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Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 08-11 January 2024

Chair: Sabine Straus – Vice-Chair: Martin Huber

08 January 2024, 10:30 – 19:30, via teleconference

09 January 2024, 08:30 – 19:30, via teleconference

10 January 2024, 08:30 – 19:30, via teleconference

11 January 2024, 08:30 – 16:00, via teleconference

Organisational, regulatory and methodological matters (ORGAM)

25 January 2024, 09:00 – 12:00, via teleconference

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PRAC plenary session to be held 08-11 January 2024. See January 2024 PRAC minutes (to be published post February 2024 PRAC meeting).

1.2. Agenda of the meeting on 08-11 January 2024

Action: For adoption

1.3. Minutes of the previous meeting on 27-30 November 2023

Action: For adoption

2. EU referral procedures for safety reasons: urgent EU procedures

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

3. EU referral procedures for safety reasons: other EU referral procedures

3.1. Newly triggered procedures

None

3.2. Ongoing procedures

3.2.1. Hydroxyprogesterone (NAP) - EMEA/H/A-31/1528

Applicant(s): various

PRAC Rapporteur: Amelia Cupelli; PRAC Co-rapporteur: Nathalie Gault

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

Action: For adoption of a revised timetable and a list of participants for the ad-hoc expert group (AHEG) meeting

3.3. Procedures for finalisation

None

3.4. Re-examination procedures¹

None

3.5. Others

None

4. Signals assessment and prioritisation²

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. Aflibercept – EYLEA (CAP), YESAFILI (CAP); ranibizumab – LUCENTIS (CAP)

Applicant(s): Bayer AG (Eylea), Biosimilar Collaborations Ireland Limited (Yesafili), Novartis Europharm Limited (Lucentis)

PRAC Rapporteur: to be appointed

Scope: Signal of nephropathy toxic after intravitreal administration

Action: For adoption of PRAC recommendation

EPITT 20024 – New signal

Lead Member State(s): FR

¹ Re-examination of PRAC recommendation under Article 32 of Directive 2001/83/EC

² Each signal refers to a substance or therapeutic class. The route of marketing authorisation is indicated in brackets (CAP for Centrally Authorised Products; NAP for Nationally Authorised Products including products authorised via Mutual Recognition Procedures and Decentralised Procedure). Product names are listed for reference Centrally Authorised Products (CAP) only. PRAC recommendations will specify the products concerned in case of any regulatory action required

4.1.2. Axicabtagene ciloleucel – YESCARTA (CAP); idecabtagene vicleucel – ABECMA (CAP); lisocabtagene maraleucel – BREYANZI (CAP); ciltabtagene autoleucel – CARVYKTI (CAP); tisagenlecleucel – KYMRIAH (CAP); brexucabtagene autoleucel – TECARTUS (CAP)

Applicant(s): Bristol-Myers Squibb Pharma EEIG (Abecma, Breyanzi), Kite Pharma EU B.V. (Tecartus, Yescarta), Janssen-Cilag International NV (Carvykti), Novartis Europharm Limited (Kymriah), ATMP

PRAC Rapporteur: to be appointed

Scope: Signal of secondary malignancy of T-cell origin

Action: For adoption of PRAC recommendation

EPITT 20040 – New signal

Lead Member State(s): BE, DE, DK, NL, SE

4.1.3. Clobazam (NAP)

Applicant(s): various

PRAC Rapporteur: to be appointed

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

Action: For adoption of PRAC recommendation

EPITT 20041 – New signal

Lead Member State(s): FI

4.1.4. Dabrafenib – TAFINLAR (CAP); FINLEE (CAP); Trametinib – MEKINIST (CAP)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: to be appointed

Scope: Signal of acute febrile neutrophilic dermatosis

Action: For adoption of PRAC recommendation

EPITT 20022 – New signal

Lead Member State(s): NO

4.1.5. Ixazomib – NINLARO (CAP)

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Signal of vasculitis

Action: For adoption of PRAC recommendation

EPITT 20023 – New signal

Lead Member State(s): SE

4.2. New signals detected from other sources

4.2.1. Baricitinib – OLUMIANT (CAP)

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Signal of hypoglycaemia in diabetic patients

Action: For adoption of PRAC recommendation

EPITT 20038 – New signal

4.2.2. Canagliflozin – INVOKANA (CAP); Dapagliflozin – EDISTRIDE (CAP), FORXIGA (CAP), NAP; Empagliflozin – JARDIANCE (CAP); Empagliflozin, metformin – SYNJARDY (CAP), NAP

Applicant(s): AstraZeneca AB (Forxiga, Edistride), Boehringer Ingelheim International GmbH (Jardiance, Synjardy), Janssen-Cilag International N.V. (Invokana), various

PRAC Rapporteur: to be appointed

Scope: Signal of polycythaemia

Action: For adoption of PRAC recommendation

EPITT 20019 – New signal

Lead Member State(s): DE, ES, SE

4.2.3. Manidipine (NAP)

Applicant(s): various

PRAC Rapporteur: to be appointed

Scope: Signal of ascites

Action: For adoption of PRAC recommendation

EPITT 20026 – New signal

Lead Member State(s): IT

4.2.4. Propofol (NAP)

Applicant(s): various

PRAC Rapporteur: to be appointed

Scope: Signal of risk of hepatic failure

Action: For adoption of PRAC recommendation

EPITT 20020 – New signal

Lead Member State(s): NO

4.3. Signals follow-up and prioritisation

4.3.1. Amphotericin B (NAP)

Applicant(s): various

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Signal of hyperkalaemia

Action: For adoption of PRAC recommendation

EPITT 19966 – Follow-up to September 2023

4.3.2. Avatrombopag – DOPTLET (CAP) – EMEA/H/C/004722/SDA/006

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Monica Martinez Redondo

Scope: Signal of antiphospholipid syndrome

Action: For adoption of PRAC recommendation

EPITT 19954 – Follow-up to September 2023

4.3.3. Cefotaxime (NAP)

Applicant(s): various

PRAC Rapporteur: Sonja Hrabcik

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

Action: For adoption of PRAC recommendation

EPITT 19960 – Follow-up to September 2023

4.3.4. Cobimetinib – COTELLIC (CAP) - EMEA/H/C/003960/SDA/006; Vemurafenib – ZELBORAF (CAP) - EMEA/H/C/002409/SDA/039

Applicant: Roche Registration GmbH

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Signal of aphthous ulcer, mouth ulceration, stomatitis

Action: For adoption of PRAC recommendation

EPITT 19961 – Follow-up to September 2023

4.4. Variation procedure(s) resulting from signal evaluation

None

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Denosumab - EMEA/H/C/005964

Scope: treatment of osteoporosis

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.2. Denosumab - EMEA/H/C/006378

Scope: prevention of skeletal related events with advanced malignancies

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.3. Efanesoctocog alfa - EMEA/H/C/005968, Orphan

Applicant: Swedish Orphan Biovitrum AB (publ)

Scope: Treatment and prophylaxis of bleeding in patients with haemophilia A

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.1.4. Sotatercept - EMEA/H/C/005647, PRIME, Orphan

Applicant: Merck Sharp & Dohme B.V.

Scope: treatment of pulmonary arterial hypertension in adults

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

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

5.2.1. Beclometasone dipropionate, formoterol fumarate dihydrate, glycopyrronium - RIARIFY (CAP) - EMEA/H/C/004836/WS2604/0029; TRYDONIS (CAP) - EMEA/H/C/004702/WS2604/0034

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: C.I.11.z - To provide a new version of the RMP for Riarify and Trydonis in order to update the post authorisation exposure data and replace the protocol of the PASS for study CLI-05993BA1-05 in Annex 3, following its approval via procedure EMEA/H/C/004257/MEA/002.3 for Trimbow (Beclometasone, formoterol, glycopyrronium bromide) concluded at PRAC in January 2023.

Action: For adoption of PRAC Assessment Report

5.2.2. Doxorubicin - CAELYX PEGYLATED LIPOSOMAL (CAP) - EMEA/H/C/000089/II/0107

Applicant: Baxter Holding B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Submission of an updated RMP version 6.1 in order to align to GVP Module V Revision 2 requirements, following a request received within the Assessment Report for procedure EMEA/H/C/PSUSA/00001172/202111

Action: For adoption of PRAC Assessment Report

5.2.3. Risdiplam - EVRYSDI (CAP) - EMEA/H/C/005145/II/0020

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: Submission of an updated RMP version 2.0 in order to remove the important potential risk of retinal toxicity with risdiplam due to the absence of evidence of retinal toxicity based on thorough ophthalmological monitoring in clinical studies to date

Action: For adoption of PRAC Assessment Report

5.2.4. Telmisartan - KINZALMONO (CAP) - EMEA/H/C/000211/WS2577/0120; MICARDIS (CAP) - EMEA/H/C/000209/WS2577/0129; PRITOR (CAP) - EMEA/H/C/000210/WS2577/0133

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Amelia Cupelli

Scope: Submission of an updated RMP version 6.1 in order to implement an overall update regarding safety concerns based on literature and post marketing data; and to adapt the RMP to the current RMP format (Rev 2.0.1), in line with GVP Module V, Revision 2.

Action: For adoption of PRAC Assessment Report

5.2.5. Telmisartan, hydrochlorothiazide - KINZALKOMB (CAP) - EMEA/H/C/000415/WS2611/0123; MICARDISPLUS (CAP) - EMEA/H/C/000413/WS2611/0130; PRITORPLUS (CAP) - EMEA/H/C/000414/WS2611/0133

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Amelia Cupelli

Scope: Submission of an updated RMP version 9.1 for MicardisPlus, PritorPlus and Kinzalkomb in order to remove all important identified and potential risks from the list of safety concerns and to adapt the RMP to the current RMP format (Rev 2.0.1), in line with GVP Module V, Revision 2

Action: For adoption of PRAC Assessment Report

5.2.6. Velaglucerase alfa - VPRIV (CAP) - EMEA/H/C/001249/II/0061

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Martin Huber

Scope: Submission of an updated RMP version 12.0 in order to remove certain risks from the list of safety concerns

Action: For adoption of PRAC Assessment Report

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

5.3.1. Amivantamab - RYBREVANT (CAP) - EMEA/H/C/005454/II/0010

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include amivantamab in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating epidermal-growth factor receptor (EGFR) Exon 20 insertion mutations for RYBREVANT, based on the final results from study 61186372NSC3001 listed as a Specific Obligation in the Annex II of the product information; this is a global, open-label, randomised Phase 3 study of ACP compared to CP alone in participants with newly diagnosed, locally advanced or metastatic NSCLC characterized by EGFR exon 20ins. The primary objective of the PAPILLON study is to compare efficacy, as demonstrated by PFS, in participants treated with ACP versus CP alone. As a consequence, sections 4.1, 4.2, 4.8, 4.9, 5.1, 5.2 and 6.6 of the SmPC are updated. The package leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II and Annex IV of the product information. Consequently, the MAH proposes a switch from marketing authorisation under exceptional circumstances to full marketing authorisation given the fulfilment of the SOB. As part of the application, the MAH also requests an extension of the market protection by one additional year

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.2. Aripiprazole - ABILIFY MAINTENA (CAP) - EMEA/H/C/002755/X/0045

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Extension application to introduce a new pharmaceutical form associated with two new strengths (720 and 960 mg Prolonged-release suspension for injection). The RMP (version 12.1) is updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.3. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/II/0020

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include treatment of moderate to severe hidradenitis suppurativa (HS) in adults, based on final results from study HS0003 (BE HEARD I) and study HS0004 (BE HEARD II). These are phase 3, randomised, double blind, placebo controlled, multicentre, pivotal studies evaluating the efficacy and safety of bimekizumab in study participants with moderate to severe HS. Further supportive data are based on the results of phase 2 study HS0001 and phase 3 currently ongoing open-label extension study HS0005. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 1.10 of the RMP has also been submitted. Furthermore, the product information is brought in line with the latest QRD template version 10.3

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.4. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/X/0021

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Extension application to add a new strength of 320 mg (160 mg/ml) for bimekizumab solution for injection in pre-filled syringe or pre-filled pen, for subcutaneous (SC) administration. Version 1.11 of the RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.5. Budesonide - KINPEYGO (CAP) - EMEA/H/C/005653/II/0008, Orphan

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to slow kidney function decline in adults with primary immunoglobulin A (IgA) nephropathy (IgAN) for KINPEYGO, based on Part B of study NefIgArd (NEF-301), listed as the final specific obligation in the Annex II; this is a Phase 3, randomised, double-blind, placebo-controlled, multicentre study to evaluate the efficacy, safety, and tolerability of oral Nefecon³ compared to matching placebo in patients with primary IgAN on a background of optimised renin-angiotensin system (RAS) inhibitor therapy. 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 1.1 of the RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.6. Coronavirus (COVID-19) vaccine (recombinant protein receptor binding domain fusion heterodimer) - BIMERVAX (CAP) - EMEA/H/C/006058/II/0010

Applicant: Hipra Human Health S.L.

