29 May 2026
EMA/PRAC/117688/2026
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Minutes of the PRAC meeting on 07-10 April 2026

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

Disclaimers

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

Of note, 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 07-10 April 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 PRAC, unless otherwise specified.

1.2. Agenda of the meeting on 07-10 April 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 09-12 March 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 09-12 March 2026 were published on the EMA website on 06 May 2026 (EMA/PRAC/91330/2026).

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

None

3.2. Ongoing Procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination procedures[1]

None

3.5. Others

None

4. Signals assessment and prioritisation[2]

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

4.1.1. Binimetinib - MEKTOVI (CAP); Encorafenib – BRAFTOVI (CAP)

Applicants: Pierre Fabre Medicament

PRAC Rapporteur: Carla Torre

Scope: Signal of neutropenia, febrile neutropenia

EPITT 20255 – New signal

Lead Member State(s): LT, PT

[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

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 neutropenia, febrile neutropenia was identified by EMA, based on 71 cases retrieved from EudraVigilance. The Rapporteur confirmed that the signal needed initial analysis and prioritisation by PRAC.

Discussion

Having considered the available evidence from case reports in EudraVigilance, PRAC agreed that further evaluation on the signal of neutropenia, febrile neutropenia is warranted.

PRAC appointed Carla Torre as Rapporteur for the signal.

Summary of recommendation(s)

- The MAH for Mektovi (binimetinib) and Braftovi (encorafenib) should submit to EMA, by 24 June 2026, a cumulative review of all cases of neutropenia, febrile neutropenia, including data from literature, spontaneous reports and studies, as well as a discussion on possible biological plausibility and mechanism of this association. In addition, the MAH should discuss the need to update the product information (PI) and/or the risk management plan (RMP), as warranted.
- 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. Axicabtagene ciloleucel – YESCARTA (CAP) - EMEA/H/C/002695/SDA/019; lisocabtagene maraleucel – BREYANZI (CAP) - EMEA/H/C/002695/SDA/025

Applicants: Bristol-Myers Squibb Pharma EEIG (Breyanzi), Kite Pharma EU B.V. (Yescarta)
ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Signal of increased risk of brain oedema in primary mediastinal large B-cell lymphoma (PMBCL) patients

EPITT 20224 – Follow-up to December 2025

Background

For background information, see PRAC minutes December 2025.

The MAHs replied to the request for information on the signal of increased risk of brain oedema in PMBCL patients and the responses were assessed by the Rapporteur.

Discussion

Having considered the cumulative review submitted by the MAH, PRAC agreed that there is sufficient evidence to establish a causal association between Yescarta (axicabtagene ciloleucel) and an increased risk of brain oedema in PMBCL patients. Therefore, the product

information (PI) of Yescarta (axicabtagene ciloleucel) should be updated to add cerebral oedema as an undesirable effect with a frequency 'uncommon' and to amend the existing warning mentioning that most cases of cerebral oedema occurred in patients with immune effector cell-associated neurotoxicity syndrome (ICANS) and that the risk for cerebral oedema may be higher in PMBCL patients.

In addition, having considered the cumulative review submitted by the MAH, PRAC concluded that the current evidence for Breyanzi (lisocabtagene maraleucel) is insufficient to establish a causal relationship between Breyanzi (lisocabtagene maraleucel) and an increased risk of brain oedema in PMBCL patients to further warrant an update to the PI and/or the risk management plan (RMP) at present.

Summary of recommendation(s)

- The MAH for Yescarta (axicabtagene ciloleucel) should submit to EMA, within 60 days, a variation to amend the product information[3].
- The MAH of Breyanzi (lisocabtagene maraleucel) should monitor the potential increased risk of brain oedema in PMBCL patients in the next PSUR, and present an updated analysis of the frequency of brain oedema in patients treated with Breyanzi (at least diffuse large B-cell lymphoma (DLBCL) and PMBCL indications). The analysis should include data from all relevant, available sources, including but not limited to clinical trials, the Global Safety Database, the Center for International Blood & Marrow Transplant Research/European Society for Blood and Marrow Transplantation (CIBMTR/EBMT) and DESCAR-T registries, insurance claims databases, and published literature.

4.2.2. Ponatinib - ICLUSIG (CAP) - EMEA/H/C/002695/SDA/019

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Signal of congenital megacolon, maternal exposure during pregnancy

EPITT 20231 – Follow-up to December 2025

Background

For background information, see PRAC minutes December 2025.

The MAH replied to the request for information on the signal of congenital megacolon, maternal exposure during pregnancy and the responses were assessed by the Rapporteur.

Discussion

Having considered the available evidence in EudraVigilance including the cumulative review submitted by the MAH, PRAC agreed that the product information (PI) should be updated to amend the existing information related to pregnancy to inform of the results of this signal review, as well as to follow-up on this information in the PSUR.

Summary of recommendation(s)

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

- The MAH for Iclusig (ponatinib) should submit to EMA, within 60 days, a variation to update the product information[4].
- In addition, the MAH should submit within the PSUR with data lock point 13/12/2026 a cumulative review of all cases reporting use during pregnancy, including 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 also discuss the need for any potential amendment to the PI and/or the risk management plan (RMP), as warranted. PRAC will assess the cumulative review within the PSUR procedure PSUSA/00010128/202612.

4.2.3. Tirzepatide - MOUNJARO (CAP); MOUNJARO KWIKPEN (CAP) - EMEA/H/C/005620/SDA/007

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

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

EPITT 20198 – Follow-up to October 2025

Background

For background information, see PRAC minutes October 2025[5].

The MAH replied to the request for information on the signal of drug interaction with warfarin and other coumarin derivatives leading to international normalised ratio decreased and the responses were assessed by the Rapporteur.

Discussion

Having considered the available evidence in EudraVigilance, the literature and the MAH responses, PRAC concluded that the current evidence is insufficient to establish a causal relationship between tirzepatide and drug interaction with warfarin and acenocoumarol leading to INR decreased to further warrant an update to the product information (PI) and/or risk management plan (RMP).

Summary of recommendation(s)

- The MAH for Mounjaro (tirzepatide) should monitor this topic in the next PSUR with data lock point 13/05/2026, with special attention should be paid to the cases containing co-reported clinical adverse event, either gastrointestinal (GI) tract issues, which may be a mechanism of the interaction, or clinical outcomes that may have been a result of INR abnormality.
- The brand leaders of warfarin (Orifarm, Teofarma and Therabel) and of acenocoumarol (Merus Labs Luco) should submit within the upcoming, respective PSURs, a cumulative review of all cases of the interaction with all GLP-1 RA leading to abnormal INR, including a review of the published literature, data from spontaneous reports and reports from studies including all cases in EudraVigilance

[4] Update of SmPC section 4.6. The package leaflet is updated accordingly.
[5] Held on 29 September – 02 October 2025

database, as well as a discussion on possible biological plausibility and mechanism of this association. The MAHs should also discuss the need for any potential amendment to the PI and/or the RMP, as warranted. PRAC will assess these cumulative reviews within the respective PSUR procedures.

4.3. Variation procedure(s) resulting from signal evaluation

None

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. Catequentinib - (CAP MAA) - EMEA/H/C/006317, Orphan

Scope (pre D-180 phase): Treatment of synovial sarcoma or leiomyosarcoma

5.1.2. Ensitrelvir - (CAP MAA) - EMEA/H/C/006063

Scope (pre D-180 phase): Treatment of coronavirus disease 2019 (COVID-19)

5.1.3. Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated - (CAP MAA) - EMEA/H/C/006692

Scope (pre D-180 phase): Prophylaxis of influenza

5.1.4. Insulin efsitora alfa - (CAP MAA) - EMEA/H/C/006388

Scope (pre D-180 phase): Treatment of type 2 diabetes mellitus

5.1.5. Leriglitazone - (CAP MAA) - EMEA/H/C/006693, Orphan

Scope (pre D-180 phase): Treatment of adrenoleukodystrophy

5.1.6. Levodopa / Carbidopa - (CAP MAA) - EMEA/H/C/006629

Scope (pre D-180 phase): Treatment of adult patients with Parkinson’s disease

5.1.7. Narsoplimab - (CAP MAA) - EMEA/H/C/005247, Orphan

Scope (pre D-180 phase): Treatment of patients with haemopoietic stem cell transplant-

associated thrombotic microangiopathy

5.1.8. Norucholic acid - (CAP MAA) - EMEA/H/C/006515, Orphan

Scope (pre D-180 phase): Treatment of primary sclerosing cholangitis (PSC) in adults

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

See Annex I 15.2

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

See also Annex I 15.3

5.3.1. Axicabtagene ciloleucel – YESCARTA (CAP); Brexucabtagene autoleucel – TECARTUS (CAP) – EMA/VR/0000308229

Applicant: Kite Pharma EU B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Update of sections 4.2, 4.4, 4.5. 4.7 and 6.4 of the SmPC in order to modify the pre- and post-infusion monitoring recommendations and requirements related to the risk of CRS (cytokine release syndrome) and ICANS (immune effector cell-associated neurotoxicity syndrome) based on data from clinical trials, post-marketing experience and literature. The Package Leaflet is updated accordingly. The RMP version 7.1 has also been submitted. In addition, Annex II has been updated accordingly. Furthermore, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the PI.

