoocclusive complications of sickle cell disease in children under 2 years of age'.

17.5.12. Inebilizumab – UPLIZNA (CAP) – EMA/PAM/0000357900

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Ad hoc interim report submission of PASS Cat.3 Study CorEvitas SPHERES (Synergy of Prospective Health & Experimental Research for Emerging Solutions) Registry for Neuromyelitis Optica Spectrum Disorder (NMOSD)

17.5.13. Interferon beta-1A – AVONEX (CAP) – EMA/PAM/0000315762

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the Study Report for joint PASS INFORM - Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden Study.

17.5.14. Interferon beta-1A – REBIF (CAP) – EMA/PAM/0000315764

Applicant: Merck Europe B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the Study Report for joint PASS INFORM - Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden Study.

17.5.15. Interferon beta-1B – BETAFERON (CAP) – EMA/PAM/0000309054

Applicant: Bayer AG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the Study Report for joint PASS INFORM - Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden Study.

17.5.16. Octocog alfa – KOVALTRY (CAP) – EMA/PAM/0000343782

Applicant: Bayer AG

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of annual PedNet (European Paediatric Network for Haemophilia Management) report of 2025 containing data for Kovaltry as interim results for epidemiological Study 15689
Procedure No.: EMEA/H/C/003825/MEA/005

17.5.17. Peginterferon beta-1A – PLEGRIDY (CAP) – EMA/PAM/0000315767

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the Study Report for joint PASS INFORM - Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden Study.

17.5.18. Ravulizumab – ULTOMIRIS (CAP) – EMA/PAM/0000358006

Applicant: Alexion Europe

PRAC Rapporteur: Kimmo Jaakkola

Scope: PAM [MEA]: Category 3 Study - Additional Pharmacovigilance Activity in the Risk Management Plan Submission of atypical haemolytic uraemic syndrome (aHUS) Registry Biennial Interim Report, Protocol M11-001, dated 18 Jun 2026. This is the third biennial interim report for Ultomiris (ravulizumab).

17.5.19. Respiratory syncytial virus vaccine (bivalent, recombinant) – ABRYSVO (CAP) – EMA/PAM/0000350900

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Progress Report 2 for the PASS C3671026 for Abrysvo, a post-authorisation safety study of Abrysvo in pregnant women and their offspring in a real world setting in Europe and UK (following EMA/PAM/0000321444 CHMP AR dated 26/03/2026)

17.5.20. Risankizumab – SKYRIZI (CAP) – EMA/PAM/0000348711

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

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

17.5.21. Selexipag – UPTRAVI (CAP) – EMA/PAM/0000357993

Applicant: Janssen Cilag International

PRAC Rapporteur: Zoubida Amimour

Scope: 9th interim report of study AC-065A401, EXPlortory Observational Study of Uptravi in Real-LifE (EXPOSURE)

17.5.22. Siponimod – MAYZENT (CAP) – EMA/PAM/0000357691

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Maria del Pilar Rayon

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

17.5.23. Sutimlimab – ENJAYMO (CAP) – EMA/PAM/0000347729

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Jan Neuhauser

Scope: Third annual interim report for PASS OBS16454 - Sutimlimab Cold Agglutinin Disease Real World Evidence Registry (CADENCE).

17.6. New Scientific Advice

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

17.7. Ongoing Scientific Advice

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

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

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

18. Annex I – Renewals of the marketing authorisation, conditional renewals and annual reassessments

Based on the review of the available pharmacovigilance data for the medicine(s) listed below and the CHMP Rapporteur's assessment report, PRAC considered that either the renewal of the marketing authorisation procedure could be concluded - and supported the renewal of their marketing authorisations for an unlimited or additional period, as applicable - or no amendments to the specific obligations of the marketing authorisation under exceptional circumstances for the medicines listed below were recommended. As per the agreed criteria, the procedures were finalised at the PRAC level without further plenary discussion.