PRAC Rapporteur: Zane Neikena

Scope: Submission of the final report from study HIPRA-HH-5, a phase III, open label, single arm, multi-centre, trial to assess the safety and immunogenicity of a booster vaccination with a recombinant protein RBD fusion heterodimer candidate (PHH-1V) against

³ Kinpeygo is referred to as "Nefecon" in clinical studies

SARS-COV-2, in adults vaccinated against COVID-19. The RMP version 1.3 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.7. Denosumab - PROLIA (CAP) - EMEA/H/C/001120/II/0099

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Mari Thorn

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to update a warning regarding hypocalcaemia and to include reports of life-threatening events and fatal cases occurred in the post marketing setting, particularly in patients with severe renal impairment, receiving dialysis or treatment with other calcium lowering drugs based on the cumulative review of MAH safety database and literature. The package leaflet is updated accordingly. The RMP version 32.0 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.8. Dolutegravir, abacavir, lamivudine - TRIUMEQ (CAP) - EMEA/H/C/002754/II/0116

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include treatment of paediatric patients from 6 kg to less than 25 kg for Triumeq dispersible tablets, based on PK, safety, and efficacy data observed in the final results of study 205860 (IMPAACT 2019), further supported by extrapolation to data generated in adults and additional data in paediatric patients with the single entities. IMPAACT 2019 is a Phase 1/2 open-label, multicentre, multiple dose study of dolutegravir/lamivudine/abacavir fixed dose combination tablets in treatment-experienced and treatment-naïve HIV-1-infected children less than 12 years of age. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The package leaflet is updated in accordance. Version 22.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the product information

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.9. Dupilumab - DUPIXENT (CAP) - EMEA/H/C/004390/II/0079

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication for DUPIXENT to include treatment of adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) with type 2 inflammation on triple therapy or double therapy if inhaled corticosteroids (ICS) are contraindicated, based on final results from study EFC15804 (BOREAS); this is a phase 3, randomised, double blind, placebo-controlled, multi-centre, parallel group, 52-week study to assess the efficacy, safety and tolerability of dupilumab in patients with moderate-to-severe COPD with type 2 inflammation. 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 10.0 of the

RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.10. [Durvalumab - IMFINZI \(CAP\) - EMEA/H/C/004771/WS2463/0063;](#) [Olaparib - LYNPARZA \(CAP\) - EMEA/H/C/003726/WS2463/0066](#)

Applicant: AstraZeneca AB

PRAC Rapporteur: Amelia Cupelli

Scope: Extension of indication for Lynparza in combination with Imfinzi for the maintenance treatment of adult patients with newly diagnosed advanced or recurrent endometrial cancer following treatment with Imfinzi and platinum-based chemotherapy, based on results from pivotal phase III study, D9311C00001 (DUO-E). This was a phase III, randomised, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of durvalumab in combination with platinum-based chemotherapy (paclitaxel + carboplatin) followed by maintenance durvalumab with or without olaparib for patients with newly diagnosed advanced or recurrent endometrial cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 30 of the RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.11. [Efgartigimod alfa - VYVGART \(CAP\) - EMEA/H/C/005849/II/0014, Orphan](#)

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Update of section 4.4 of the SmPC in order to amend an existing warning on infusion reactions and hypersensitivity reactions, and update of section 5.1 of the SmPC to update the mechanism of action of efgartigimod in relation to albumin; based on final results from study ARGX-113-1705 listed a category 3 study in the RMP. This is a long-term, single-arm, open-label, multicentre, phase 3 follow-on study of ARGX-113-1704 to evaluate the safety and tolerability of ARGX-113 in patients with myasthenia gravis having generalised muscle weakness. The RMP version 2.2 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.12. [Encorafenib - BRAFTOVI \(CAP\) - EMEA/H/C/004580/WS2538/0034;](#) [Binimetinib - MEKTOVI \(CAP\) - EMEA/H/C/004579/WS2538/0030](#)

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Rugile Pilviniene

Scope: Extension of indication to include binimetinib in combination with encorafenib for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with a BRAF V600 mutation for MEKTOVI and BRAFTOVI based on results from study PHAROS (study ARRAY-818-202) at the primary completion date; this is a phase II, open-label, multicentre, non-comparative study (interventional). As a consequence, sections 4.1, 4.4, 4.8, 5.1, 5.2, 9 and 10 of the SmPC are updated. The package leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. As part of the application, the MAH is requesting a

1-year extension of the market protection for MEKTOVI

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.13. Esketamine - SPRAVATO (CAP) - EMEA/H/C/004535/II/0020

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Kirsti Villikka

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on severe hepatic impairment and to include the long-term safety information based on final results from study 54135419TRD3008: an open-label long-term extension safety study of esketamine nasal spray in treatment-resistant depression (TRD), listed as a category 3 study in the RMP; this was a multicentre, open-label, long-term extension safety study to evaluate safety, tolerability, and efficacy of esketamine in participants with TRD. The RMP version 5.1 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the product information

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.14. Florbetapir (¹⁸F) - AMYVID (CAP) - EMEA/H/C/002422/II/0046

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include monitoring response to therapy for AMYVID, based on supporting literature. As a consequence, sections 4.1 and 4.4 of the SmPC are updated. The package leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update section 4.8 of the SmPC to reflect the current clinical trial exposures to align it with the updated RMP

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.15. Ibandronic acid - BONDRONAT (CAP) - EMEA/H/C/000101/WS2451/0090; BONVIVA (CAP) - EMEA/H/C/000501/WS2451/0075

Applicant: Atnahs Pharma Netherlands B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add information regarding the risk of 'atypical fractures of long bones other than femour' based on literature. The package leaflet is updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to bring the product information in line with the latest QRD template version 10.3

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.16. Idecabtagene vicleucel - ABECMA (CAP) - EMEA/H/C/004662/II/0031, Orphan

Applicant: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD-38 antibody and have demonstrated disease progression on the last therapy for Abecma (idecabtagene vicleucel, ide-cel), based on results from study BB2121-MM-003 (MM-003, KarMMa-3). This is a Phase 3, multicentre, randomised, open-label study to compare the efficacy and safety of ide-cel versus standard regimens in subjects with RRMM. As a consequence, sections 2.1, 2.2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated. The package leaflet and labelling are updated in accordance. Version 3.0 of the RMP has also been submitted. Furthermore, the product information is brought in line with the Guideline on core SmPC, labelling and package leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CAT and CHMP

5.3.17. [Isavuconazole - CRESEMBA \(CAP\) - EMEA/H/C/002734/X/0042/G, Orphan](#)

Applicant: Basilea Pharmaceutica Deutschland GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to add a new strength of 40 mg hard capsule to be used in paediatric patients 6 years and older grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of paediatric patients aged 1 year and older for CRESEMBA 200 mg powder, based on final results from studies 9766-CL-0107 and 9766-CL-0046. Study 9766-CL-0046 is a phase 1, open-label, multicentre study to evaluate the PK, safety and tolerability of intravenous and oral isavuconazonium sulfate in paediatric patients. This study was conducted in two sequential parts: Part 1 with three intravenous dosing cohorts, and Part 2 with two oral dosing cohorts. Study 9766-CL-0107 is a phase 2, open-label, non-comparative, multicentre study to evaluate the safety and tolerability, efficacy, and PK of isavuconazole for the treatment of invasive aspergillosis or mucormycosis in paediatric patients aged 1 to < 18 years. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, and 6.6 of the SmPC are updated. The package leaflet is updated in accordance. Version 9.1 of the RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.18. [Meningococcal Group A, C, W and Y conjugate vaccine - MENQUADFI \(CAP\) - EMEA/H/C/005084/II/0027](#)

Applicant: Sanofi Pasteur

PRAC Rapporteur: Jean-Michel Dogné

Scope: Submission of the final report from study MET52, listed as a category 3 study in the RMP. This was a phase III, open-label, randomised, parallel-group, active-controlled, multicentre study to evaluate the immunogenicity and describe the safety of MenACYW conjugate vaccine when administered concomitantly with a Meningococcal Group B vaccine and other routine paediatric vaccines as part of the national immunization schedule in healthy infants and toddlers in the United Kingdom. The RMP version 1.3 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.19. [Nivolumab - OPDIVO \(CAP\) - EMEA/H/C/003985/II/0137](#)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include in combination with cisplatin-based chemotherapy the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma for OPDIVO, based on interim results from study CA209901 (CheckMate901); this is a Phase 3, open-label, randomised study of nivolumab combined with ipilimumab, or with standard of care chemotherapy, versus standard of care chemotherapy in participants with previously untreated unresectable or metastatic urothelial cancer. 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 35.0 of the RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.20. [Ocrelizumab - OCREVUS \(CAP\) - EMEA/H/C/004043/X/0039](#)

Applicant: Roche Registration GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (920 mg) and new route of administration (subcutaneous use). The RMP (version 9.0) is updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.21. [Ozanimod - ZEPOSIA \(CAP\) - EMEA/H/C/004835/II/0023](#)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Update of sections 4.4 and 5.1 of the SmPC in order to update efficacy and safety information based on the final results from study RPC01-3001, listed as a category 3 study in the RMP. This is a multi-site, open label extension trial of RPC1063 in relapsing multiple sclerosis. The study's main objectives were to characterise the long-term safety and tolerability, and the long-term efficacy of ozanimod in patients with relapsing multiple sclerosis. The RMP version 7.0 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.22. [Pembrolizumab - KEYTRUDA \(CAP\) - EMEA/H/C/003820/II/0145](#)

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy) the treatment of high-risk locally advanced cervical cancer in adults who have not received prior definitive therapy [stage