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.

CHMP is evaluating a worksharing variation for Yescarta and Tecartus, centrally authorised products containing axicabtagene ciloleucel and brexucabtagene autoleucel, respectively, to update the PI to modify the pre- and post-infusion monitoring recommendations and requirements related to the risk of CRS and ICANS based on data from clinical trials, post-marketing experience and literature. PRAC is responsible for providing advice to CHMP on the necessary updates to the RMP to support this procedure.

Summary of advice

- The RMPs for Yescarta (axicabtagene ciloleucel) and Tecartus (brexucabtagene autoleucel) in the context of the variation procedure under evaluation by CHMP could be considered acceptable provided that updates to RMP version 12.1 for Yescarta and version 7.1 for Tecartus are submitted.
- PRAC supported the PRAC Rapporteur's assessment to update RMP Annex 6 and Annex IID to remove the key message from the patient card that advised the patients to

remain in close proximity to the treatment centre or appropriately trained clinical facility following infusion.

5.3.2. Influenza vaccine (live, nasal) – FLUENZ (CAP) – EMA/VR/0000302352

Applicant: AstraZeneca AB

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.2 and 4.4 of the SmPC in order to introduce self-administration instructions based on postmarketing data and literature. The Package Leaflet and Labelling updated accordingly. The RMP version 13.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.

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.

CHMP is evaluating a variation for Fluenz, a centrally authorised product containing influenza vaccine (live, nasal), to update the PI in order to introduce self-administration in adolescents and administration of the vaccine by adult caregivers based on a human factor study, postmarketing data and literature. PRAC is responsible for providing advice to CHMP on the necessary updates to the RMP to support this procedure.

Summary of advice

- The RMP for Fluenz (influenza vaccine (live, nasal)) in the context of the variation procedure under evaluation by CHMP could be considered acceptable provided that an update to RMP version 13.1 is submitted.
- PRAC considered that medication errors should be included as important potential risk in the list of safety concerns in the RMP. Additionally, PRAC considered that additional risk minimisation measures are deemed necessary (such as a QR code linking to a video, included in the Instruction for Use in the package leaflet), given the importance of ensuring that adult caregivers administering Fluenz receive appropriate information to support the correct use of the vaccine.

5.3.3. 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'.

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.

CHMP is evaluating a variation for Nyxoid, a centrally authorised product containing naloxone, to change in the legal status from 'medicinal product subject to medical prescription' to 'medicinal products not subject to medical prescription'. PRAC is responsible for providing advice to CHMP on the necessary updates to the risk management plan (RMP) to support this procedure.

Summary of advice

- The RMP for Nyxoid (naloxone) in the context of the variation procedure under evaluation by CHMP could be considered acceptable provided that an update to RMP version 4.0 is submitted.
- PRAC supported the removal of all safety concerns from the RMP and considered that routine pharmacovigilance is sufficient to identify and characterise the risks of the product. Regarding RMMs, PRAC agreed with the removal of existing additional risk minimisation measures (aRMMs). However, as the warning "not to prime" is considered one of the most important key messages of aRMMs, and taking into account the removal of the need for the healthcare professionals (HCPs) to provide training, it is critical that the warning "to not prime" is clearly communicated through routine RMMs. Therefore, the MAH should discuss if the visual pictogram to accompany the warning "do not prime" as proposed in the package leaflet by the MAH could also be included on the blister packaging and on the outer packaging next to already existing textual warning to not prime.

5.3.4. Pandemic influenza vaccine (H5N1) (live attenuated, nasal) – PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) – EMA/VR/0000321324

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Extension of indication to remove the upper age limit from the indication for Pandemic influenza vaccine (H5N1) (live, nasal), based on efficacy and safety data previously submitted in the Marketing Authorisation Application (MAA). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, and 5.3 of the SmPC are updated. The Annex II and the Package Leaflet are updated in accordance. Version 2.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes throughout the PI and update the list of local representatives in the Package Leaflet.

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.

CHMP is evaluating an extension of the therapeutic indication for Pandemic influenza vaccine H5N1 Astrazeneca, a centrally authorised product containing pandemic influenza vaccine

(H5N1) (live attenuated, nasal). PRAC is responsible for providing advice to CHMP on the necessary updates to the RMP to support this procedure.

Summary of advice

- The RMP for Pandemic influenza vaccine H5N1 Astrazeneca (pandemic influenza vaccine (H5N1) (live attenuated, nasal)) in the context of the variation procedure under evaluation by CHMP could be considered acceptable provided that an update to RMP version 2.2 is submitted.
- PRAC considered that the MAH should use this variation procedure as an opportunity to revise the summary of safety concerns, taking into account any new available data and in accordance with GVP Module V Revision 2 (removal of 'vaccination failure (lack of efficacy)' as important potential risk and rewording of several safety concerns listed as missing information in the RMP).

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. Cenobamate – ONTOZRY (CAP) – EMA/PSUR/0000317671

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

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00010921/202509)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Ontozry, a centrally authorised medicine containing cenobamate 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, and on the data provided by the MAH in writing and during an oral explanation (held on 09 April 2026), the benefit-risk balance of Ontozry (cenobamate) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include liver injury as an undesirable effect with a frequency 'rare'. Additionally, all hepatic undesirable effects should be regrouped under the system organ class (SOC) 'Hepatobiliary disorders'. Therefore, the current terms of the marketing authorisation(s) should be varied[6].

[6] 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.

Finally, PRAC agreed the distribution of a direct healthcare professional communication (DHPC) together with a communication plan, to inform about the new requirements for liver monitoring due to reports of severe liver injury.

- In the next PSUR, the MAH should provide cumulative reviews of each preferred terms (PTs) included in the signal of 'psychiatric disorders', and of the cases reporting 'weight loss' including a discussion of possible underlying causes (decreased appetite, gastro-intestinal problems, etc) and of the need to update the product information, as warranted. In addition, both 'severe liver injury' and 'effects of cenobamate on bone density and bone turnover' should be included as new important identified risk and important potential risk respectively, and thus discussed in the PSURs.

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. Influenza vaccine (live, nasal) – FLUENZ (CAP) – EMA/PSUR/0000317656

Applicant: AstraZeneca AB

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00001742/202508)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Fluenz, a centrally authorised medicine containing influenza vaccine (live, nasal) 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 Fluenz (influenza vaccine (live, nasal)) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include syncope 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[7].
- In the next PSUR, the MAH should provide cumulative reviews of cases of dizziness, (with a stratification of dizziness associated with syncope, dizziness occurring in the context of hypersensitivity reactions, and dizziness occurring independently), of cases of febrile seizures/convulsions, and of any new safety information regarding Bell's palsy and encephalitis including a literature review as applicable. Furthermore, the MAH should provide a detailed assessment of late-onset syncope cases (i.e. time-to-onset (TTO) of 60 minutes or more) including a discussion on the potential underlying mechanisms and a comparison between early- vs late-onset syncope.

[7] 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 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. Linaclotide – CONSTELLA (CAP) – EMA/PSUR/0000317653

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010025/202508)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Constella, a centrally authorised medicine containing linaclotide 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 Constella (linaclotide) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include anaphylactic reaction as an undesirable effect with a frequency 'not known'. Therefore, the current terms of the marketing authorisation(s) should be varied[8].
- In the next PSUR, the MAH should provide the signal evaluation report for muscle spasms under linaclotide treatment based on the article of *Fan et al., 2025*[9] and ensure a proper follow-up of cases of urinary retention (including the follow-up questionnaire), with discussion on possible mechanisms for both situations considering also data on absorption. In addition, the MAH should clarify the criteria to distinguish cases reporting diarrhoea as being or not medical significant.

The frequency of PSUR submission should be revised from yearly to three-yearly and the next PSUR should be submitted to EMA within 90 days of the data lock point. The EURD list provided for under Article 107c(7) of Directive 2001/83/EC is updated accordingly.

6.1.4. Lorlatinib – LORVIQUA (CAP) – EMA/PSUR/0000317668

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00010760/202509)

Background

[8] 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.
[9] Fan X, Li Y, Lin X. A pharmacovigilance study of the association between linaclotide/plecanatide and muscle spasms based on Food and Drug Administration Adverse Event Reporting System. Frontiers in Pharmacology. 2025;16:1635792.