18.1. Annual reassessments of the marketing authorisation

18.1.1. Maralixibat – LIVMARLI (CAP) – EMA/S/0000317715

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

18.1.2. Tofersen – QALSODY (CAP) – EMA/S/0000349866

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Annual reassessment of the marketing authorisation

18.2. Conditional renewals of the marketing authorisation

18.2.1. Adagrasib – KRAZATI (CAP) – EMA/R/0000350422

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Conditional renewal of the marketing authorisation

18.2.2. Brexucabtagene autoleucel – TECARTUS (CAP) – EMA/R/0000355892

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

18.2.3. Loncastuximab tesirine – ZYNLONTA (CAP) – EMA/R/0000358132

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Eva Jirsová

Scope: Conditional renewal of the marketing authorisation

18.2.4. Repotrectinib – AUGTYRO (CAP) – EMA/R/0000357913

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Conditional renewal of the marketing authorisation

18.2.5. Sotorasib – LUMYKRAS (CAP) – EMA/R/0000360417

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Conditional renewal of the marketing authorisation

18.2.6. Spesolimab – SPEVIGO (CAP) – EMA/R/0000348377

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Zoubida Amimour

Scope: Conditional renewal of the marketing authorisation

18.2.7. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/R/0000360418

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Conditional renewal of the marketing authorisation

18.3. Renewals of the marketing authorisation

18.3.1. Enfortumab vedotin – PADCEV (CAP) – EMA/R/0000351076

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: 5-year renewal of the marketing authorisation

18.3.2. Eptinezumab – VYEPTI (CAP) – EMA/R/0000336059

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

18.3.3. Finerenone – KERENDIA (CAP) – EMA/R/0000340433

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

18.3.4. Lisocabtagene maraleucel / Lisocabtagene maraleucel – BREYANZI (CAP) – EMA/R/0000355073

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: 5-year renewal of the marketing authorisation

18.3.5. Pegfilgrastim – STIMUFEND (CAP) – EMA/R/0000351198

Applicant: Fresenius Kabi Deutschland GmbH

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

18.3.6. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) – PREVENAR 20 (CAP) – EMA/R/0000340648

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: 5-year renewal of the marketing authorisation

18.3.7. Risperidone – OKEDI (CAP) – EMA/R/0000343015

Applicant: Laboratorios Farmaceuticos Rovi S.A.

PRAC Rapporteur: Dennis Lex

Scope: 5-year renewal of the marketing authorisation

18.3.8. Sapropterin – SAPROPTERIN DIPHARMA (CAP) – EMA/R/0000348315

Applicant: DIPHARMA Arzneimittel GmbH

PRAC Rapporteur: Eamon O Murchu

Scope: 5-year renewal of the marketing authorisation

18.3.9. Sitagliptin / Metformin hydrochloride – SITAGLIPTIN METFORMIN HYDROCHLORIDE MYLAN (CAP) – EMA/R/0000349188

Applicant: Mylan Pharmaceuticals Limited

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

18.3.10. Somatrogon – NGENLA (CAP) – EMA/R/0000340629

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

18.3.11. Tebentafusp – KIMMTRAK (CAP) – EMA/R/0000355059

Applicant: Immunocore Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

18.3.12. Tecovirimat – TECOVIRIMAT SIGA (CAP) – EMA/R/0000340615

Applicant: Siga Technologies Netherlands B.V.