IB2-IIB (with node-positive disease) or stage III-IVA based on FIGO 2014] for Keytruda, based on KEYNOTE-A18: A randomised, phase 3, double-blind study of chemoradiotherapy with or without pembrolizumab for the treatment of high-risk, locally advanced cervical cancer. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. Version 44.1 of the RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.23. [Risankizumab - SKYRIZI \(CAP\) - EMEA/H/C/004759/X/0043/G](#)

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Extension application to a new strength of 180 mg of risankizumab (solution for injection in cartridge) grouped with a type II variation extension of indication (C.I.6.a) to include treatment of adult patients with moderately to severely active ulcerative colitis, for SKYRIZI, based on final results from studies M16-067 sub-study 2: a phase 2b/3 multicentre, randomised, double-blind, placebo-controlled induction study to evaluate the efficacy and safety of risankizumab in subjects with moderately to severely active ulcerative colitis, and M16-066 sub-study 1: a multicentre, randomised, double-blind, placebo controlled 52-week maintenance and an open-label extension study of the efficacy and safety of risankizumab in subjects with ulcerative colitis, as well as drug-drug interaction (DDI) study M19-974. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC for the Skyrizi 600 mg concentrate for solution for infusion, and sections 1, 2, 4.1, 4.2, 4.8, 5.1, 5.2, 5.3, 6.5 and 6.6 of the SmPC for the Skyrizi 360 mg solution for injection in cartridge are updated. The Annex II, Labelling and package leaflets are updated in accordance. Version 5.0 of the RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.24. [Sapropterin - KUVAN \(CAP\) - EMEA/H/C/000943/II/0078](#)

Applicant: BioMarin International Limited

PRAC Rapporteur: Eamon O'Murchu

Scope: Submission of the final report from study KOGNITO, listed as a category 3 study in the RMP. This is a phase IV open-label, single-cohort study of the long-term neurocognitive outcomes in 4- to 5-year old children with phenylketonuria treated with sapropterin dihydrochloride (Kuvan) for 7 years. The RMP version 16.0 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.25. [Selexipag - UPTRAVI \(CAP\) - EMEA/H/C/003774/X/0038](#)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Nathalie Gault

Scope: Extension application to add a new strength of 100 µg film-coated tablets in HDPE bottle. The RMP (version 10.1) is updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.26. Selpercatinib - RETSEVMO (CAP) - EMEA/H/C/005375/II/0021

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include the treatment of adults and adolescents 12 years and older with advanced rearranged during transfection (RET) fusion-positive thyroid cancer in the first-line setting for RETSEVMO based on interim data from studies LIBRETTO-001 (LOXO-RET-17001) and LIBRETTO-121; LIBRETTO-001 is an open-label, multicentre, global phase 1/2 study of selpercatinib in patients with RET-altered advanced solid tumors. LIBRETTO-121 is a phase 1/2 study of selpercatinib in paediatric patients with advanced RET-altered solid or primary central nervous system tumours. 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 3.2 of the RMP has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.27. Selpercatinib - RETSEVMO (CAP) - EMEA/H/C/005375/II/0022

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include the treatment of adults with advanced or metastatic re-arranged during transfection (RET) fusion-positive solid tumours with disease progression on or after prior systemic therapies or who have no satisfactory therapeutic options, based on interim data from study LIBRETTO-001 (LOXO-RET-17001); LIBRETTO-001 is an open-label, multicentre, global Phase 1/2 study of selpercatinib in adult and adolescent patients with advanced RET-altered tumours. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.28. Sodium phenylbutyrate - PHEBURANE (CAP) - EMEA/H/C/002500/X/0037

Applicant: Eurocept International B.V.

PRAC Rapporteur: Eamon O'Murchu

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (500 mg film-coated tablets). The RMP (version 1.1) is updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.29. Sotorasib - LUMYKRAS (CAP) - EMEA/H/C/005522/II/0007

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Update of sections 4.2 and 5.2 of the SmPC in order to update recommendations for patients with moderate to severe hepatic impairment following final results from study

20200362 listed as a category 3 PASS in the EU RMP; this is a phase I clinical study to evaluate the pharmacokinetics (PK) of a single oral dose of sotorasib administered in subjects with moderate or severe hepatic impairment compared with subjects who have normal hepatic function. The EU RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to bring the product information in line with the latest QRD template version 10.3

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.30. Tenofovir alafenamide - VEMLIDY (CAP) - EMEA/H/C/004169/II/0043/G

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Valentina Di Giovanni

Scope: Grouped application consisting of 1) submission of the final report from study GS-US-320-0108 listed as category 3 studies in the RMP: a phase 3, randomised, double-blind study to evaluate the safety and efficacy of tenofovir alafenamide (TAF) 25 mg QD versus tenofovir disoproxil fumarate (TDF) 300 mg QD for the treatment of HBeAg-negative, chronic hepatitis B. The RMP version 10.1 has also been submitted; 2) submission of the final report from study GS-US-320-0110 listed as category 3 studies in the RMP: a phase 3, randomised, double-blind study to evaluate the safety and efficacy of TAF 25 mg QD versus TDF 300 mg QD for the treatment of HBeAg-positive, chronic hepatitis B. The RMP version 10.1 has also been submitted

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.31. Thiotepa - TEPADINA (CAP) - EMEA/H/C/001046/X/0049

Applicant: ADIENNE S.r.l. S.U.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Extension application to add a new strength (200 mg powder and solvent for solution for infusion). The RMP (version 015) is updated in accordance

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

5.3.32. Trastuzumab deruxtecan - ENHERTU (CAP) - EMEA/H/C/005124/II/0040

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Update of sections 4.2 and 5.2 of the SmPC based on final results from studies DS8201-A-J101, DS8201-A-J102, DS8201-A-A103, DS8201-A-A104, DS8201-A-U201, DS8201-A-J202, DS8201-A-J203, DS8201-A-U204, DS8201-A-U205, DS8201-A-U206, DS8201-A-U207, DS8201-A-U301, DS8201-A-U302, and DS8201-A-U303, listed as category 3 activity in the RMP. The updated RMP version 7.1 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the SmPC and Annex II.D

Action: For adoption of PRAC RMP AR, PRAC RMP assessment overview and advice to CHMP

6. Periodic safety update reports (PSURs)

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

6.1.1. Afamelanotide - SCENESSE (CAP) - PSUSA/00010314/202306

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.2. Alpelisib - PIQRAY (CAP) - PSUSA/00010871/202305

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.3. Amivantamab - RYBREVANT (CAP) - PSUSA/00010977/202305

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.4. Artesunate - ARTESUNATE AMIVAS (CAP) - PSUSA/00010958/202306

Applicant: Amivas Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.5. Binimetinib - MEKTOVI (CAP) - PSUSA/00010717/202306

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.6. Bromfenac - YELLOX (CAP) - PSUSA/00000436/202305

Applicant: Bausch + Lomb Ireland Limited

PRAC Rapporteur: Karin Erneholt

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.7. Budesonide⁴ - KINPEYGO (CAP) - PSUSA/00011007/202306

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.8. Buprenorphine⁵ - SIXMO (CAP) - PSUSA/00010778/202305

Applicant: L. Molteni & C. dei Fratelli Alitti Societa di Esercizio S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.9. Cannabidiol⁶ - EPIDYOLEX (CAP) - PSUSA/00010798/202306

Applicant: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.10. Cholera vaccine, oral, live - VAXCHORA (CAP) - PSUSA/00010862/202306

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.11. Coronavirus (COVID-19) vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - PSUSA/00010972/202306

Applicant: Novavax CZ, a.s.

⁴ For centrally authorised products indicated for primary immunoglobulin A nephropathy only

⁵ Implant

⁶ For centrally authorised product(s) only

PRAC Rapporteur: Gabriele Maurer
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.12. Darunavir, cobicistat - REZOLSTA (CAP) - PSUSA/00010315/202305

Applicant: Janssen-Cilag International N.V.
PRAC Rapporteur: Valentina Di Giovanni
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.13. Decitabine - DACOGEN (CAP) - PSUSA/00009118/202305

Applicant: Janssen-Cilag International N.V.
PRAC Rapporteur: Tiphaine Vaillant
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.14. Delafloxacin - QUOFENIX (CAP) - PSUSA/00010822/202306

Applicant: A. Menarini Industrie Farmaceutiche Riunite s.r.l.
PRAC Rapporteur: Petar Mas
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.15. Efgartigimod alfa - VYVGART (CAP) - PSUSA/00011014/202306

Applicant: Argenx
PRAC Rapporteur: Rhea Fitzgerald
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.16. Efmoroctocog alfa - ELOCTA (CAP) - PSUSA/00010451/202306

Applicant: Swedish Orphan Biovitrum AB (publ)
PRAC Rapporteur: Sonja Hrabcik
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.17. [Eladocagene exuparvovec - UPSTAZA \(CAP\) - PSUSA/00011004/202306](#)

Applicant: PTC Therapeutics International Limited, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.18. [Elasomeran \(Spikevax\), elasomeran, imelasomeran \(Spikevax bivalent Original/Omicron BA.1\), elasomeran, davesomeran \(Spikevax bivalent Original/Omicron BA.4-5\), andusomeran \(Spikevax XBB.1.5\) - SPIKEVAX \(CAP\) - PSUSA/00010897/202306](#)

Applicant: Moderna Biotech Spain, S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.19. [Emedastine - EMADINE \(CAP\) - PSUSA/00001207/202305](#)

Applicant: Immedica Pharma AB

PRAC Rapporteur: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. [Encorafenib - BRAFTOVI \(CAP\) - PSUSA/00010719/202306](#)

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.21. [Enfortumab vedotin - PADCEV \(CAP\) - PSUSA/00010989/202306](#)

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.22. [Entrectinib - ROZLYTREK \(CAP\) - PSUSA/00010874/202306](#)

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.23. Etranacogene dezaparovec - HEMGENIX (CAP) - PSUSA/00011037/202305

Applicant: CSL Behring GmbH, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.24. Fenfluramine - FINTEPLA (CAP) - PSUSA/00010907/202306

Applicant: UCB Pharma SA

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.25. Fidaxomicin - DIFICLIR (CAP) - PSUSA/00001390/202305

Applicant: Tillotts Pharma GmbH

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.26. Fluciclovine (¹⁸F) - AXUMIN (CAP) - PSUSA/00010594/202305

Applicant: Blue Earth Diagnostics Ireland Limited

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.27. Follitropin beta - PUREGON (CAP) - PSUSA/00001465/202305

Applicant: Organon N.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.28. [Formoterol fumarate dihydrate, glycopyrronium bromide, budesonide - RILTRAVA AEROSPHERE \(CAP\); TRIXEO AEROSPHERE \(CAP\) - PSUSA/00010908/202306](#)

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.29. [Gemtuzumab ozogamicin - MYLOTARG \(CAP\) - PSUSA/00010688/202305](#)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.30. [Givosiran - GIVLAARI \(CAP\) - PSUSA/00010839/202305](#)

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.31. [Human fibrinogen, human thrombin - EVICEL \(CAP\); TACHOSIL \(CAP\); VERASEAL \(CAP\) - PSUSA/00010297/202306](#)

Applicant: Omrix Biopharmaceuticals N. V. (Evicel), Corza Medical GmbH (TachoSil), Instituto Grifols, S.A. (VeraSeal)

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.32. [Hydroxycarbamide⁷ - SIKLOS \(CAP\); XROMI \(CAP\) - PSUSA/00001692/202306](#)