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Lorviqua, a centrally authorised medicine containing lorlatinib 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 Lorviqua (lorlatinib) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include alanine aminotransferase increased and aspartate aminotransferase increased as undesirable effects with a frequency 'very common'. Therefore, the current terms of the marketing authorisation(s) should be varied[10].
- In the next PSUR, the MAH should continue the close monitoring cases of pulmonary arterial hypertension (PAH) as an important potential risk (submit new cases and discuss the potential causal association), and of all cases reporting the following preferred terms (PTs): blindness, blindness unilateral, blindness transient, central vision loss, sudden visual loss, optic neuropathy, optic atrophy, optic nerve disorder, toxic optic neuropathy, optic neuritis and optic perineuritis. In addition, the MAH should include 'hepatic function disorder' as an important potential risk, providing the requested evaluation (standardised MedDRA query (SMQ): hepatic disorders [narrow and broad]) focusing on serious liver events, and should further characterise the hepatotoxicity profile.

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. Mepolizumab – NUCALA (CAP) – EMA/PSUR/0000317655

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010456/202509)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Nucala, a centrally authorised medicine containing mepolizumab 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 Nucala (mepolizumab) in the approved indication(s) remains unchanged.
- The current terms of the marketing authorisation(s) should be maintained.

[10] 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.

- In the next PSUR, the MAH should continue monitoring cases of alopecia, and present an analysis of fatal cases discussing the effectiveness and planned timelines of the proposed measures to improve their follow-up process.
- The MAH should remove the important potential risk 'alterations in cardiovascular safety' from the RMP safety specification, within an upcoming regulatory procedure affecting the RMP or at the latest one year after PRAC recommendation, as the existing pharmacovigilance activities are not expected to further characterise this potential risk.

The frequency of PSUR submission should be revised from yearly to three-yearly and the next PSUR should be submitted to EMA within 90 days of the data lock point. The EURD list provided for under Article 107c(7) of Directive 2001/83/EC is updated accordingly.

6.1.6. Naltrexone hydrochloride / Bupropion hydrochloride – MYSIMBA (CAP) – EMA/PSUR/0000317654

Applicant: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010366/202509)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Mysimba, a centrally authorised medicine containing naltrexone hydrochloride/bupropion hydrochloride 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 Mysimba (naltrexone hydrochloride/bupropion hydrochloride) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) in the existing warning of severe cutaneous adverse reactions (SCARs), and add them as undesirable effects with a frequency 'not known'. Therefore, the current terms of the marketing authorisation(s) should be varied[11].
- In the next PSUR, the MAH should address the following issues: eosinophilic pneumonia; co-administration with other anti-obesity drugs; injury, fall and fracture in adult and elderly patients, along with an analysis of underlying causes; medication errors, off-label use and abuse, along with an analysis of underlying causes; Brugada syndrome; an effectiveness evaluation of the patient card and product information updates related to the risk of opioid interactions; restless legs syndrome; otolithiasis; dysphemia. In addition, the important identified risk 'hypersensitivity reactions including severe reactions like Stevens-Johnson Syndrome' should be updated to include TEN, DRESS, and 'acute generalised exanthematous pustulosis' (AGEP).

[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.

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.

6.1.7. Ofatumumab – KESIMPTA (CAP) – EMA/PSUR/0000317682

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010927/202509)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Kesimpta, a centrally authorised medicine containing ofatumumab 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 Kesimpta (ofatumumab) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include 'hepatic enzymes increased' as 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 cumulative reviews of all relevant cases of weight increased and related preferred terms (PTs). The MAH should also provide a cumulative review of all hepatic events to further characterise the potential risk of hepatotoxicity discussing also the need to update the product information (PI) or the risk management plan (RMP) as warranted, and include liver injury as an important potential risk in the list of safety concerns of the PSUR. The MAH should continue monitoring cardiovascular events, including QT prolongation or arrhythmia and ischaemic cardiovascular events, and monitoring bowel obstruction including appendicitis. Furthermore, the MAH should provide a comprehensive analysis with a critical discussion of all relevant cases with cytopenia including neutropenia, and a cumulative summary of all off-label use detailing serious cases reported, with an assessment of the clinical impact of dosing deviations including underlying causes and need for additional risk minimisation measures (aRMMs).

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

6.1.8. Rezafungin – REZZAYO (CAP) – EMA/PSUR/0000317633

Applicant: Mundipharma GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000221/202509)

[12] 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.

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Rezzayo, a centrally authorised medicine containing rezafungin 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 Rezzayo (rezafungin) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include anaphylactic reaction and anaphylactic shock as warnings and an undesirable effect with a frequency 'not known'. Therefore, the current terms of the marketing authorisation(s) should be varied[13].

The frequency of PSUR submission should be revised from 6-monthly to yearly and the next PSUR should be submitted to EMA within 90 days of the data lock point. The EURD list provided for under Article 107c(7) of Directive 2001/83/EC is updated accordingly.

6.1.9. Ruxolitinib – OPZELURA (CAP) – EMA/PSUR/0000317686

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011052/202509)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Opzelura, a centrally authorised medicine containing ruxolitinib 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 Opzelura (ruxolitinib) in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include a warning regarding Herpes zoster reactivation and to add Herpes zoster as an undesirable effect with a frequency 'uncommon'. Therefore, the current terms of the marketing authorisation(s) should be varied[14].
- In the next PSUR, the MAH should continue discussing new safety information in relation to cytopenia and skin malignancies.

[13] 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

[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 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.

6.1.10. Zilucoplan – ZILBRYSQ (CAP) – EMA/PSUR/0000317635

Applicant: UCB Pharma

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000169/202509)

Background

Based on the assessment of the PSUR, PRAC reviewed the benefit-risk balance of Zilbrysq, a centrally authorised medicine containing zilucoplan 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 Zilbrysq (zilucoplan) in the approved indication(s) remains unchanged.
- The current terms of the marketing authorisation(s) should be maintained.
- The MAH should remove the controlled access program (CAP), within an upcoming regulatory procedure affecting the risk management plan (RMP) or at the latest within 6 months after the PRAC recommendation. In addition, the educational materials (guide for healthcare professionals and patient/carer guide) should be updated to remove any references to the CAP, while the key message '*The vaccination and re-vaccination dates should be included on the patient card*' should be added in the patient card in alignment with the other products in the class. The Annex IID should be updated accordingly, and if the CAP is mentioned in other parts of the additional risk minimisation measures (aRMMs), this needs to be updated as well.

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 Annex 16.2.

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

See also Annex 16.3.

6.3.1. Metronidazole / neomycin / nystatin – EMA/PSUR/0000317665

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00010508/202509)

Background

Metronidazole is an anti-infective agent belonging to the nitro-imidazole family; neomycin is a bactericidal antibiotic belonging to aminoglycoside family; and nystatin is a polyene antifungal agent mainly active against *Candida* species. Metronidazole/neomycin/nystatin is an anti-infective combination indicated for the local treatment of vaginitis due to sensitive micro-organisms and non-specific vaginitis.

Based on the assessment of the PSUR(s), PRAC reviewed the benefit-risk balance of nationally authorised medicine(s) containing metronidazole/neomycin/nystatin 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 metronidazole/neomycin/nystatin-containing medicinal products in the approved indication(s) remains unchanged.
- Nevertheless, the product information should be updated to include information on vulvovaginal discomfort due to incomplete dissolution of the vaginal tablet, and fixed-drug eruption 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 MAHs should revise the list of safety concerns and classify leukopenia as an identified risk.

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

See Annex 16.5

6.6. Expedited summary safety reviews[16]

None

[15] Update of SmPC sections 4.2 and 4.8. The package leaflet is updated accordingly. The PRAC AR and PRAC recommendation are transmitted to CMDh for adoption of a position.
[16] 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)[17]

See Annex 17.1

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[18]

See also Annex 17.2

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

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

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

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 part of the risk management plan (RMP) for Agamree (vamorolone), the MAH was required to conduct a non-interventional registry-based PASS in order to evaluate the safety in patients with Duchenne muscular dystrophy in a real world setting. The MAH initially submitted protocol version 1.0 (as part of the RMP but outside the scope of Article 107n of Directive 2001/83/EC) which was assessed by the Rapporteur with further revisions requested, see PRAC minutes September 2025.

Summary of advice

- No further revisions are requested for the submitted PASS protocol version 2.0 for Agamree (vamorolone). PRAC considered that, given the limitations identified and the fact that the feasibility of a registry-based PASS has not been demonstrated, this study should be removed from the pharmacovigilance plan of the RMP. In addition, PRAC considered that the ongoing GUARDIAN study should be added to the RMP as a category 3 additional pharmacovigilance activity to help characterise information on vamorolone, including long-term safety. An updated RMP should be submitted to amend the pharmacovigilance plan.

7.3. Results of PASS imposed in the marketing authorisation(s)[19]

None

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

7.4. Results of PASS imposed and non-imposed in the marketing authorisation(s)[20]

See also Annex 17.4.

7.4.1. 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.

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 Vimizim (elosulfase alfa), the MAH conducted a non-interventional post-authorisation safety study (PASS) (MARS, Study 110-504) to assess the long-term safety and effectiveness of Vimizim (elosulfase alfa). The Rapporteur assessed the MAH's final study report in addition to the MAH's answers to the request for supplementary information (RSI). For further background, see PRAC minutes July 2025 and PRAC minutes December 2025.