PRAC Rapporteur: Dennis Lex

Scope: 5-year renewal of the marketing authorisation

18.3.13. Tofacitinib – XELJANZ (CAP) – EMA/R/0000350878

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

19. Annex II – List of participants

including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 31 August 2026 – 03 September 2026 PRAC meeting, which was held remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Ulla Wändel Liminga	Chair	Sweden	No interests declared	
Sonja Radowan	Alternate	Austria	No interests declared	
Jean-Michel Dogné	Member	Belgium	No restrictions applicable to this meeting	
Jo Robays	Alternate	Belgium	No interests declared	
Maria Popova-Kiradjieva	Member	Bulgaria	No interests declared	
Petar Mas	Member	Croatia	No interests declared	
Barbara Kovacic Bytyqi	Alternate	Croatia	No interests declared	
Panagiotis Psaras	Member	Cyprus	No interests declared	
Elena Kaisis	Alternate	Cyprus	No interests declared	
Eva Jirsová	Member	Czechia	No interests declared	
Veronika Macurova	Alternate	Czechia	No interests declared	
Marie Louise Schougaard Christiansen	Member	Denmark	No interests declared	
Karin Erneholm	Alternate	Denmark	No interests declared	
Maia Uusküla	Member	Estonia	No interests declared	
Krõõt Aab	Alternate	Estonia	No interests declared	
Terhi Lehtinen	Member	Finland	No interests declared	
Kimmo Jaakkola	Alternate	Finland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Tiphaine Vaillant	Member	France	No interests declared	
Zoubida Amimour	Alternate	France	No participation in discussion, final deliberations and voting on:	6.1.1. EMA/PSUR/0000344377 6.2.2. EMA/PSUR/0000344392 14.1.3. Deucravacitinib – SOTYKTU (CAP) 14.1.4. Gefitinib - IRESSA (CAP) 15.3.5. EMA/VR/0000327005 15.3.14. EMA/VR/0000356665 16.1.25. EMA/PSUR/0000344421 17.2.4. EMA/PAM/0000357688 17.2.11. EMA/PAM/0000343701 18.2.1. EMA/R/0000350422 18.2.4. EMA/R/0000357913 18.3.4. EMA/R/0000355073
Dennis Lex	Member	Germany	No interests declared	
Dirk Mentzer	Alternate	Germany	No interests declared	
Georgia Gkegka	Member	Greece	No interests declared	
Maria Poulianiti	Alternate	Greece	No participation in discussion, final deliberations	3.1.1 EMA/REF/0000369747 4.1.1. Fentanyl (transdermal patches) (NAP)

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
			and voting on:	6.2.2. EMA/PSUR/0000344392
Julia Pallos	Member	Hungary	No participation in discussion, final deliberations and voting on:	6.1.1. EMA/PSUR/0000344377 6.2.2. EMA/PSUR/0000344392 14.1.3. Deucravacitinib – SOTYKTU (CAP) 14.1.4. Gefitinib - IRESSA (CAP) 15.3.5. EMA/VR/0000327005 15.3.14. EMA/VR/0000356665 16.1.25. EMA/PSUR/0000344421 17.2.4. EMA/PAM/0000357688 17.2.11. EMA/PAM/0000343701 18.2.1. EMA/R/0000350422 18.2.4. EMA/R/0000357913 18.3.4. EMA/R/0000355073
Melinda Palfi	Alternate	Hungary	No interests declared	
Guðrún Stefánsdóttir	Member	Iceland	No participation in discussion, final deliberations and voting on:	16.1.2. EMA/PSUR/0000344425 16.1.47. EMA/PSUR/0000344456 16.1.50. EMA/PSUR/0000344407 17.2.10. EMA/PAM/0000357017

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
				17.2.9. EMA/PAM/0000357209 17.5.12. EMA/PAM/0000357900 18.2.5. EMA/R/0000360417
Rhea Fitzgerald	Member	Ireland	No interests declared	
Eamon O Murchu	Alternate	Ireland	No interests declared	
Amelia Cupelli	Member	Italy	No interests declared	
Zane Neikena	Member	Latvia	No interests declared	
Diana Litenboka	Alternate	Latvia	No interests declared	
Rugile Pilviniene	Member	Lithuania	No restrictions applicable to this meeting	
Magdalena Wielowieyska	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	16.3.8. EMA/PSUR/0000344418
John Joseph Borg	Member	Malta	No restrictions applicable to this meeting	
Liana Martirosyan	Member (Vice-Chair)	Netherlands	No interests declared	
Bianca Mulder	Alternate	Netherlands	No restrictions applicable to this meeting	
David Olsen	Member	Norway	No participation in discussion,	4.1.4. Progestogens (NAP)