Applicant: Theravia (Siklos), Nova Laboratories Ireland Limited (Xromi)

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

⁷ For centrally authorised product only

6.1.33. Imiglucerase - CERZYME (CAP) - PSUSA/00001727/202305

Applicant: Sanofi B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. Indacaterol, mometasone furoate - ATECTURA BREEZHALER (CAP); BEMRIST BREEZHALER (CAP) - PSUSA/00010850/202305

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.35. Inebilizumab - UPLIZNA (CAP) - PSUSA/00010996/202306

Applicant: Horizon Therapeutics Ireland DAC

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.36. Ixazomib - NINLARO (CAP) - PSUSA/00010535/202305

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.37. Larotrectinib - VITRAKVI (CAP) - PSUSA/00010799/202305

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.38. Latanoprost, netarsudil - ROCLANDA (CAP) - PSUSA/00010905/202306

Applicant: Santen Oy

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. Levodopa - INBRIJA (CAP) - PSUSA/00107800/202306

Applicant: Acorda Therapeutics Ireland Limited

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.40. Lonafarnib - ZOKINVY (CAP) - PSUSA/00011005/202305

Applicant: EigerBio Europe Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. Lumacaftor, ivacaftor - ORKAMBI (CAP) - PSUSA/00010455/202305

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.42. Luspatercept - REBLOZYL (CAP) - PSUSA/00010860/202306

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.43. Maribavir - LIVTENCITY (CAP) - PSUSA/00011024/202305

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Methylthioninium chloride - LUMEBLUE (CAP); METHYLTHIONINIUM CHLORIDE PROVEBLUE (CAP) - PSUSA/00002029/202305

Applicant: Alfasigma S.p.A. (Lumeblue), Provepharm SAS (Methylthioninium chloride)

Proveblue)

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Mosunetuzumab - LUNSUMIO (CAP) - PSUSA/00010999/202306

Applicant: Roche Registration GmbH

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Netarsudil - RHOKIINSA (CAP) - PSUSA/00107812/202306

Applicant: Santen Oy

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Nonacog beta pegol - REFIXIA (CAP) - PSUSA/00010608/202305

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. Nusinersen - SPINRAZA (CAP) - PSUSA/00010595/202305

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.49. Obeticholic acid - OCALIVA (CAP) - PSUSA/00010555/202305

Applicant: Advanz Pharma Limited

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.50. Octreotide⁸ - MYCAPSSA (CAP) - PSUSA/00011036/202306

Applicant: Amryt Pharmaceuticals DAC

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.51. Onasemnogene abeparvovec - ZOLGENSMA (CAP) - PSUSA/00010848/202305

Applicant: Novartis Europharm Limited, ATMP

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.52. Ozanimod - ZEPOSIA (CAP) - PSUSA/00010852/202305

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.53. Pandemic influenza vaccine (H5N1) (live attenuated, nasal) - PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) - PSUSA/00010501/202305

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.54. Pertuzumab, trastuzumab - PHESGO (CAP) - PSUSA/00010906/202306

Applicant: Roche Registration GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.55. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - APEXXNAR (CAP) - PSUSA/00010981/202306

Applicant: Pfizer Europe MA EEIG

⁸ For centrally authorised product(s) only

PRAC Rapporteur: Jean-Michel Dogné
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.56. [Polatuzumab vedotin - POLIVY \(CAP\) - PSUSA/00010817/202306](#)

Applicant: Roche Registration GmbH
PRAC Rapporteur: Ulla Wändel Liminga
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.57. [Relugolix, estradiol, norethisterone acetate - RYEQO \(CAP\) - PSUSA/00010942/202305](#)

Applicant: Gedeon Richter Plc.
PRAC Rapporteur: Martin Huber
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.58. [Roxadustat - EVRENZO \(CAP\) - PSUSA/00010955/202306](#)

Applicant: Astellas Pharma Europe B.V.
PRAC Rapporteur: Anna Mareková
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.59. [Satralizumab - ENSPRYNG \(CAP\) - PSUSA/00010944/202305](#)

Applicant: Roche Registration GmbH
PRAC Rapporteur: Jan Neuhauser
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.60. [Semaglutide - OZEMPIC \(CAP\); RYBELSUS \(CAP\); WEGOVY \(CAP\) - PSUSA/00010671/202305](#)

Applicant: Novo Nordisk A/S
PRAC Rapporteur: Mari Thorn
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.61. Setmelanotide - IMCIVREE (CAP) - PSUSA/00010941/202305

Applicant: Rhythm Pharmaceuticals Netherlands B.V.,

PRAC Rapporteur: Anna Mareková

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.62. Sonidegib - ODOMZO (CAP) - PSUSA/00010408/202306

Applicant: Sun Pharmaceutical Industries Europe B.V.

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.63. Sotorasib - LUMYKRAS (CAP) - PSUSA/00010970/202305

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.64. Sunitinib - SUTENT (CAP) - PSUSA/00002833/202304

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.65. Tabelecleucel - EBVALLO (CAP) - PSUSA/00011028/202306

Applicant: Pierre Fabre Medicament, ATMP

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.66. Tezepelumab - TEZSPIRE (CAP) - PSUSA/00011015/202306

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.67. Tilmanocept - LYMPHOSEEK (CAP) - PSUSA/00010313/202305

Applicant: Navidea Biopharmaceuticals Europe Ltd.

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.68. Tirbanibulin - KLISYRI (CAP) - PSUSA/00010943/202306

Applicant: Almirall, S.A.

PRAC Rapporteur: Anna Mareková

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.69. Tozinameran (COMIRNATY), tozinameran, riltozinameran (COMIRNATY Original/Omicron BA.1), tozinameran, famtozinameran (COMIRNATY Original/Omicron BA.4-5), raxtozinameran (COMIRNATY Omicron XBB.1.5) - COMIRNATY (CAP) - PSUSA/00010898/202306

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.70. Tralokinumab - ADTRALZA (CAP) - PSUSA/00010937/202306

Applicant: LEO Pharma A/S

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.71. Trametinib - MEKINIST (CAP) - PSUSA/00010262/202305

Applicant: Novartis Europharm Limited

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.72. Trastuzumab deruxtecan - ENHERTU (CAP) - PSUSA/00010894/202306

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.73. Treosulfan⁹ - TRECONDI (CAP) - PSUSA/00010777/202306

Applicant: medac Gesellschaft für klinische Spezialpräparate mbH

PRAC Rapporteur: Julia Pallos

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.74. Turoctocog alfa pegol - ESPEROCT (CAP) - PSUSA/00010782/202306

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.75. Vadadustat - VAFSEO (CAP) - PSUSA/00011050/202306

Applicant: AKEBIA EUROPE Limited

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.76. Varenicline - CHAMPIX (CAP) - PSUSA/00003099/202305

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.77. Vutrisiran - AMVUTTRA (CAP) - PSUSA/00011021/202306

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Liana Martirosyan

⁹ For centrally authorised product

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

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

6.2.1. Fentanyl¹⁰ - EFFENTORA (CAP); INSTANYL (CAP); PECFENT (CAP); NAP - PSUSA/00001369/202304

Applicant: Teva B.V. (Effentora), Takeda Pharma A/S (Instanyl), Kyowa Kirin Holdings B.V. (PecFent), various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.2. Mycophenolate mofetil, mycophenolic acid - CELLCEPT (CAP); MYCLAUSEN (CAP); MYCOPHENOLATE MOFETIL TEVA (CAP); MYFENAX (CAP); NAP - PSUSA/00010550/202305

Applicant: Roche Registration GmbH (CellCept), Passauer Pharma GmbH (Myclausen), Teva B.V. (Mycophenolate mofetil Teva, Myfenax), various

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.3. Treprostinil - TREPULMIX (CAP); NAP - PSUSA/00003013/202305

Applicant: SciPharm Sarl (Trepulmix), various

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

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

6.3.1. Aciclovir (NAP) - PSUSA/00000048/202306

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

¹⁰ Transmucosal route of administration

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.2. Azithromycin¹¹ (NAP) - PSUSA/00010491/202304

Applicant(s): various

PRAC Lead: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Azithromycin¹² (NAP) - PSUSA/00010492/202304

Applicant(s): various

PRAC Lead: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.4. Ceftriaxone (NAP) - PSUSA/00000613/202305

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. Chlorpromazine (NAP) - PSUSA/00000715/202305

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.6. Cyproterone, ethinylestradiol (NAP) - PSUSA/00000906/202305

Applicant(s): various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

¹¹ Systemic use formulation(s) only

¹² Ocular use formulation(s) only

6.3.7. Ebastine (NAP) - PSUSA/00001191/202305

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. Fluorescein¹³ (NAP) - PSUSA/00009153/202304

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.9. Gadobenic acid (NAP) - PSUSA/00001500/202304

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. Gadobutrol (NAP) - PSUSA/00001502/202304

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. Gadopentetic acid (NAP) - PSUSA/00001504/202304

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. Gadoteric acid¹⁴ (NAP) - PSUSA/00001506/202304

Applicant(s): various

PRAC Lead: Bianca Mulder

¹³ Systemic use only

¹⁴ IV and intravascular formulations

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. Gadoteridol (NAP) - PSUSA/00001507/202304

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.14. Gadoxetic acid disodium (NAP) - PSUSA/00001509/202304

Applicant(s): various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.15. Irinotecan¹⁵ (NAP) - PSUSA/00001783/202305

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.16. Lanreotide (NAP) - PSUSA/00001826/202305

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.17. Latanoprost¹⁶ (NAP) - PSUSA/00001834/202304

Applicant(s): various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

¹⁵ Except for liposomal formulation(s)

¹⁶ Products with paediatric indication only

6.3.18. Levonorgestrel¹⁷ (NAP) - PSUSA/00010828/202305

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.19. Mifepristone (NAP) - PSUSA/00002060/202305

Applicant(s): various

PRAC Lead: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.20. Mifepristone, misoprostol (NAP) - PSUSA/00010378/202305

Applicant(s): various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.21. Misoprostol¹⁸ (NAP) - PSUSA/00010353/202305

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.22. Misoprostol¹⁹ (NAP) - PSUSA/00010354/202305

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.23. Mometasone (NAP) - PSUSA/00002085/202305

Applicant(s): various

¹⁷ All indications except emergency contraception

¹⁸ Gynaecological indication - labour induction

¹⁹ Gynaecological indication - termination of pregnancy

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.24. [Moxifloxacin²⁰ \(NAP\) - PSUSA/00009231/202305](#)

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.25. [Nalbuphine \(NAP\) - PSUSA/00002110/202305](#)

Applicant(s): various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.26. [Norfloxacin \(NAP\) - PSUSA/00002190/202306](#)

Applicant(s): various

PRAC Lead: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.27. [Patent blue V sodium \(NAP\) - PSUSA/00002320/202304](#)

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.28. [Pelargonium sidoides DC and/or pelargonium reniforme Curt., radix \(NAP\) - PSUSA/00002329/202306](#)

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

²⁰ Systemic use only

6.3.29. Thiamphenicol (NAP) - PSUSA/00002925/202305

Applicant(s): various

PRAC Lead: Valentina Di Giovanni

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.30. Xylometazoline (NAP) - PSUSA/00003134/202305

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.31. Zuclopenthixol (NAP) - PSUSA/00003155/202305

Applicant(s): various

PRAC Lead: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Tisagenlecleucel - KYMRIA[®] (CAP) - EMEA/H/C/004090/LEG 021.1

Applicant: Novartis Europharm Limited, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: MAH's response to LEG 021 [Submission of further data on cases of secondary malignancies, as requested in the conclusions of the PSUR single assessment (PSUSA) procedure (PSUSA/00010702/202208) adopted in March 2023] as per request for supplementary information (RSI) adopted in September 2023

Action: For adoption of advice to CAT and CHMP

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Alglucosidase alfa - MYOZYME (CAP) - EMEA/H/C/000636/II/0094

Applicant: Sanofi B.V.