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 could be considered acceptable provided that the MAH submits satisfactory responses to a RSI.
- Gven the limitations of the MARS study, PRAC did not support the MAH's proposal to update SmPC section 4.4 to include the information on spinal cord compression. However, PRAC agreed to include the different types of rashes as a footnote as initially proposed by the MAH (SmPC section 4.8 table 2), and update information regarding the use in pregnancy, to state that there are limited data on the use of elosulfase alfa in pregnant women. PRAC concluded that this Annex II condition has been fulfilled, and thereby this medicinal product should be removed from the list of medicines under additional monitoring. Therefore, in addition to the update of SmPC Annex IID, the black triangle warning should be removed from the PI and educational materials. The MAH is also reminded to update the educational material (Dosing and Administration Guide) at national level in the member states to reflect the changes of the product information agreed within this procedure.

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

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

See also Annex 17.5.

7.5.1. Naltrexone hydrochloride / Bupropion hydrochloride – MYSIMBA (CAP) – EMA/PAM/0000292603

Applicant: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: Study NB-451: Interim report of Drug Utilisation and Safety Study (Study NB-451) for Mysimba/ Contrave in Europe and the United States.

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 risk management plan (RMP) for Mysimba (naltrexone hydrochloride/ bupropion hydrochloride), the MAH had committed to perform Study NB-451 – a drug utilisation study of Mysimba/Contrave in Europe and the United States examining the long-term real-world utilisation patterns and safety outcomes of Mysimba under routine clinical practice across Europe and the United States. The interim results of this study were assessed by the Rapporteur for PRAC review.

Summary of advice

- PRAC considered that since it is not expected to receive any further information from the MAH and therefore no further assessment round is required, the post-authorisation measure (PAM) is considered fulfilled in this sense.
- However, PRAC considered that the study report submitted by the MAH does not meet the criteria for a final clinical study report (CSR) according to the study protocol and is therefore considered an interim report. An extension of the study period for Sweden until 31 December 2024 is considered necessary to achieve the required sample size without compromising the protocol determined observational period and thus, the MAH is requested to amend the study protocol accordingly and to submit it to EMA within 3 months. The MAH should also amend the due date in the RMP through the appropriate regulatory procedure. Additionally, the MAH should conduct certain sensitivity analyses and provide further information on the sample size and follow-up period .

7.5.2. Fenfluramine – FINTEPLA (CAP) – EMA/PAM/0000323622

Applicant: UCB Pharma

PRAC Rapporteur: Dennis Lex

Scope: EP0241 Final Clinical Study Report for non-interventional retrospective cohort study using national pharmacy database to evaluate the real-world use of fenfluramine (Fintepla) for Dravet syndrome, Lennox-Gastaut syndrome, and other epilepsies in the United States.

The timetable of this procedure was extended. The PRAC outcome is expected to be adopted at the PRAC June 2026 plenary.

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

None

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

10.1.1. Anti-t lymphocyte immunoglobulin for human use, rabbit (NAP) – ES 2026/62650/II/0122, DE II-2601996-20251223-01, IE/H/xxxx/WS/395, SE/H/xxxx/WS/1162, FR/H/xxxx/WS/627, DK/H/xxxx/WS/495

Applicant(s): Sanofi B.V.

PRAC Lead: Maria Martinez Gonzalez

Scope: PRAC consultation on variation procedures (ES 2026/62650/II/0122 and DE II-2601996-20251223-01) and worksharing variations (IE/H/xxxx/WS/395,

SE/H/xxxx/WS/1162, FR/H/xxxx/WS/627, DK/H/xxxx/WS/495) to update the product information of anti-t lymphocyte immunoglobulin for human use, rabbit-containing medicinal products, regarding thrombotic microangiopathy (TMA), at request of Spain.

Background

Rabbit antihuman thymocyte immunoglobulin contains purified anti-human thymocyte IgG produced by immunizing rabbits and it is indicated for the prevention and treatment of graft rejection after solid organ transplantation, as well as the treatment of aplastic anaemia, prevention of acute and chronic graft versus host disease (GVHD) after hematopoietic stem cell transplantation (HSCT), and the treatment of steroid resistant acute GVHD.

The MAH has submitted several variations grouping Member States based on the approved indications, in order to update the product information of anti-t lymphocyte immunoglobulin for human use, rabbit-containing medicinal products, regarding thrombotic microangiopathy (TMA). Spain requested PRAC advice on these procedures.

Summary of advice

- PRAC concluded that no update of the product information is warranted, at this stage, as the presented evidence for a causal relationship between rabbit antihuman thymocyte immunoglobulin and TMA is insufficient. In addition, PRAC concluded that based on the presented evidence, no update of the product information of other products with the same active substance is warranted. However, a cumulative review of the risk of TMA should be included in all PSURs subject to the next PSUSA for 'anti-t lymphocyte immunoglobulin for human use, rabbit' next year.

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

None

12.1.2. Nominated proxy

None

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

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

None

12.4. Cooperation within the EU regulatory network

12.4.1. Health threats and EMA Emergency Task Force (ETF) activities – update

The EMA Secretariat presented to PRAC an update on the flu season and the effectiveness of vaccines over the years, as well as on the Nipah virus outbreaks. In addition, PRAC was informed on the conclusions from the EMA workshop on non-clinical data for regulatory decision-making on the efficacy of medical countermeasures and was provided with an overview of the previous and upcoming ETF events.

12.4.2. PRAC strategic review and learning meeting (SRLM) under the Cyprus presidency of the European Union (EU) Council – Pafos, Cyprus, 12 – 13 May 2026 - agenda

PRAC lead: Panagiotis Psaras

PRAC was informed on the draft agenda for the 'PRAC strategic review and learning meeting (SRLM)', to be held on 11-13 May 2026 in Paphos, Cyprus, under the Cypriot presidency of the Council of the European Union (EU). The topics to be discussed cover artificial intelligence in pharmacovigilance, addressing misinformation and strengthening communication, pharmacovigilance tools and regulatory updates, operational excellence in pharmacovigilance, as well as the role of healthcare professionals and patients in pharmacovigilance.

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

None

12.8. Planning and reporting

None

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. PSURs repository

None

12.10.3. 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, PRAC endorsed the draft revised EURD list, version April 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 April 2026, the updated EURD list was adopted by CHMP and CMDh at their April 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

None

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

12.12.4. Good Pharmacovigilance Practice (GVP) module VI on Management and reporting of adverse reactions to medicinal products - revision

PRAC lead: Dennis Lex

The EMA Secretariat presented to PRAC an update on the revision of GVP module VI (revision 3) with the plan to initiate its update to incorporate changes related to the new ICH E2D(R1) Guideline, and to integrate clarifications based on questions raised by stakeholders . PRAC members can express their interest to participate in this update by 24 April 2026, while a provisional timetable and a high-level summary of already identified items to be addressed in the frame of this revision were also provided. PRAC agreed with the proposal.

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

12.20.1. Strategy on measuring the impact of pharmacovigilance – PRAC interest group (IG) Impact - Annual activity report 2025

PRAC Lead: Liana Martirosyan

PRAC was informed on the PRAC IG Impact annual activity report covering the 2025 activities of the group. PRAC endorsed the report.

12.21. Others

12.21.1. Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling

PRAC lead: Ulla Wändel Liminga

The EMA Secretariat along with the PRAC lead presented to PRAC an update on the revision of the guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling. The guideline is now open for PRAC and CHMP consultation before its adoption to release for public consultation.

13. Any other business

None

14. Annex I – Signals assessment and prioritisation[21]

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[22].

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

None

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. Denosumab - (CAP MAA) - EMEA/H/C/006626

Scope (pre D-180 phase): Prevention of skeletal related events and treatment of giant cell tumour of bone

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.

15.2.1. Bosentan – STAYVEER (CAP); TRACLEER (CAP) – EMA/VR/0000316336

Applicant: Janssen Cilag International

[21] 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

[22] 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

PRAC Rapporteur: Zoubida Amimour

Scope: Submission of an updated RMP version 12 for TRACLEER and STAYVEER to remove the Liver Safety Update Report (LSUR) as a routine pharmacovigilance activity for the important identified risk of hepatotoxicity. The Annex II is updated accordingly. In addition, the MAH is updating the list of safety concerns in line with requests from the PRAC in their assessment report for procedure PSUSA/00000425/202411.

15.2.2. Carfilzomib – KYPROLIS (CAP) – EMA/VR/0000325402

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Submission of an updated RMP version 13.0 in order to remove important identify risks from the list of safety concerns following PSUSA procedure EMEA/H/C/PSUSA/00010448/202207.

15.2.3. Ocrelizumab – OCREVUS (CAP) – EMA/VR/0000291534

Applicant: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of an updated RMP version 13.0 in order to add non-infectious colitis as an important potential risk along with an additional pharmacovigilance activity in the form of a voluntary Category 3 non-interventional post-authorization study to further characterize this risk.

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

15.3.1. 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.