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
			final deliberations and voting on:	5.1.4. EMEA/H/C/006443 15.3.43. EMA/VR/0000350998 15.3.44. EMA/VR/0000351078 16.1.15. EMA/PSUR/0000344463 16.1.51. EMA/PSUR/0000344417 16.3.13. EMA/PSUR/0000344397 16.3.20. EMA/PSUR/0000344452 17.5.15. EMA/PAM/0000309054 17.5.16. EMA/PAM/0000343782 18.3.3. EMA/R/0000340433
Pernille Harg	Alternate	Norway	No interests declared	
Adam Przybylkowski	Member	Poland	No restrictions applicable to this meeting	
Ana Sofia Diniz Martins	Member	Portugal	No interests declared	
Carla Torre	Alternate	Portugal	No restrictions applicable to this meeting	
Roxana Dondera	Member	Romania	No interests declared	
Roxana Stefania Udrescu	Alternate	Romania	No interests declared	
Miroslava Gocova	Member	Slovakia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Jana Pecherova	Alternate	Slovakia	No interests declared	
Polona Golmajer	Member	Slovenia	No interests declared	
Maria del Pilar Rayon	Member	Spain	No interests declared	
Maria Martinez Gonzalez	Alternate	Spain	No interests declared	
Karin Bolin	Member	Sweden	No restrictions applicable to this meeting	
Jenny-Maria Jönsson	Alternate	Sweden	No restrictions applicable to this meeting	
Annalisa Capuano	Member	Independent scientific expert	No restrictions applicable to this meeting	
Milou-Daniel Drici	Member	Independent scientific expert	No restrictions applicable to this meeting	
Maria Teresa Herdeiro	Member	Independent scientific expert	No restrictions applicable to this meeting	
Patricia McGettigan	Member	Independent scientific expert	No restrictions applicable to this meeting	
Anette Kirstine Stark	Member	Independent scientific expert	No restrictions applicable to this meeting	
Roberto Frontini	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Martin Votava	Alternate	Healthcare Professionals' Representative	No restrictions	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
			applicable to this meeting	
Yiannoula Koulla	Member	Patients' Organisation Representative	No interests declared	
Michal Rataj	Alternate	Patients' Organisation Representative	No interests declared	
Britta Kuhn	Expert	Austria	No interests declared	
Christelle Bizimungu	Expert	Belgium	No interests declared	
Petra Vacková	Expert	Czech Republic	No interests declared	
Aviaja Højegaard Ammentorp	Expert	Denmark	No interests declared	
Sofie Lindholm	Expert	Denmark	No interests declared	
Nicklas Hasselblad Lundstrøm	Expert	Denmark	No interests declared	
Lærke Skov Nilausen	Expert	Denmark	No restrictions applicable to this meeting	
Cecilie Louise Pedersen	Expert	Denmark	No participation in discussion, final deliberations and voting on:	4.1.4. Progestogens (NAP) 15.3.48. EMA/VR/000035 0795 16.1.17. EMA/PSUR/000 0344447 16.2.2. EMA/PSUR/000 0344399 16.3.21. EMA/PSUR/000 0344394 18.3.2. EMA/R/000033 6059
Moritz Sander	Expert	Denmark	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Ditte Søgaard	Expert	Denmark	No interests declared	
Pauline Dayani	Expert	France	No interests declared	
Alexis Jacquet	Expert	France	No restrictions applicable to this meeting	
Violaine Vermillard	Expert	France	No interests declared	
Tania Meier	Expert	Germany	No interests declared	
Birte Niemann	Expert	Germany	No interests declared	
Laura Zein	Expert	Germany	No interests declared	
Birna Kristín Eiríksdóttir	Expert	Iceland	No restrictions applicable to this meeting	
Gareth Bowen	Expert	Ireland	No interests declared	
Risteard Prendergast	Expert	Ireland	No interests declared	
Anni Chen	Expert	Netherlands	No interests declared	
Anita Volkers	Expert	Netherlands	No interests declared	
Charlotte Backman	Expert	Sweden	No interests declared	
Charlotte Welsh	Expert	Sweden	No interests declared	
A representative from the European Commission attended the meeting.				
Observers from Health Canada attended the meeting.				
Meeting run with support from relevant EMA staff				

Experts were evaluated against the agenda topics or activities they participated in.

20. Annex III - List of acronyms and abbreviations

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

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

21. Explanatory notes

None

The Notes give a brief explanation of relevant minute's items and should be read in conjunction with the minutes.

EU Referral procedures for safety reasons: Urgent EU procedures and Other EU referral procedures

(Items 2 and 3 of the PRAC minutes)

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, 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 minutes)

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 minutes)

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 minutes)

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 minutes)

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 minutes)

Inspections carried out by regulatory agencies to ensure that marketing authorisation holders comply with their pharmacovigilance obligations.

Article 58 of Regulation (EC) No 726/2004 (EU-M4all)

Article 58 (EU-M4all) procedure 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).

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