PRAC Rapporteur: Nathalie Gault

Scope: Update of section 4.2 of the SmPC in order to add home infusion upon request by PRAC following the assessment of PSUSA/00000086/202109 based on a cumulative search

of the MAH Global Pharmacovigilance database and literature. The package leaflet and Annex II are updated accordingly. The RMP version 10.0 has also been submitted

Action: For adoption of PRAC Assessment Report

6.5.2. [Amlodipine, valsartan - COPALIA \(CAP\) - EMEA/H/C/000774/WS2610/0132;](#)
[DAFIRO \(CAP\) - EMEA/H/C/000776/WS2610/0136;](#) [EXFORGE \(CAP\) -](#)
[EMEA/H/C/000716/WS2610/0131](#)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Karin Erneholm

Scope: To add interaction with tacrolimus to section 4.5 of the SmPC following the outcome of the amlodipine/ramipril PSUSA (PSUSA/00000181/201503). The package leaflet was updated accordingly. In addition the MAH is removing the Adverse Events in section 4.8 of SmPC where "Hypokalaemia, Anorexia, Hypercalcaemia, Hyperlipidaemia and Hyperuricaemia" that had been added in error. The MAH is also including a QRD update to package leaflet section 5 on the expiry of the product

Action: For adoption of PRAC Assessment Report

6.5.3. [Amlodipine, valsartan, hydrochlorothiazide - COPALIA HCT \(CAP\) -](#)
[EMEA/H/C/001159/WS2609/0110;](#) [DAFIRO HCT \(CAP\) -](#)
[EMEA/H/C/001160/WS2609/0112;](#) [EXFORGE HCT \(CAP\) -](#)
[EMEA/H/C/001068/WS2609/0109](#)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Karin Erneholm

Scope: To add interaction with tacrolimus to section 4.5 of the SmPC following the outcome of the amlodipine/ramipril PSUSA (PSUSA/00000181/201503). The package leaflet was updated accordingly

Action: For adoption of PRAC Assessment Report

6.5.4. [Laronidase - ALDURAZYME \(CAP\) - EMEA/H/C/000477/II/0085](#)

Applicant: Sanofi B.V.

PRAC Rapporteur: Nathalie Gault

Scope: To update section 4.2 of the SmPC in order to modify the administration instructions following the periodic safety update single assessment (PSUSA) procedure (PSUSA/00001830/202104) adopted in December 2021 based on literature review. The package leaflet is updated accordingly. The RMP version 1.0 has also been submitted

Action: For adoption of PRAC Assessment Report

6.6. Expedited summary safety reviews²¹

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)²²

7.1.1. Alemtuzumab – LEMTRADA (CAP) - EMEA/H/C/PSA/S/0110

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: Substantial amendment to the protocol for a non-interventional PASS to investigate the risk of mortality in multiple sclerosis patients treated with alemtuzumab (LEMTRADA) relative to comparable multiple sclerosis patients using other disease modifying therapies: a cohort study

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.1.2. Axicabtagene ciloleucel – YESCARTA (CAP) - EMEA/H/C/PSA/S/0102.3

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: MAH's response to S/0102.2 on the substantial amendment to a protocol for a long-term, non-interventional study of recipients of Yescarta for treatment of relapsed or refractory diffuse large B-cell lymphoma and primary mediastinal B-cell lymphoma

Action: For adoption of PRAC Assessment Report, PRAC outcome letter

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)²³

7.2.1. Abaloparatide - ELADYNOS (CAP) - EMEA/H/C/005928/MEA 001.1

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Karin Erneholm

Scope: MAH's response to MEA 001 [Submission of a protocol for an European non-interventional PASS to assess serious cardiovascular events of MI, stroke, all-cause and cardiovascular mortality, and arrhythmias for abaloparatide] as per the request for supplementary information (RSI) adopted in June 2023

²¹ 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

²² In accordance with Article 107n of Directive 2001/83/EC

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

Action: For adoption of advice to CHMP

7.2.2. Cabotegravir - APRETUDE (CAP) - EMEA/H/C/005756/MEA 002

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of a protocol for a non-interventional PASS as category 3 of the RMP: Antiretroviral Pregnancy Registry (APR) to monitor CAB LA PrEP use in Pregnancy. The APR is an international registry that monitors prenatal exposures to antiretroviral (ARV) drugs to detect a potential increase in the risk of birth defects through a prospective exposure registration cohort. The registry's primary objective is to monitor for birth defects among ARV exposed pregnancies. The registry has been monitoring pregnancies with prenatal exposure to ARVs used for PrEP since the approval of ARVs used in oral PrEP. The APR is a MAH-sponsored study involving the collaborative effort of multiple companies. Data from the APR will assess maternal (pregnancy outcomes, abortions, still births) and foetal outcomes (premature births and low birth weight) following CAB LA PrEP use during pregnancy. Exposure to CAB LA PrEP relative to gestation period and conception will be captured in the registry, thus enabling assessment of pre-conception exposures along with first, second and third trimester exposures

Action: For adoption of advice to CHMP

7.2.3. Cabotegravir - VOCABRIA (CAP) - EMEA/H/C/004976/MEA 006.4

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of an amended protocol for a category 3 study (Study No 215325) included in the RMP: Pregnancy and Neonatal Outcomes following Prenatal Exposure to Cabotegravir: Data from The Antiretroviral Pregnancy Registry (APR)

Action: For adoption of advice to CHMP

7.2.4. Coronavirus (COVID-19) vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - EMEA/H/C/005808/MEA 005.2

Applicant: Novavax CZ, a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Amended protocol (v.3.0) for study 2019nCoV-405: Global Safety Surveillance Study of Pregnancy and Infant Outcomes Study Using C-VIPER. A registry-based observational cohort safety surveillance study to characterise the population of pregnant women who are vaccinated with Nuvaxovid, estimate the frequency of selected adverse pregnancy outcomes in women and selected adverse foetal/neonatal/infant outcomes at birth and up to the first 12 months of life of infants from pregnancies in women who received Nuvaxovid during pregnancy

Action: For adoption of advice to CHMP

7.2.5. Efgartigimod alfa - VYVGART (CAP) - EMEA/H/C/005849/MEA 007

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Protocol for a PASS (non-imposed/non-interventional/Cat. 3): Evaluation of long-term risk of malignancies in patients with myasthenia gravis (MG) treated with efgartigimod compared to MG patients on any other MG therapy and who do not have malignancy history in the look back period

Action: For adoption of advice to CHMP

7.2.6. Fentanyl - INSTANYL (CAP) - EMEA/H/C/000959/MEA 029.5

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Tiphaine Vaillant

Scope: MAH's response to MEA 029.4 [Updated protocol for study Instanyl-5002 (listed as a category 3 study in the RMP): a non-interventional study to assess the effectiveness of updated educational materials on prescribers' knowledge and behaviour with respect to risks associated with Instanyl (fentanyl) off-label use together with an interim report and the statistical analysis plan (SAP)] as per request for supplementary information (RSI) adopted in September 2023

Action: For adoption of advice to CHMP

7.2.7. Gozetotide - LOCAMETZ (CAP) - EMEA/H/C/005488/MEA 003

Applicant: Novartis Europharm Limited

PRAC Rapporteur: John Joseph Borg

Scope: Protocol for a non-interventional PASS as category 3 of the RMP (CAAA517A12401): a cross-sectional knowledge and understanding survey to evaluate the effectiveness of the Locametz educational material on interpreting PET scans of patients, distributed to medical practitioners qualified to interpret PET scans

Action: For adoption of advice to CHMP

7.2.8. Ipilimumab - YERVOY (CAP) - EMEA/H/C/002213/MEA 036.6

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Protocol Amendment (v. 3.0/Study no.: CA184557): 'long-term follow-up of nivolumab and ipilimumab (as monotherapy and as combination therapy)-treated paediatric patients enrolled in the Dutch melanoma treatment registry (DMTR)'

Action: For adoption of advice to CHMP

7.2.9. Niraparib, abiraterone acetate - AKEEGA (CAP) - EMEA/H/C/005932/MEA 001.1

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Protocol for a non-interventional PASS (PCSONCA0485, RMP Cat. 3): PASS to characterise the risk of second primary malignancies (SPM) including MDS/AML among metastatic prostate cancer patients exposed to AKEEGA

Action: For adoption of advice to CHMP

7.2.10. Nivolumab - OPDIVO (CAP) - EMEA/H/C/003985/MEA 057

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Martin Huber

Scope: PASS Protocol Amendment (v. 3.0 / Study no.: CA184557): long-term follow-up of nivolumab and ipilimumab (as monotherapy and as combination therapy)-treated paediatric patients enrolled in the Dutch melanoma treatment registry (DMTR)

Action: For adoption of advice to CHMP

7.2.11. Ponesimod – PONVORY (CAP) - EMEA/H/C/005163/MEA/004.4

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Karin Erneholm

EMA resources:

Scope: Revised Protocol for study number: PCSNSP003693: Survey among healthcare professionals (neurologists treating patients with MS along with MS specialist nurses) in selected European countries to evaluate knowledge and behaviors required for the safe use of ponesimod. Due date: 1 year after the end of data collection [cat.3]

Action: For adoption of advice to CHMP

7.2.12. Risankizumab - SKYRIZI (CAP) - EMEA/H/C/004759/MEA 010.2

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Revised PASS Protocol (v2.1 / Study no.: P23-654): long-term comparative cohort study in patients with Crohn's disease in a real world setting. Additional long-term data from the real-world experience of patients with Crohn's disease treated with risankizumab to assess product potential risks. A comparative cohort study will be conducted to estimate rates of malignancy (malignancy excluding NMSC, NMSC), serious infections, serious hypersensitivity reactions, and MACE in risankizumab treated patients with Crohn's disease, relative to alternative systemic therapies (e.g., biologics)

Action: For adoption of advice to CHMP

7.2.13. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 001.9

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Protocol amendment for study OP0005: European non-interventional PASS to study the adherence to the risk minimisation measures (RMMs) in the product information by estimating the compliance with contraindications and target indication(s) amongst incident romosozumab users, and analysing the utilisation pattern using the EU-adverse drug reactions (EU-ADR) Alliance as per request for supplementary information (RSI) adopted in July 2023 (MEA 001.6)

Action: For adoption of advice to CHMP

7.2.14. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 002.9

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Protocol amendment for study OP0004: European non-interventional PASS to evaluate potential differences in terms of serious cardiovascular adverse events between romosozumab and currently available therapies used in comparable patients in real-world conditions using the EU-adverse drug reactions (EU-ADR) Alliance as per request of supplementary information (RSI) adopted in July 2023 (MEA 002.6)