15.3.2. Alpelisib – PIQRAY (CAP) – EMA/VR/0000317159

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication for PIQRAY in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following an endocrine-based regimen; based on the primary analysis (DCO 15-Oct-2024) from the Phase III Study CBYL719C2303 (C2303, EPIK-B5). This is a Phase III, randomized, double-blind, placebo-controlled study of alpelisib (BYL719) in combination with fulvestrant for men and

postmenopausal women with HR-positive, HER2-negative advanced breast cancer with PIK3CA mutation, who progressed on or after aromatase inhibitor and a CDK4/6 inhibitor. As a consequence, sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.0 of the RMP has also been submitted.

15.3.3. Atogepant – AQUIPTA (CAP) – EMA/VR/0000310717

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: A grouped application comprised of 1 Type II Variation and 3 Type I Variations, as follows:

Type II (C.I.6): Extension of indication to include acute treatment of migraine with or without aura in adults, based on interim results from study M24-305; this is a 24-week, global, Phase 3, multicenter, randomized, double blind, placebo-controlled, multiple-migraine attack study with an open label period to evaluate the safety and efficacy of atogepant in adult participants for the acute treatment of migraine (ECLIPSE). 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 2.2 of the RMP has also been submitted.

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

Applicant: Biocryst Ireland Limited

PRAC Rapporteur: Julia Pallos

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

15.3.5. 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.

15.3.6. Ceftolozane / Tazobactam – ZERBAXA (CAP) – EMA/VR/0000320716

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Adam Przybylkowski

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

C.I.6: Extension of indication to include treatment of hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP), in paediatric patients from birth to less than 18 years of age for ZERBAXA, based on the final results from study MK-7625A-036. This is a Phase 1, open-label, non-comparative, multicentre clinical study to evaluate the safety, tolerability, and pharmacokinetics of ceftolozane/tazobactam in paediatric participants with nosocomial pneumonia. 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 accordingly.

C.I.4: Update of sections 4.2 and 5.2 of the SmPC in order to include dosing recommendations for paediatric patients with impaired renal function, for the indications of complicated Intra-Abdominal Infections (cIAI), Acute pyelonephritis (AP) and complicated Urinary Tract Infections (cUTI), based on an M&S analysis integrating adult and pediatric data sources as described in M&S report "Population pharmacokinetic and probability of target attainment analyses of MK-7625A (ZERBAXA) in pediatric patients in support of nosocomial pneumonia".

Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, section 5.1 “Susceptibility testing breakpoints” in the SmPC has been brought in line with the Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections.

15.3.7. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/VR/0000320534

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

C.I.6.a. To modify the approved therapeutic indication by extending from COMIRNATY concentrate for dispersion for injection formulation to Comirnaty dispersion for injection formulation as well as the overall change of posology from 3mcg to 10mcg and dosing regimen simplification (i.e. from 3-dose to a 2-dose primary course for 6 months to <2 years of age and to a single dose for 2 years to <5 years of age) for the active immunization to prevent COVID-19 caused by SARS-CoV-2 in infants and children from 6 months to <5 years without history of completion of COVID-19 primary series based on sub-study A (SSA) phase 2/3 Groups 1-5 of study C4591048 as well as to support the approved 10mcg single dose simplified posology in vaccine-naïve children from 5 to 11 years of age based on substudy E (SSE) of study C4591048, listed as a category 3 study in the
RMP. As consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 6.5, 6.6 and 8 of the SmPC and sections 1, 2, 3, 4 and 6 of the PL are updated accordingly. Study C4591048 is a master phase 1/2/3 protocol to investigate the safety, tolerability, and immunogenicity of variant adapted BNT162b2 RNA – based vaccine candidate(s) in healthy children. The updated RMP

version 15.2 has also been submitted. In addition, the MAH took the opportunity to implement minor editorial changes in the PI.

C.I.7.b. To delete the 3mcg strength from the Comirnaty Marketing authorisation (EU/1/20/1528/035-036, EU/1/20/1528/042, EU/1/20/1528/050).

15.3.8. 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.

15.3.9. Decitabine / Cedazuridine – INAQOVI (CAP) – EMA/VR/0000304730

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy for INAQOVI in combination with venetoclax, based on interim results from study ASTX727-07; this is a single-arm, open-label pharmacokinetic, safety, and efficacy study of ASTX727 in combination with venetoclax in adult patients with acute myeloid leukemia; As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and bring editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

15.3.10. Deucravacitinib – SOTYKTU (CAP) – EMA/VR/0000309456

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.6, 5.2 and 5.3 of the SmPC based on final results from study IM011-1123. This is a Phase 4, open-label, single-group, single-dose study evaluating deucravacitinib concentrations in the breast milk and plasma of healthy lactating female subjects. The updated RMP (version 4.0) has also been submitted.

15.3.11. Evolocumab – REPATHA (CAP) – EMA/VR/0000322435

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to extend the indication for REPATHA to include adults at high risk for a first cardiovascular event, based on the final results from study 20170625 (VESALIUS); this is a Phase 3, double-blind, randomized, placebo-controlled, multicenter

study to evaluate the impact of evolocumab on major cardiovascular events in patients at high cardiovascular risk without prior myocardial infarction or stroke. 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 9.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, some typographical errors were corrected, and the PI is brought in line with the latest QRD template version.

15.3.12. Fedratinib – INREBIC (CAP) – EMA/VR/0000324950

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Sonja Radowan

Scope: A grouped application consisting of:

C.4. Update of sections 4.4, 4.8, and 5.1 of the SmPC in order to update clinical pharmacology, efficacy and safety information based on final results from study FEDR MF 002 listed as a category 3 study in the RMP; this is a phase 3, multicenter, open-label, randomized study to evaluate the efficacy and safety of fedratinib compared to best available therapy in subjects with dipss-intermediate or high-risk primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis and previously treated with ruxolitinib; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted.

C.3. Update of section 4.8 of the SmPC in order to add subdural hematoma to the list of adverse drug reactions (ADRs) following recommendation of PSUSA PSUSA/00010909/202508.

15.3.13. Human normal immunoglobulin – PRIVIGEN (CAP) – EMA/VR/0000304719

Applicant: CSL Behring GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: A grouped application consisting of:

C.I.6: Extension of indication to include treatment of patients with measles pre/post-exposure prophylaxis in whom active immunisation is contraindicated or not advised, for PRIVIGEN, in alignment with the IVIg core SmPC (EMA/CHMP/BPWP/94038/2007 Rev); As a consequence, sections 2, 4.1, 4.2 and 5.2 of the SmPC. The Package Leaflet is updated accordingly. The RMP version 9 has also been submitted.

15.3.14. Insulin icodec / Semaglutide – KYINSU (CAP) – EMA/VR/0000322527

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise for KYINSU, based on results from the Phase 3b study NN1535-4988 (COMBINE 4); this is a 40-week study comparing the efficacy and safety of once weekly IcoSema and daily insulin glargine 100 units/mL in participants with type 2 diabetes inadequately controlled on oral anti-diabetic drugs. As a

consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.

15.3.15. Lisocabtagene maraleucel / Lisocabtagene maraleucel – BREYANZI (CAP) – EMA/VR/0000327431

Applicant: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of the final report from study CA082-1105 listed as a Specific Obligation in the Annex II of the Product Information. This is a non-interventional study submitted to summarize the consistency of Breyanzi product batch quality data measured at the time of release and clinical outcomes in patients treated with Breyanzi in the post-marketing setting for R/R LBCL within the approved indications and dose range per the EU PI. The Annex II and the RMP version 10.0 are updated accordingly. In addition, the MAH took the opportunity to make a minor editorial update by removing some grey shading from Annex III.

15.3.16. Mavacamten – CAMZYOS (CAP) – EMA/VR/0000294573

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: A grouped application consisting of:

C.I.4: Update of section 4.2 of the SmPC in order to remove the Week 8 echocardiography monitoring and associated down-titration opportunity based on the modelling and simulation analyses along with safety data from two studies conducted in Japan (HORIZON-HCM; CV027004) and China (EXPLORER-CN; CV0271097/LB2001301). The updated RMP version 7.0 has also been submitted.

C.I.4: Update of sections 4.2, and 4.5 of the SmPC in order modify maximum dose requirement from 5 mg to 15 mg for CYP2C19 poor metabolisers (PM), in alignment with the requirement for non-PM based on the modelling and simulation analyses along with safety data from two studies conducted in Japan (HORIZON-HCM; CV027004) and China (EXPLORER-CN; CV0271097/LB2001301). The updated RMP version 7.0 has also been submitted.

15.3.17. Nivolumab – OPDIVO (CAP) – EMA/VR/0000304938

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include OPDIVO for the treatment of adults and adolescents 12 years of age and older with previously untreated Stage III or IV classical Hodgkin Lymphoma (cHL), based on results from the pivotal study CA2098UT (SWOG 1826), a Phase 3, randomized, open-label study of nivolumab (Opdivo) + AVD (N-AVD) versus brentuximab vedotin (Adcetris) + AVD (Bv-AVD) in patients (age ≥12 years) with newly diagnosed, advanced stage cHL. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are

updated. The Package Leaflet is updated in accordance. Version 51.0 of the RMP has also been submitted.