Action: For adoption of advice to CHMP

7.2.15. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 003.7

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Protocol amendment for study OP0006: evaluate potential differences in terms of serious infection between romosozumab and currently available therapies used in comparable patients in real-world conditions using the EU-adverse drug reactions (EU-ADR) Alliance as per request of supplementary information (RSI) adopted in July 2023 (MEA 003.4)

Action: For adoption of advice to CHMP

7.2.16. Ruxolitinib - OPZELURA (CAP) - EMEA/H/C/005843/MEA 001

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Protocol for study INCB88888-037 (PASS) (non-interventional, RMP Category 3) to evaluate the safety of long-term ruxolitinib cream use with respect to incidence of non-melanoma skin cancers

Action: For adoption of advice to CHMP

7.2.17. Tezepelumab - TEZSPIRE (CAP) - EMEA/H/C/005588/MEA 001.2

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: MAH's response to MEA 001.1 [PROTOCOL D5180R00010:: A Non-Interventional Multi-Database Post-Authorisation Study to Assess Pregnancy-Related Safety Data from Women with Severe Asthma Exposed to Tezepelumab] as per RSI adopted in October 2023

Action: For adoption of advice to CHMP

7.2.18. Tofacitinib - XELJANZ (CAP) - EMEA/H/C/004214/MEA 011.7

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Protocol amendment for study A3921317 (listed as a category 3 study in the RMP): a prospective non-interventional comparative active surveillance PASS of serious infection, malignancy, cardiovascular and other safety events of interest among patients treated with Xeljanz (tofacitinib) for moderately to severely active rheumatoid arthritis (RA) within the German registry Rheumatoide Arthritis: Beobachtung der Biologika-Therapie (RABBIT) following on the recommendation of the signal on major adverse cardiovascular events (MACE) and malignancies excluding non-melanoma skin cancer (NMSC) (EPITT 19382) finalised in June 2021

Action: For adoption of advice to CHMP

7.2.19. Tofacitinib - XELJANZ (CAP) - EMEA/H/C/004214/MEA 025.2

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: MAH's response to MEA 025.1 and revised protocol for PASS Study No921403 (RMP Cat. 3): a PASS of the Utilisation and Prescribing Patterns of Xeljanz (tofacitinib) Using an Administrative Healthcare Database in France: a descriptive drug utilisation study using real-world data collected from routine clinical care in France. The overall goal is to determine if there is evidence that prescribers in France are compliant with the recommendations and limitations for use described in the tofacitinib additional risk minimisation measures (aRMM) materials as per the request for supplementary information (RSI) adopted in September 2023

Action: For adoption of advice to CHMP

7.2.20. Ublituximab - BRIUMVI (CAP) - EMEA/H/C/005914/MEA 001.1

Applicant: Neuraxpharm Pharmaceuticals S.L.

PRAC Rapporteur: Liana Martirosyan

Scope: MAH's response to MEA 001 [Protocol for PASS Study TG1101-RMS402 (cat. 3): a long-term observational study of the safety and effectiveness of ublituximab in patients with relapsing multiple sclerosis, to assess the incidence of serious infections and malignancies in

relapsing multiple sclerosis (MS) participants treated with ublituximab compared with other disease-modifying treatments (DMTs) observed longitudinally, to evaluate the long-term safety of ublituximab compared to other DMTs in patients with relapsing forms of MS in a real world setting and to assess long-term effectiveness of ublituximab compared with other DMTs in participants with relapsing forms of MS] as per request for supplementary information (RSI) adopted in October 2023 (25-28 September 2023)

Action: For adoption of advice to CHMP

7.2.21. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/MEA 048.4

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 048.3 [Revised protocol for an observational PASS to describe the safety of ustekinumab and other ulcerative colitis treatments in a cohort of patients with ulcerative colitis using SNDS PCSIMM002659 together with the first progress report] as per request for supplementary information (RSI) adopted in December 2021

Action: For adoption of advice to CHMP

7.2.22. Vosoritide - VOXZOGO (CAP) - EMEA/H/C/005475/MEA 005.3

Applicant: BioMarin International Limited

PRAC Rapporteur: Zane Neikena

Scope: MAH's response to MEA 005.2 [Protocol Amendment (v.6., PASS 111-603): a multicentre, non-interventional study to evaluate long-term safety in patients with achondroplasia treated with Voxzogo (vosoritide)] as per request for supplementary information (RSI) adopted in December 2022

Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)²⁴

7.3.1. Chlormadinone acetate, ethinyl estradiol (NAP) - EMEA/H/N/PSR/J/0042

Applicant: GEDEON RICHTER Plc (on behalf of a consortium: acis Arzneimittel GmbH, ALIUD PHARMA GmbH, Aristo Pharma GmbH, Dermapharm GmbH, DR. KADE/BESINS Pharma GmbH, Gynial GmbH, HEATON k.s, HEXAL AG, Hormosan Pharma GmbH, ITF Farmahealth, Produtos Farmacêuticos, Lda, Jenapharm, Kwizda Pharma GmbH, Laboratorio STADA, S.L., MEDA Pharma GmbH & Co KG, Mylan Germany GmbH, PUREN Pharma GmbH, SANDOZ S.P.A., STADapharm GmbH, Sun-Farm Sp. z.o.o.)

PRAC Rapporteur: Martin Huber

Scope: Final study report for: risk of venous thromboembolism – The role of oral contraceptives – a case control study comparing levonorgestrel and chlormadinone acetate to compare the VTE risk of COCs containing CMA 2mg / ethinylestradiol (EE) 30 µg, compared to COCs containing levonorgestrel (LNG) 0.15mg, both combined with 30 µg

²⁴ In accordance with Article 107p-q of Directive 2001/83/EC

ethinylestradiol (EE)

Action: For adoption of recommendation to CMDh (or request for supplementary information (RSI))

7.3.2. Valproate²⁵ (NAP) - EMEA/H/N/PSR/J/0043

Applicant: Sanofi-Aventis Recherche & Développement (on behalf of a consortium)

PRAC Rapporteur: Liana Martirosyan

Scope: Final study report for a retrospective observational study to investigate the association between paternal exposure to valproate and the risk of congenital anomalies and neurodevelopmental disorders including autism spectrum disorders (ASD) in the offspring

Action: For adoption of recommendation to CMDh (or request for supplementary information (RSI))

7.4. Results of PASS non-imposed in the marketing authorisation(s)²⁶

7.4.1. Adalimumab - HEFIYA (CAP) - EMEA/H/C/004865/WS2591/0050/G; HYRIMOZ (CAP) - EMEA/H/C/004320/WS2591/0049/G

Applicant: Sandoz GmbH

PRAC Rapporteur: Mari Thorn

Scope: C.I.13: Submission of the final report from study RABBIT. This is a German registry for the long-term observation of therapy with biologics in adult patients with rheumatoid arthritis. C.I.13: Submission of the final report from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR). This is a registry to investigate the long-term safety outcomes of psoriasis patients treated with biologic therapy. C.I.13: Submission of the final report from the Inflammatory Bowel Disease Registry (UK-IBD). This registry was used to identify adverse reactions to Hyrimoz in a cohort of inflammatory bowel disease patients managed in a real-world setting

Action: For adoption of PRAC Assessment Report

7.4.2. Agalsidase alfa - REPLAGAL (CAP) - EMEA/H/C/000369/II/0126

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final report from the Fabry Outcome Survey (FOS) registry study. The FOS (Fabry Outcome Survey) was a prospective, multicenter, observational, open-ended disease registry designed to document the clinical outcome over time of patients with Fabry disease, irrespective of their treatment

²⁵ Valproic acid, sodium valproate, valproate pivoxil, valproate semisodium, valpromide, valproate bismuth, calcium valproate, valproate magnesium

²⁶ 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

Action: For adoption of PRAC Assessment Report

7.4.3. [Alglucosidase alfa - MYOZYME \(CAP\) - EMEA/H/C/000636/II/0093](#)

Applicant: Sanofi B.V.

PRAC Rapporteur: Nathalie Gault

Scope: Submission of the final non-interventional Pompe Registry Report 2022 (MEA024 and MEA025)

Action: For adoption of PRAC Assessment Report

7.4.4. [Denosumab - PROLIA \(CAP\) - EMEA/H/C/001120/II/0100](#)

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Mari Thorn

Scope: Submission of the final report from the post marketing observational study 20090522, listed as a category 3 study in the RMP. This is a denosumab global safety assessment among women with postmenopausal osteoporosis (PMO), men with osteoporosis, and men and women who receive Prolia with glucocorticoid exposure in multiple observational databases

Action: For adoption of PRAC Assessment Report

7.4.5. [Fentanyl - INSTANYL \(CAP\) - EMEA/H/C/000959/II/0082](#)

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of the final report from study Instanyl-5002 listed as a category 3 study in the RMP. This is a non-interventional PASS study with title "Assessment of the Effectiveness of Updated Educational Materials on Prescribers' Knowledge and Behavior with Respect to Risks Associated with INSTANYL Off-Label Use". The RMP version 20.0 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.6. [Filgrastim - NIVESTIM \(CAP\) - EMEA/H/C/001142/II/0074/G](#)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Kirsti Villikka

Scope: Grouped application consisting of:

C.I.13: Submission of the final report from non-interventional PASS study ZOB-NIV-1513/C1121008 listed as a category 3 study in the RMP. This is a multinational, multi-centre, prospective, non-interventional, PASS in Healthy Donors (HDs) exposed to nivestim (biosimilar filgrastim) for Haematopoietic Stem Cell (HSC) Mobilisation (NEST). The RMP version 12 has also been submitted.

C.I.11 for RMP: Submission of an updated RMP version 12.0 in order to align it with the reference product, Neupogen, RMP v. 6.3 dated June 2022

Action: For adoption of PRAC Assessment Report

7.4.7. [Isatuximab - SARCLISA \(CAP\) - EMEA/H/C/004977/II/0024](#)

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Monica Martinez Redondo

Scope: Submission of the final report from study SARSAC09715, listed as a category 3 study in the RMP. This is a non-interventional survey to evaluate the effectiveness of the isatuximab educational materials to minimize the risk of interference for blood typing (minor antigen) (positive indirect Coombs test). The RMP version 1.3 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.8. [Luspatercept - REBLOZYL \(CAP\) - EMEA/H/C/004444/II/0023, Orphan](#)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Jo Robays

Scope: Submission of the final report from study ACE-536-MDS-005 listed as a category 3 study in the RMP. This is a non-interventional PASS to evaluate the effectiveness of the additional risk minimization measure (aRMM) for Reblozyl among Healthcare Providers (HCPs) in the EU/EEA. The RMP version 3.0 has been submitted in order to reflect the completion of the study and to remove the healthcare professional (HCP) checklist as aRMM. The Annex II is updated accordingly

Action: For adoption of PRAC Assessment Report

7.4.9. [Naltrexone hydrochloride, bupropion hydrochloride - MYSIMBA \(CAP\) - EMEA/H/C/003687/II/0066](#)

Applicant: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Submission of final report from study NB-453 study, listed as a category 3 study in the RMP. This is a non-interventional qualitative research using online focus groups to assess understanding, attitude and behaviour for usage of the Mysimba Physician Prescribing Checklist (PPC) among physicians in the European Union (EU), following a previous cross-sectional survey that aimed at evaluating the effectiveness of the same PPC (Study NB-452). The RMP version 12.10 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.10. [Piperaquine tetraphosphate, arteminol - EURARTESIM \(CAP\) - EMEA/H/C/001199/II/0040/G](#)

Applicant: Alfasigma S.p.A.

PRAC Rapporteur: Martin Huber

Scope: C.I.13: Submission of the final report from the effectiveness evaluation survey for Eurartesim (protocol no. 3366) listed as a category 3 study in the RMP. This is a European

multi-centre online survey to assess physician understanding of the revised edition of the educational material. Consequential changes to RMP version 16.1 have been implemented.
C.I.11.b: Submission of an updated RMP version 16.1 in order to delete "Severe Malaria" from the Missing Information

Action: For adoption of PRAC Assessment Report

7.4.11. Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - MOSQUIRIX (Art 58) - EMEA/H/W/002300/II/0077

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Jean-Michel Dogné

Scope: Submission of the final report from study EPI-MALALARIA-002 VS AME (115055). This is a non-interventional study, designed to estimate the incidence of diseases specified as adverse events of special interest, of other adverse events leading to hospitalisation or death, and of meningitis in infants and young children in sub-Saharan Africa

Action: For adoption of PRAC Assessment Report

7.4.12. Trastuzumab deruxtecan - ENHERTU (CAP) - EMEA/H/C/005124/II/0036

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Submission of the final report from study 'EU survey of relevant healthcare professionals on understanding of key risk minimisations measures pertaining to ILD/pneumonitis' listed as a category 3 study in the RMP. This is a non-imposed non-interventional PASS

Action: For adoption of PRAC Assessment Report

7.4.13. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/II/0100

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Update of section 4.6 of the SmPC in order to update information on pregnancy based on the final synoptic report from study CNTO1275PSO4037 (OTIS); this is a pregnancy exposure registry for Stelara. The package leaflet is updated accordingly. The RMP version 26.2 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.14. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/II/0104

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Submission of the final report from study RRA-20745 listed as a category 3 study in the RMP. This is an observational PASS to describe the safety of ustekinumab and other

Crohn's disease treatments in a cohort of patients with Crohn's disease. The RMP version 27.2 has also been submitted

Action: For adoption of PRAC Assessment Report

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

7.5.1. Botulinum toxin type A - NUCEIVA (CAP) - EMEA/H/C/004587/MEA 002.4

Applicant: Evolus Pharma B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual update for the Non-Interventional PASS of NUCEIVA for the Treatment of Moderate-to-Severe Glabellar Lines

Action: For adoption of advice to CHMP

7.5.2. Ciltacabtagene autoleucl - CARVYKTI (CAP) - EMEA/H/C/005095/ANX 003.1

Applicant: Janssen-Cilag International NV, ATMP

PRAC Rapporteur: Jo Robays

Scope: First interim report for study: An Observational PASS to Evaluate the Safety of Multiple Myeloma Patients Treated with Ciltacabtagene Autoleucl

Action: For adoption of advice to CAT and CHMP

7.5.3. Coronavirus (COVID-19) vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - EMEA/H/C/005808/MEA 006.3

Applicant: Novavax CZ, a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Interim report for study 2019nCoV-404: US PASS to evaluate the pooled of risk of selected AESI within specified time periods after vaccination with Nuvaxovid using a claim and/or EHR database

Action: For adoption of advice to CHMP

7.5.4. Damoctocog alfa pegol - JIVI (CAP) - EMEA/H/C/004054/ANX 001.2

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Second interim report for an observational study evaluating long-term safety of real-world treatment with damoctocog alfa pegol in previously treated patients with hemophilia A' (HA-SAFE). The HA-SAFE study is a post-authorisation measure defined in Annex II.D of the Jivi EU product information. The study protocol was agreed with EMA/PRAC in Nov 2019 (outcome letter); the date of FPFV was 14 May 2021 (impacted by the Covid-19 pandemic). As Annex to the first interim report also the statistical analysis plan is submitted

Action: For adoption of advice to CHMP

7.5.5. Difelikefalin - KAPRUVIA (CAP) - EMEA/H/C/005612/MEA 002.1

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: Interim report DSUR version 10.0 for study CR845- 310301 (listed as category 3 study in the RMP): a Multicenter, Randomised, Double-blind, Placebo-controlled 12-Week Study to Evaluate the Safety and Efficacy of Oral Difelikefalin in Advanced Chronic Kidney Disease Subjects With Moderate-to-Severe Pruritus and Not on Dialysis With an up to 52-Week Long-term Extension

Action: For adoption of advice to CHMP

7.5.6. Difelikefalin - KAPRUVIA (CAP) - EMEA/H/C/005612/MEA 003.1

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: Interim report DSUR version 10.0 for study CR845- 310302 (listed as category 3 study in the RMP): a Multicenter, Randomised, Double-blind, Placebo-controlled 12-Week Study to Evaluate the Safety and Efficacy of Oral Difelikefalin in Advanced Chronic Kidney Disease Subjects With Moderate-to-Severe Pruritus and Not on Dialysis With an up to 52-Week Long-term Extension

Action: For adoption of advice to CHMP

7.5.7. Difelikefalin - KAPRUVIA (CAP) - EMEA/H/C/005612/MEA 004.1

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: Interim report DSUR version 10.0 for study CR845- 310501 (listed as category 3 study in the RMP): a Two-part, Multicenter, Randomised, Double-blind Study to Evaluate the Efficacy and Safety of Oral Difelikefalin as Adjunct Therapy to a Topical Corticosteroid for Moderate-to-Severe Pruritus in Adult Subjects With Atopic Dermatitis

Action: For adoption of advice to CHMP

7.5.8. Elasmoran - SPIKEVAX (CAP) - EMEA/H/C/005791/MEA 066.3

Applicant: Moderna Biotech Spain, S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Second Interim Report for study mRNA-1273-P911 Long-term outcomes of myocarditis following administration of Spikevax (COVID-19 vaccine mRNA) and MAH's responses to MEA 066.2

Action: For adoption of advice to CHMP

7.5.9. Hydroxycarbamide - SIKLOS (CAP) - EMEA/H/C/000689/MEA 035.1

Applicant: Theravia

PRAC Rapporteur: Jo Robays

Scope: Third interim report for ESCORT-HU Extension: European Sickle Cell Disease Cohort – Hydroxyurea

Action: For adoption of advice to CHMP

7.5.10. Idecabtagene vicleucel - ABECMA (CAP) - EMEA/H/C/004662/MEA 007

Applicant: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Ulla Wändel Liminga

Scope: First interim report for long-term follow-up study (GC-LTFU-001) to assess the risk of delayed AEs following exposure to GM T cells, to monitor for long-term persistence of GM T cells, including analysis of vector integration sites, as appropriate and to monitor for generation of replication competent retroviruses

Action: For adoption of advice to CAT and CHMP

7.5.11. Ketoconazole - KETOCONAZOLE HRA (CAP) - EMEA/H/C/003906/ANX 002.11

Applicant: HRA Pharma Rare Diseases

PRAC Rapporteur: Petar Mas

Scope: Sixth interim annual report for PASS EUPAS21731: Prospective, multi-country, observational registry to collect clinical information on patients with endogenous Cushing's syndrome exposed to Ketoconazole (using the existing European Registry on Cushing's Syndrome (ERCUSYN)), to assess drug utilization pattern and to document the safety (e.g. hepatotoxicity, QT prolongation) and effectiveness of Ketoconazole

Action: For adoption of advice to CHMP

7.5.12. Lisocabtagene maraleucel, lisocabtagene maraleucel - BREYANZI (CAP) - EMEA/H/C/004731/MEA 007

Applicant: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Interim report for LTFU study (GC LTFU 001): Long-term follow-up of safety and efficacy for all paediatric and adult subjects exposed to a GM T cell therapy in Bristol-Myers Squibb sponsored, or Bristol Myers Squibb alliance partner sponsored, clinical trials in accordance with Health Authorities' guidance for long-term (up to 15 years) follow-up of subjects treated with gene therapy products

Action: For adoption of advice to CAT and CHMP

7.5.13. Natalizumab - TYSABRI (CAP) - EMEA/H/C/000603/MEA 064.4

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Seventh annual interim report for an observational study utilising data from the US Tysabri TOUCH programme and select EU MS Registries to estimate the risk of progressive multifocal leukoencephalopathy (PML) and other serious opportunistic infections among patients who were exposed to an MS disease modifying treatment prior to treatment with Tysabri. Objectives: to estimate the risk of PML among patients on Tysabri switching from the newer DMTs (including fingolimod, dimethyl fumarate, teriflunomide) and from established DMTs (interferon beta and glatimer acetate). Safety concerns addressed: PML risk in patients switching from DHMTs with immunosuppressant effect

Action: For adoption of advice to CHMP

7.5.14. Natalizumab - TYSABRI (CAP) - EMEA/H/C/000603/MEA 066.5

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Annual report of a retrospective analysis of extended interval dosing (EID) versus standard interval dosing (SID) to further investigate the efficacy and safety in terms of progressive multifocal leukoencephalopathy (PML) risk reduction with EID relative to SID (TOUCH database)

Action: For adoption of advice to CHMP

7.5.15. Patisiran - ONPATTRO (CAP) - EMEA/H/C/004699/MEA 003.6

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Third interim study report for Patisiran-LNP Pregnancy Surveillance Program. To collect primary data on pregnant women from the US, the United Kingdom (UK), France, Spain, Italy, Portugal and Germany, and other potential countries, who have been exposed to patisiran during the exposure window, defined as 12 weeks prior to their last menstrual period (LMP), or at any time during pregnancy. Establish a worldwide Pregnancy Surveillance Program (PSP) to collect and analyze information pertaining to pregnancy complications and birth outcomes in women exposed to patisiran during pregnancy. The collection and analysis of data should continue for a minimum of 10 years

Action: For adoption of advice to CHMP

7.5.16. Pitolisant - WAKIX (CAP) - EMEA/H/C/002616/ANX 001.6

Applicant: Bioprojet Pharma

PRAC Rapporteur: Kirsti Villikka

Scope: Sixth annual interim study report for study P15-11: a 5-year multicentre, observational PASS to document the utilisation of Wakix (pitolisant) in the treatment of

narcolepsy with or without cataplexy and to collect information on its long-term safety when used in routine medical practice

Action: For adoption of advice to CHMP

7.5.17. Ponesimod - PONVORY (CAP) - EMEA/H/C/005163/MEA 001.4

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Karin Erneholm

Scope: MAH's response to MEA 001.3 [First annual progress report for study POEM: PASS: Ponesimod Pregnancy Outcomes Program Utilizing Enhanced Pharmacovigilance Monitoring] as per the RSI adopted in September 2023

Action: For adoption of advice to CHMP

7.5.18. Risankizumab - SKYRIZI (CAP) - EMEA/H/C/004759/MEA 001.7

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Progress report for PASS Study P19-633 (NI/NI, RMP): A post-marketing registry-based prospective cohort study of long term safety of risankizumab in Denmark and Sweden. Long-Term Prospective Cohort Study in Real World Setting

Action: For adoption of advice to CHMP

7.5.19. Selexipag - UPTRAVI (CAP) - EMEA/H/C/003774/MEA 003.5

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Nathalie Gault

Scope: Progress report for PASS to evaluate risk minimisation measures for medication errors with Uptravi during the titration phase in patients with pulmonary arterial hypertension (PAH) in Clinical prAcTicE (EDUCATE)

Action: For adoption of advice to CHMP

7.5.20. Semaglutide - OZEMPIC (CAP) - EMEA/H/C/004174/MEA 002.6

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Fourth progress report for PASS Study No. NN9535-4447: Epidemiological assessment of the risk for pancreatic cancer associated with the use of semaglutide in patients with type 2 diabetes – A cohort study based on Nordic registry data

Action: For adoption of advice to CHMP

7.5.21. Semaglutide - RYBELSUS (CAP) - EMEA/H/C/004953/MEA 002.4

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Fourth progress report for PASS Study No. NN9535-4447: Epidemiological assessment of the risk for pancreatic cancer associated with the use of semaglutide in patients with type 2 diabetes – A cohort study based on Nordic registry data

Action: For adoption of advice to CHMP

7.5.22. Tozinameran - COMIRNATY (CAP) - EMEA/H/C/005735/MEA 017.8

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Statistical analysis plan amendment and interim report for study C4591021 (former ACCESS/VAC4EU: Assessment of occurrence of safety events of interest, including severe or atypical COVID 19 in real-world use of COVID-19 mRNA vaccine (ACCESS/VAC4EU). Post Conditional approval active surveillance study among individuals in Europe receiving the Pfizer BioNTech Coronavirus Disease 2019 (COVID-19) vaccine. (Non-Interv.)