15.3.18. Risankizumab – SKYRIZI (CAP) – EMA/X/0000296763

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Extension application to introduce a new strength of 55 mg solution for injection grouped with a type II variation C.I.6.a to include treatment of paediatric plaque psoriasis (6 to < 18 years) for Skyrizi, based on final results from study M19-977 and interim results from study M19-973. M19-977 is a randomized, active-controlled, efficacy assessor-blinded study to evaluate pharmacokinetics, safety, and efficacy of risankizumab in patients from 6 to less than 18 years of age with moderate to severe plaque psoriasis; M19-973 is a phase 3 multicenter, single-arm, open-label extension study to assess the safety, tolerability, and efficacy of risankizumab in subjects with moderate to severe plaque psoriasis who have completed participation in study M19-977. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.4, 6.5, 6.6, and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.0 of the RMP has also been submitted.

15.3.19. Sacituzumab govitecan – TRODELVY (CAP) – EMA/VR/0000320818

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include Trodelvy, in combination with pembrolizumab, for the treatment of adult patients with unresectable locally advanced or metastatic TNBC who have not received prior systemic therapy for metastatic disease and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10, based on results from study GS-US-592-6173 (ASCENT-04), which is a phase 3 study of sacituzumab govitecan (IMMU-132) and Pembrolizumab versus treatment of physician's choice and Pembrolizumab in patients with previously untreated, locally advanced inoperable or metastatic triple-negative breast cancer, whose tumors express PD-L1. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.2 of the RMP has also been submitted.

15.3.20. Semaglutide – WEGOVY (CAP) – EMA/X/0000296344

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Extension application to introduce a new pharmaceutical form (tablet), associated with four new strengths (1.5 mg, 4 mg, 9mg and 25 mg) and a new route of administration (oral use).

15.3.21. Semaglutide – WEGOVY (CAP) – EMA/VR/0000327359

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Update of sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to reflect clinical results related to adults with overweight/obesity and metabolic dysfunction-associated steatohepatitis (MASH) based on interim results from phase 3a clinical study NN9931-4553 (ESSENCE) as well as three additional clinical trials NN9931-4381, NN9931-4296 and NN9931-4492 in adults with metabolic dysfunction-associated steatotic liver disease and/or MASH; supportive non-clinical results have also been submitted. The Package Leaflet is updated accordingly. The RMP version 10.2 has also been submitted.

15.3.22. Teclistamab – TECVAYLI (CAP) – EMA/VR/0000322279

Applicant: Janssen Cilag International

PRAC Rapporteur: Veronika Macurova

Scope: Extension of indication to include in combination with daratumumab treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy for TECVAYLI, based on interim analysis data from the pivotal study MajesTEC-3 (64007957MMY3001). This is an on-going multicentre, randomised, open-label, Phase 3 study to determine whether adding teclistamab to daratumumab (Tec-Dara) is more efficacious than adding pomalidomide/dexamethasone (DPd) or bortezomib/dexamethasone (DVd) to daratumumab in participants with multiple myeloma who previously received 1 to 3 prior line(s) of therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.7, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated accordingly. References to the conditional MA have been removed throughout the document. Additionally, the MAH took the opportunity to update the latest renewal date in section 9 of the SmPC, the list of local representatives in the Package Leaflet and made editorial changes throughout. And updated RMP version 6.1 has been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

15.3.23. Tedizolid phosphate – SIVEXTRO (CAP) – EMA/X/0000282136

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension application to introduce a new pharmaceutical form (powder for oral suspension, 200 mg). The RMP (version 8.1) is updated in accordance. Additionally, the marketing authorisation holder took the opportunity to align the PI with the latest QRD template.

15.3.24. Tezepelumab – TEZSPIRE (CAP) – EMA/VR/0000321455

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

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

C.I.13: Submission of the report from study D5180C00024 (SUNRISE) listed as a category 3 study in the RMP. This is a randomised, double-blind, parallel-group, placebo-controlled 28-week phase 3 efficacy and safety study of tezepelumab in reducing oral corticosteroid use in adults with oral corticosteroid dependent asthma. The RMP version 7 has also been updated accordingly.

C.I.11: Submission of an updated RMP version 7 in order to add study D5241C00006 (EMBARK) and study D5241C00007 (JOURNEY) as additional pharmacovigilance activities to further characterize the important potential risks: "Serious infections" and "Malignancies".

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

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

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

15.3.26. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/VR/0000322236

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include the indication first-line treatment of adult patients with unresectable or metastatic HER2-positive breast cancer for Enhertu (trastuzumab deruxtecan) in combination with pertuzumab is based on results from the phase 3 DESTINY-Breast09 study. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 of SmPC are updated and the Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted.

15.3.27. Trastuzumab deruxtecan – ENHERTU (CAP) – EMA/VR/0000293327

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumours who have received prior treatment and who have no satisfactory alternative treatment options for Enhertu, based on pooled pop-PK analysis and interim results from study D967VC00001 (DESTINY-PanTumor02); this is a Phase II, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of Trastuzumab Deruxtecan (T-DXd, DS-8201a) for the Treatment of Selected HER2-expressing Tumors; 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 9.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI.

15.3.28. Vamorolone – AGAMREE (CAP) – EMA/VR/0000293535

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of 2 to <4 year olds for AGAMREE, based on final results from study VBP15-006; this is a phase II open-label, multiple dose study to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and exploratory efficacy of vamorolone in boys ages 2 to <4 years and 7 to <18 years with Duchenne Muscular Dystrophy (DMD) and an updated paediatric extrapolation report referencing 4 to <7-year-old subjects with DMD from Study VBP15-004, compared to the 2 to <4-year-old population from Study VBP15-006. 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. In addition, the Marketing authorisation holder took the opportunity to make some editorial corrections to SmPC.

15.3.29. Venetoclax – VENCLYXTO (CAP) – EMA/VR/0000322237

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include, in combination with ibrutinib, the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) for VENCLYXTO based on the results of the phase 3 study 54179060CLL3011 (GLOW) and phase 2 study PCYC-1142-CA (CAPTIVATE). GLOW is a randomized, open-label, phase 3 study of the combination of ibrutinib plus venetoclax versus chlorambucil plus obinutuzumab for the first-line treatment of subjects with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL). CAPTIVATE study is a phase 2, multicenter, international, efficacy and safety study assessing treatment with venetoclax plus ibrutinib in subjects with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet.

15.3.30. Venetoclax – VENCLYXTO (CAP) – EMA/VR/0000322240

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include, in combination with acalabrutinib with or without obinutuzumab, the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) for VENCLYXTO based on the results from the pivotal study ACE-CL-311/D8221C00001 (AMPLIFY); this is a randomized, multicenter, open-label, Phase 3 study to compare the efficacy and safety of acalabrutinib (ACP-196) in combination with venetoclax with and without obinutuzumab compared to investigator's choice of chemoimmunotherapy in subjects with previously untreated chronic lymphocytic leukemia without del(17p) or TP53 mutation. 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. The RMP version 11.1 has also been submitted.

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. Abrocitinib – CIBINQO (CAP) – EMA/PSUR/0000317674

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010976/202509)

16.1.2. Aprocitentan – JERAYGO (CAP) – EMA/PSUR/0000317689

Applicant: Idorsia Pharmaceuticals Deutschland GmbH

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00011067/202509)

16.1.3. Asenapine – SYCREST (CAP) – EMA/PSUR/0000317636

Applicant: Organon N.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00000256/202508)

16.1.4. Bedaquiline – SIRTURO (CAP) – EMA/PSUR/0000317651

Applicant: Janssen Cilag International

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010074/202509)

16.1.5. Brentuximab vedotin – ADCETRIS (CAP) – EMA/PSUR/0000317688

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010039/202508)

16.1.6. Caplacizumab – CABLIVI (CAP) – EMA/PSUR/0000317662

Applicant: Ablynx

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010713/202508)

16.1.7. Crizotinib – XALKORI (CAP) – EMA/PSUR/0000317663

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00010042/202508)

16.1.8. Damoctocog alfa pegol – JIVI (CAP) – EMA/PSUR/0000317669

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010732/202508)

16.1.9. Dasiglucagon – ZEGALOGUE (SRD) (CAP) – EMA/PSUR/0000317683

Applicant: Zealand Pharma A/S

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00011078/202508)

16.1.10. Deucravacitinib – SOTYKTU (CAP) – EMA/PSUR/0000317694

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011046/202509)

16.1.11. Doravirine – PIFELTRO (CAP) – EMA/PSUR/0000317664

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010729/202508)

16.1.12. Doravirine / Lamivudine / Tenofovir disoproxil – DELSTRIGO (CAP) – EMA/PSUR/0000317666

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010731/202508)

16.1.13. Duvelisib – COPIKTRA (SRD) (CAP) – EMA/PSUR/0000317672

Applicant: Secura Bio Limited

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010939/202509)

16.1.14. Ebola vaccine (Ad26.ZEBOV-GP [recombinant]) – ZABDENO (CAP); Ebola vaccine (MVA-BN-Filo [recombinant]) – MVABEA (CAP) – EMA/PSUR/0000317690

Applicant: Janssen Cilag International

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010857/202509)

16.1.15. Epcoritamab – TEPKINLY (CAP) – EMA/PSUR/0000317637

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00000107/202509)

16.1.16. Filgotinib – JYSELECA (CAP) – EMA/PSUR/0000317681

Applicant: Alfasigma S.p.A.