Action: For adoption of advice to CHMP

7.5.23. Tozinameran - COMIRNATY (CAP) - EMEA/H/C/005735/MEA 047.4

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: MAH's response to MEA 047 [Protocol for study C4591038 (listed as a category 3 study in the RMP): a post conditional approval active surveillance study among individuals in Europe receiving the Pfizer BioNTech coronavirus disease 2019 (COVID-19) vaccine to investigate natural history of post-vaccination myocarditis and pericarditis] as per RSI adopted in May 2022

Action: For adoption of advice to CHMP

7.5.24. Turoctocog alfa pegol - ESPEROCT (CAP) - EMEA/H/C/004883/ANX 001.3

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Gabriele Maurer

Scope: Third progress report for study ID: NN7088-4029: PASS: In order to investigate the potential effects of PEG accumulation in the choroid plexus of the brain and other tissues/organs, the MAH should conduct and submit the results of a PASS according to an agreed protocol. Study ID: NN7088-4029 A multinational, prospective, open labelled, non-controlled, non-interventional post-authorisation study of turoctocog alfa pegol (N8-GP) during long-term routine prophylaxis and treatment of bleeding episodes in patients with haemophilia A. MAH also includes the interim results of the study with the data cut-off date 23-Apr-2023

Action: For adoption of advice to CHMP

7.5.25. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/MEA 047.4

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Interim report for an Observational PASS to Describe The Safety of Ustekinumab and Other Biologic Treatments in a Cohort of Patients With Ulcerative Colitis or Crohn's Disease Using Compulsory Swedish Nationwide Healthcare Registers and the Independent Swedish National Quality Register for Inflammatory Bowel Disease

Action: For adoption of advice to CHMP

7.6. Others

7.6.1. Alemtuzumab - LEMTRADA (CAP) - EMEA/H/C/003718/ANX 009.4

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: MAH's response to ANX 009.3 [The provision of answers to questions about the feasibility report of the non-interventional PASS to investigate the risk of mortality in multiple sclerosis (MS) patients treated with alemtuzumab (Lemtrada) relative to comparable MS patients using other disease modifying treatments (DMTs)] as per request for supplementary information (RSI) adopted in September 2023

Action: For adoption of advice to CHMP

7.7. New Scientific Advice

None

7.8. Ongoing Scientific Advice

None

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

None

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Lonafarnib - ZOKINVY (CAP) - EMEA/H/C/005271/S/0008 (without RMP)

Applicant: EigerBio Europe Limited

PRAC Rapporteur: Adam Przybylkowski
Scope: Annual reassessment of the marketing authorisation
Action: For adoption of advice to CHMP

8.1.2. Metreleptin - MYALEPTA (CAP) - EMEA/H/C/004218/S/0035 (without RMP)

Applicant: Amryt Pharmaceuticals DAC
PRAC Rapporteur: Adam Przybylkowski
Scope: Annual reassessment of the marketing authorisation
Action: For adoption of advice to CHMP

8.1.3. Odevixibat - BYLVAY (CAP) - EMEA/H/C/004691/S/0016 (without RMP)

Applicant: Albireo
PRAC Rapporteur: Adam Przybylkowski
Scope: Annual reassessment of the marketing authorisation
Action: For adoption of advice to CHMP

8.2. Conditional renewals of the marketing authorisation

8.2.1. Andexanet alfa - ONDEXXYA (CAP) - EMEA/H/C/004108/R/0041 (without RMP)

Applicant: AstraZeneca AB
PRAC Rapporteur: Bianca Mulder
Scope: Conditional renewal of the marketing authorisation
Action: For adoption of advice to CHMP

8.2.2. Ciltacabtagene autoleucel - CARVYKTI (CAP) - EMEA/H/C/005095/R/0025 (without RMP)

Applicant: Janssen-Cilag International NV, ATMP
PRAC Rapporteur: Jo Robays
Scope: Conditional renewal of the marketing authorisation
Action: For adoption of advice to CAT and CHMP

8.2.3. Lorlatinib - LORVIQUA (CAP) - EMEA/H/C/004646/R/0031 (with RMP)

Applicant: Pfizer Europe MA EEIG
PRAC Rapporteur: Nikica Mirošević Skvrce
Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Ambrisentan - AMBRISENTAN MYLAN (CAP) - EMEA/H/C/004985/R/0009 (without RMP)

Applicant: Mylan Pharmaceuticals Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.2. Angiotensin II - GIAPREZA (CAP) - EMEA/H/C/004930/R/0027 (without RMP)

Applicant: Paion Deutschland GmbH

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Buprenorphine - SIXMO (CAP) - EMEA/H/C/004743/R/0017 (with RMP)

Applicant: L. Molteni & C. dei Fratelli Alitti Societa di Esercizio S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Dolutegravir, lamivudine - DOVATO (CAP) - EMEA/H/C/004909/R/0045 (without RMP)

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: David Olsen

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.5. Hydroxycarbamide - XROMI (CAP) - EMEA/H/C/004837/R/0023 (without RMP)

Applicant: Nova Laboratories Ireland Limited

PRAC Rapporteur: Jo Robays

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.6. Ioflupane (¹²³I) - STRIASCAN (CAP) - EMEA/H/C/004745/R/0012 (with RMP)

Applicant: CIS BIO International

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.7. L-lysine hydrochloride, l-arginine hydrochloride - LYSAKARE (CAP) - EMEA/H/C/004541/R/0016 (without RMP)

Applicant: Advanced Accelerator Applications

PRAC Rapporteur: Adam Przybylkowski

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.8. Ravulizumab - ULTOMIRIS (CAP) - EMEA/H/C/004954/R/0040 (without RMP)

Applicant: Alexion Europe SAS

PRAC Rapporteur: Kimmo Jaakkola

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.9. Talazoparib - TALZENNA (CAP) - EMEA/H/C/004674/R/0017 (without RMP)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Carla Torre

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.10. Trientine - CUFENCE (CAP) - EMEA/H/C/004111/R/0016 (without RMP)

Applicant: Univar Solutions BV

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.11. Volanesorsen - WAYLIVRA (CAP) - EMEA/H/C/004538/R/0026 (without RMP)

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspections

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

9.3. Others

None

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

10.1. Safety related variations of the marketing authorisation

10.1.1. Ruxolitinib - JAKAVI (CAP) - EMEA/H/C/002464/II/0068

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of sections 4.4 and 5.1 of the SmPC in order to add new warnings on 'major adverse cardiac events (MACE)', 'thrombosis' and 'second primary malignancies', following an Article 20 class referral involving JAK inhibitors approved to treat rheumatoid arthritis and to update efficacy information regarding the effects of ruxolitinib in relation to thromboembolic events based on recently published data from MAJIC-PV study (a randomised, controlled open-label study in polycythemia vera (PV))

Action: For adoption of advice to CHMP

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

None

10.3. Other requests

None

10.4. Scientific Advice

None

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

11.1. Safety related variations of the marketing authorisation

None

11.2. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC membership

Action: For information

12.1.2. Vote by proxy

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

Action: For discussion

12.5. Cooperation with International Regulators

None

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

None

12.7. PRAC work plan

12.7.1. PRAC work plan 2024

PRAC lead: Sabine Straus, Martin Huber

Action: For adoption

12.8. Planning and reporting

None

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

PRAC lead: To be appointed

Action: For discussion

12.10.3. PSURs repository

None

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

Action: For adoption

12.11. Signal management

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

PRAC lead: Martin Huber

Action: For discussion

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

12.20.1. EU pharmacovigilance impact research 2016-2022: lessons learnt for PRAC regulatory decision-making – final report

PRAC lead: Liana Martirosyan

Action: For discussion

12.20.2. Implementation of controlled access to and distribution of medicinal products in EU Member States – draft technical specification for tender

PRAC lead: Liana Martirosyan

Action: For discussion

12.21. Others

12.21.1. IRIS - update on variations, Art. 61(3) and Marketing authorisation transfers

Action: For discussion

12.21.2. Marketing authorisation applications (MAA) forecast for 2023 – planning update dated Q4 2023

Action: For discussion

12.21.3. PRAC drafting group on the risks of dependence and addiction of opioids – update

PRAC lead: Liana Martirosyan

Action: For discussion

12.21.4. PRAC drafting group on multiple sclerosis and use of disease modifying drugs in women of childbearing potential: considerations on approach to labelling and risk management planning

PRAC lead: Nathalie Gault

Action: For discussion

13. Any other business

Next meeting on: 05-08 February 2024

14. Explanatory notes

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

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

(Items 2 and 3 of the PRAC agenda)

A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the European Union (EU). For further detailed information on safety related referrals please see:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000150.jsp&mid=WC0b01ac05800240d0

Signals assessment and prioritisation

(Item 4 of the PRAC agenda)

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have a comprehensive knowledge of a medicine's benefits and risks.

The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.

The evaluation of safety signals may not necessarily conclude that the medicine caused the adverse event in question. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary and this usually takes the form of an update of the summary of product characteristics and the package leaflet.

Risk Management Plans (RMPs)

(Item 5 of the PRAC agenda)

The RMP describes what is known and not known about the side effects of a medicine and states how these risks will be prevented or minimised in patients. It also includes plans for studies and other activities to gain more knowledge about the safety of the medicine and risk factors for developing side effects.

RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available.

Assessment of Periodic Safety Update Reports (PSURs)

(Item 6 of the PRAC agenda)

A PSUR is a report providing an evaluation of the benefit-risk balance of a medicine, which is submitted by marketing authorisation holders at defined time points following a medicine's authorisation.

PSURs summarises data on the benefits and risks of a medicine and includes the results of all studies carried out with this medicine (in the authorised and unauthorised indications).

Post-authorisation Safety Studies (PASS)

(Item 7 of the PRAC agenda)

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

Product related pharmacovigilance inspections

(Item 9 of the PRAC agenda)

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

For a list of acronyms and abbreviations, see:

[List of abbreviations used in EMA human medicines scientific committees and CMDh documents, and in](#)

[Pharmacovigilance Risk Assessment Committee \(PRAC\)](#)

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