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00010879/202509)

16.1.17. Fruquintinib – FRUZAQLA (CAP) – EMA/PSUR/0000317678

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011069/202509)

16.1.18. Ganaxolone – ZTALMY (CAP) – EMA/PSUR/0000317639

Applicant: Immedica Pharma AB

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000093/202509)

16.1.19. Infliximab – FLIXABI (CAP); INFLECTRA (CAP); REMICADE (CAP); REMSIMA (CAP); ZESSLY (CAP) – EMA/PSUR/0000317670

Applicants: Janssen Cilag International, Celltrion Healthcare Hungary Kft., Pfizer Europe MA EEIG, Samsung Bioepis NL B.V., Sandoz GmbH

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010759/202508)

16.1.20. Insulin icodec – AWIQLI (CAP) – EMA/PSUR/0000317726

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011053/202508)

16.1.21. Lebrikizumab – EBGLYSS (CAP) – EMA/PSUR/0000317693

Applicant: Almirall S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000175/202509)

16.1.22. Mecasermin – INCRELEX (CAP) – EMA/PSUR/0000317644

Applicant: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001942/202508)

16.1.23. Momelotinib – OMJJARA (CAP) – EMA/PSUR/0000317675

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00000263/202509)

16.1.24. Retifanlimab – ZYNYZ (CAP) – EMA/PSUR/0000317673

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011059/202509)

16.1.25. Ritonavir – NORVIR (CAP) – EMA/PSUR/0000317692

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00002651/202508)

16.1.26. Serplulimab – HETRONIFLY (CAP) – EMA/PSUR/0000317684

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011112/202509)

16.1.27. Sotatercept – WINREVAIR (CAP) – EMA/PSUR/0000317685

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00011076/202509)

16.1.28. Spesolimab – SPEVIGO (CAP) – EMA/PSUR/0000317676

Applicant: LEO PHARMA A/S

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00011033/202509)

16.1.29. Tasonermin – BEROMUN (CAP) – EMA/PSUR/0000317660

Applicant: Belpharma S.A.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00002850/202508)

16.1.30. Tenecteplase – METALYSE (CAP) – EMA/PSUR/0000317658

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00002888/202508)

16.1.31. Tisotumab vedotin – TIVDAK (CAP) – EMA/PSUR/0000317687

Applicant: Genmab A/S

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00011127/202509)

16.1.32. Vemurafenib – ZELBORAF (CAP) – EMA/PSUR/0000317646

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00009329/202508)

16.1.33. Vernakalant – BRINAVESS (CAP) – EMA/PSUR/0000317649

Applicant: Advanz Pharma Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00003109/202508)

16.1.34. Vibegron – OBGEMSA (CAP) – EMA/PSUR/0000317679

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011068/202509)

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

16.2.1. Atropine sulfate – RYJUNEA (CAP); NAP – EMA/PSUR/0000317677

Applicants: Santen Oy, various

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011142/202508)

16.2.2. Budesonide / Formoterol – BIRESP SPIROMAX (CAP); DUORESP SPIROMAX (CAP); Budesonide / Formoterol fumarate dihydrate – GORESP DIGIHALER (CAP); NAP – EMA/PSUR/0000317659

Applicants: Teva Pharma B.V., various

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010585/202508)

16.2.3. Octocog alfa – ADVATE (CAP); KOVALTRY (CAP); NAP – EMA/PSUR/0000317640

Applicants: Takeda Manufacturing Austria AG, Bayer AG, various

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00002200/202508)

16.2.4. Trientine – CUFENCE (CAP); CUPRIOR (CAP); NAP – EMA/PSUR/0000317661

Applicants: Orphalan, Univar Solutions B.V., various

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010637/202509)

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

16.3.1. Biperiden – EMA/PSUR/0000317634

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000415/202508)

16.3.2. Clonidine – EMA/PSUR/0000317638

Applicants: various

PRAC Lead: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00000813/202508)

16.3.3. Drospirenone / ethinylestradiol – EMA/PSUR/0000317652

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010217/202509)

16.3.4. Finasteride – EMA/PSUR/0000317641

Applicants: various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00001392/202508)

16.3.5. Fluocinolone acetonide (intravitreal implant in applicator) – EMA/PSUR/0000317680

Applicants: various

PRAC Lead: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010224/202508)

16.3.6. Hexoprenaline sulfate – EMA/PSUR/0000317650

Applicants: various

PRAC Lead: Roxana Dondera

Scope: Evaluation of a PSUSA procedure (PSUSA/00003170/202508)

16.3.7. Losartan – EMA/PSUR/0000317642

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001912/202509)

16.3.8. Meclozine – EMA/PSUR/0000317667

Applicants: various

PRAC Lead: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00001945/202508)

16.3.9. Nifedipine – EMA/PSUR/0000317647

Applicants: various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00002156/202508)

16.3.10. Poractant alfa – EMA/PSUR/0000317645

Applicants: various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00002478/202508)

16.3.11. Povidone, polyvinyl alcohol / povidone – EMA/PSUR/0000317643

Applicants: various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00002475/202509)

16.3.12. Raltitrexed – EMA/PSUR/0000317648

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00002605/202509)

16.4. Follow-up to PSUR/PSUSA procedures

None

16.5. Variation procedure(s) resulting from PSUSA evaluation

16.5.1. Natalizumab – TYSABRI (CAP) – EMA/VR/0000315289

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Update of sections 4.2, 4.4 of the SmPC, and Annex II in order to align with the revised content of the additional risk minimisation materials in the RMP following the PRAC

recommendation in EU PSUR 23 for the Tysabri (EMEA/H/C/PSUSA/00002127/202408). The Package Leaflet is updated accordingly. The RMP version 34.1 has been submitted; the due date for the provision of the final CSR for category 3 PASS study 101MS412 is also being revised.

16.6. Expedited summary safety reviews[23]

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.

17.1. Protocols of PASS imposed in the marketing authorisation(s)[24]

17.1.1. Lisocabtagene maraleucel / Lisocabtagene maraleucel – BREYANZI (CAP) – EMA/PASS/0000328042

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: PASS amendment [107o]: Non-interventional PASS of patients treated with commercially available liso-cel (lisocabtagene maraleucel) for large B-cell lymphomas

17.1.2. 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)[25]

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

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Liana Martirosyan

[23] 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
[24] In accordance with Article 107n of Directive 2001/83/EC
[25] In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

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

17.2.2. Inebilizumab – UPLIZNA (CAP) – EMA/PAM/0000325493

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) and immunoglobulin G4-related disease (IgG4-RD) treated with inebilizumab (UPLIZNA) in Europe

17.3. Results of PASS imposed in the marketing authorisation(s)[26]

None

17.4. Results of PASS non-imposed in the marketing authorisation(s)[27]

17.4.1. COVID-19 mRNA vaccine – COMIRNATY (CAP) – EMA/VR/0000302705

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final report, protocol amendment #6 and SAP amendment #5 for the non-interventional study C4591021, listed as a category 3 PASS in the RMP. This is a post conditional approval active surveillance study among individuals in Europe receiving the Pfizer BioNTech Coronavirus Disease 2019 (COVID-19) vaccine. The RMP version 15.1 has also been submitted.

17.4.2. Fenfluramine – FINTEPLA (CAP) – EMA/VR/0000296039

Applicant: UCB Pharma

PRAC Rapporteur: Dennis Lex

Scope: Submission of the final report for study EP0220 listed as a category 3 study in the RMP. This is a non-interventional study to assess the effectiveness of risk minimization measures in approved indications for fenfluramine hydrochloride. The RMP version 5.1 has been updated accordingly.

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

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Dennis Lex

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

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

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

17.5.1. 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,

17.5.2. Damoctocog alfa pegol – JIVI (CAP) – EMA/PAM/0000324421

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: 17th annual report for Study 14149: EUHASS Registry (European Haemophilia Safety Surveillance)

17.5.3. Infliximab – REMSIMA (CAP) – EMA/PAM/0000325710

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Kimmo Jaakkola

Scope: 3rd annual recruitment report for Study CT-P13 4.8, an observational, prospective cohort study to evaluate safety of Remsima SC (subcutaneous) in patients with Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis and Psoriasis; former MEA 020

17.5.4. Nirmatrelvir / Ritonavir – PAXLOVID (CAP) – EMA/PAM/0000324414

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Dennis Lex

Scope: The second interim report (31 December 2025) for PASS C4671047: Use and safety of Paxlovid among patients with moderate or severe hepatic impairment.

17.5.5. Nonacog beta pegol – REFIXIA (CAP) – EMA/PAM/0000323326

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Dirk Mentzer

Scope: 7th progress report of study NN7999-4031: A non-interventional post-authorisation safety study (PASS) in male haemophilia B patients receiving Nonacog Beta Pegol (N9-GP) prophylaxis treatment.

17.5.6. Rivaroxaban – XARELTO (CAP) – EMA/PAM/0000316572

Applicant: Bayer AG

PRAC Rapporteur: Mari Thorn

Scope: Third study progress report for the Paediatric VTE PASS Drug Utilization Study (XAPAEDUS): An observational, longitudinal, multi-source drug utilization safety study to evaluate the drug use patterns and safety of rivaroxaban oral suspension in children under two years with venous thromboembolism.

17.5.7. Sebelipase alfa – KANUMA (CAP) – EMA/PAM/0000320327

Applicant: Alexion Europe

PRAC Rapporteur: Mari Thorn

Scope: LAL-D registry 8th interim report of Study ALX-LALD-501, An observational disease and clinical outcomes registry of patients with lysosomal acid lipase (lal) deficiency dated 02 December 2025 (cut-off date: 28 August 2025)

17.5.8. Selexipag – UPTRAVI (CAP) – EMA/PAM/0000309454

Applicant: Janssen Cilag International

PRAC Rapporteur: Zoubida Amimour

Scope: Second interim Clinical study report of study AC-065A403 (EDUCATE), a category 3 PASS study (EMEA/H/C/003774/MEA/003) with a data cut-off date of 11 July 2025.

17.5.9. Vosoritide – VOXZOGO (CAP) – EMA/PAM/0000321452

Applicant: Biomarin International Limited

PRAC Rapporteur: Zane Neikena

Scope: Provision of 2nd Bi-annual safety report for PASS study 111-603 (former MEA 005.6).

17.5.10. Zanubrutinib – BRUKINSA (CAP) – EMA/PAM/0000319828

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Interim report of study BGB-3111-LTE1: an open-label, multicenter, long-term extension study of zanubrutinib (BGB-3111) regimens in patients with B-cell malignancies

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. Afamelanotide – SCENESSE (CAP) – EMA/S/0000322534

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Dennis Lex

Scope: Annual reassessment of the marketing authorisation

18.1.2. Glucarpidase – VORAXAZE (CAP) – EMA/S/0000322329

Applicant: Serb

PRAC Rapporteur: Dennis Lex

Scope: Annual reassessment of the marketing authorisation

18.1.3. Histamine dihydrochloride – CEPLENE (CAP) – EMA/S/0000319752

Applicant: Laboratoires Delbert

PRAC Rapporteur: Eamon O Murchu

Scope: Annual reassessment of the marketing authorisation

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

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

18.1.5. Tagraxofusp – ELZONRIS (CAP) – EMA/S/0000320819

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Annual reassessment of the marketing authorisation

18.1.6. Vilobelimab – GOHIBIC (CAP) – EMA/S/0000319310

Applicant: InflaRx GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Annual reassessment of the marketing authorisation

18.2. Conditional renewals of the marketing authorisation

18.2.1. Imlifidase – IDEFIRIX (CAP) – EMA/R/0000327647

Applicant: Hansa Biopharma AB

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

18.2.2. Resmetirom – REZDIFFRA (CAP) – EMA/R/0000326759

Applicant: Madrigal Pharmaceuticals EU Limited

PRAC Rapporteur: Lina Seibokiene

Scope: Conditional renewal of the marketing authorisation

18.2.3. Talquetamab – TALVEY (CAP) – EMA/R/0000327092

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Conditional renewal of the marketing authorisation

18.2.4. Teclistamab – TECVAYLI (CAP) – EMA/R/0000327677

Applicant: Janssen Cilag International

PRAC Rapporteur: Veronika Macurova

Scope: Conditional renewal of the marketing authorisation

18.3. Renewals of the marketing authorisation

None

19. Annex II – List of participants

including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 07-10 April 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	
Jan Neuhauser	Member	Austria	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	
Stanislav Stoilov	Alternate	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	
Terhi Lehtinen	Member	Finland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Kimmo Jaakkola	Alternate	Finland	No interests declared	
Tiphaine Vaillant	Member	France	No interests declared	
Zoubida Amimour	Alternate	France	No participation in discussion, final deliberations and voting on:	4.2.1. Axicabtagene ciloleucel – YESCARTA (CAP) - EMEA/H/C/002695/SDA/019; lisocabtagene maraleucel – BREYANZI (CAP) - EMEA/H/C/002695/SDA/025 15.3.10. EMA/VR/00003 09456 15.3.12. EMA/VR/00003 24950 15.3.15. EMA/VR/00003 27431 15.3.16. EMA/VR/00002 94573 15.3.17. EMA/VR/00003 04938 16.1.10. EMA/PSUR/000 0317694 17.1.1. EMA/PASS/000 0328042
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 restrictions applicable to this meeting	
Julia Pallos	Member	Hungary	No participation	4.2.1. Axicabtagene ciloleucel –

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
			in discussion, final deliberations and voting on:	YESCARTA (CAP) - EMEA/H/C/002695/SDA/019; lisocabtagene maraleucel – BREYANZI (CAP) - EMEA/H/C/002695/SDA/025 15.3.10. EMA/VR/0000309456 15.3.12. EMA/VR/0000324950 15.3.15. EMA/VR/0000327431 15.3.16. EMA/VR/0000294573 15.3.17. EMA/VR/0000304938 16.1.10. EMA/PSUR/0000317694 17.1.1. EMA/PASS/0000328042
Melinda Palfi	Alternate	Hungary	No interests declared	
Guðrún Stefánsdóttir	Member	Iceland	No participation in discussion, final deliberations and voting on:	15.2.2. EMA/VR/0000325402 15.3.11. EMA/VR/0000322435 17.2.2. EMA/PAM/0000325493
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Diana Litenboka	Alternate	Latvia	No interests declared	
Rugile Pilviniene	Member	Lithuania	No restrictions applicable to this meeting	
Anne-Cecile Vuillemin	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No restrictions applicable to this meeting	
Benjamin Micallef	Alternate	Malta	No interests declared	
Liana Martirosyan	Member	Netherlands	No interests declared	
Bianca Mulder	Alternate	Netherlands	No restrictions applicable to this meeting	
David Olsen	Member	Norway	No participation in discussion, final deliberations and voting on:	16.1.8. EMA/PSUR/0000317669 16.2.3. EMA/PSUR/0000317640 16.3.3. EMA/PSUR/0000317652 16.3.9. EMA/PSUR/0000317647 17.5.2. EMA/PAM/0000324421 17.5.6. EMA/PAM/0000316572
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
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	
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	
Mari Thorn	Member	Sweden	No restrictions applicable to this meeting	
Karin Bolin	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Hedvig Marie Egeland Nordeng	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 applicable to this meeting	
Yiannoula Koulla	Member	Patients' Organisation Representative	No interests declared	
Michal Rataj	Alternate	Patients' Organisation Representative	No interests declared	
Christelle Bizimungu	Expert	Belgium	No interests declared	
Piyush Jain	Expert	Belgium	No interests declared	
Fabrice Moore	Expert	Belgium	No interests declared	
Dominik Dautović	Expert	Croatia	No interests declared	
Lucie Skalova	Expert	Czech Republic	No interests declared	
Nicklas Hasselblad Lundstrøm	Expert	Denmark	No interests declared	
Natacha Leininger Severin	Expert	Denmark	No interests declared	
Moritz Sander	Expert	Denmark	No restrictions applicable to this meeting	
Emma Stadsbjerg	Expert	Denmark	No restrictions	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
			applicable to this meeting	
Pauline Dayani	Expert	France	No interests declared	
Nina Pannwitz	Expert	Germany	No interests declared	
Laura Zein	Expert	Germany	No interests declared	
Eleanor Carey	Expert	Ireland	No interests declared	
Sheena Kennedy	Expert	Ireland	No restrictions applicable to this meeting	
Helen Gatling	Expert	Netherlands	No interests declared	
Fakhredin Sayed Tabatabaei	Expert	Netherlands	No interests declared	
Maria Vanenburg	Expert	Netherlands	No interests declared	
Anita Volkers	Expert	Netherlands	No interests declared	
Joao Fernandes	Expert	Portugal	No restrictions applicable to this meeting	
Linnea Asp	Expert	Sweden	No interests declared	
Charlotte Backman	Expert	Sweden	No interests declared	
Elin Blom	Expert	Sweden	No interests declared	
Jenny Jönsson	Expert	Sweden	No restrictions applicable to this meeting	
Miriam Taekema	Expert	Sweden	No interests declared	
Linnea Willdén Melin	Expert	Sweden	No interests declared	
A representative from the European Commission attended the meeting				
Observers from Health Canada attended the meeting.				

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
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