02 September 2024
EMA/PRAC/323875/2024
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 02-05 September 2024

Chair: Ulla Wändel Liminga – Vice-Chair: Martin Huber

02 September 2024, 13:00 – 19:30, room 1C

03 September 2024, 08:30 – 19:30, room 1C

04 September 2024, 08:30 – 19:30, room 1C

05 September 2024, 08:30 – 16:00, room 1C

Organisational, regulatory and methodological matters (ORGAM)

19 September 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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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 02-05 September 2024. See September month 2024 PRAC minutes (to be published post October 2024 PRAC meeting).

1.2. Agenda of the meeting on 02-05 September 2024

Action: For adoption

1.3. Minutes of the previous meeting on 08-11 July 2024

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

2.3.1. Metamizole (NAP); metamizole, caffeine (NAP); metamizole, caffeine, codeine (NAP); metamizole, caffeine, codeine, paracetamol (NAP); metamizole, caffeine, codeine, paracetamol, phenobarbital (NAP); metamizole, caffeine, drotaverine (NAP); metamizole, caffeine, thiamine (NAP); metamizole, hyoscine (NAP); metamizole, pitofenone (NAP); metamizole, pitofenone, fenpipramide (NAP); metamizole, pitofenone, fenpiverinium (NAP); metamizole, triacetonamine (NAP) – EMEA/H/A-107i/1537

Applicant(s): various

PRAC Rapporteur: Julia Pallos; PRAC Co-rapporteur: Barbara Kovacic Bytiqi

Scope: Review of the benefit-risk balance following notification by Finland of a referral under Article 107i of Directive 2001/83/EC, based on pharmacovigilance data

Action: For adoption of recommendation to CMDh

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

3.1. Newly triggered procedures

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination procedures[1]

None

3.5. Others

None

4. Signals assessment and prioritisation[2]

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

4.1.1. Canagliflozin – INVOKANA (CAP); canagliflozin, metformin – VOKANAMET (CAP); dapagliflozin - DAPAGLIFLOZIN VIATRIS, EDISTRIDE, FORXIGA (CAP), NAP; dapagliflozin, metformin - EBYMECT, XIGDUO (CAP), NAP; saxagliptin, dapagliflozin – QTERN (CAP)

Applicants: AstraZeneca AB (Ebymect, Edistride, Forxiga, Qtern, Xigduo), Janssen-Cilag International N.V. (Invokana), Viatris Limited (Dapagliflozin Viatris), various

PRAC Rapporteur: To be appointed

Scope: Signal of sarcopenia

[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

Action: For adoption of PRAC recommendation

EPITT 20111 – New signal

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

4.1.2. Lenvatinib – KISPLYX (CAP), LENVIMA (CAP)

Applicant: Eisai GmbH

PRAC Rapporteur: To be appointed

Scope: Signal of tumour lysis syndrome

Action: For adoption of PRAC recommendation

EPITT 20108 – New signal

Lead Member State(s): SE, NO

4.1.3. Lisocabtagene maraleucel – BREYANZI (CAP)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Signal of progressive multifocal leukoencephalopathy (PML)

Action: For adoption of PRAC recommendation

EPITT 20109 – New signal

Lead Member State(s): DE

4.1.4. Sacubitril, valsartan – ENTRESTO (CAP), NEPARVIS (CAP)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Karin Erneholm

Scope: Signal of myoclonus

Action: For adoption of PRAC recommendation

EPITT 20097 – New signal

Lead Member State(s): DK

4.2. Signals follow-up and prioritisation

4.2.1. Medroxyprogesterone acetate (NAP)

Applicant: various

PRAC Rapporteur: Bianca Mulder

Scope: Signal of meningioma

Action: For adoption of PRAC recommendation

EPITT 20030 – Follow-up to June 2024

Lead Member State(s): NL

4.3. Variation procedure(s) resulting from signal evaluation

4.3.1. Anakinra - KINERET (CAP) - EMEA/H/C/000363/II/0093

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Karin Erneholm

Scope: Update of section 4.4 of the SmPC in order to add a new warning on 'Amyloidosis (systemic)' based on an updated safety review, following the PRAC recommendation on a signal. In addition, the MAH took the opportunity to correct a numerical error in the SmPC

Action: For adoption of PRAC Assessment Report

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Aflibercept (CAP MAA) - EMEA/H/C/006607

Scope: treatment of age-related macular degeneration (AMD) and visual impairment

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

5.1.2. Aflibercept (CAP MAA) - EMEA/H/C/005980

Scope (pre D-180 phase): Treatment of age-related macular degeneration (AMD) and visual impairment

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

5.1.3. Aflibercept (CAP MAA) - EMEA/H/C/005899

Scope (pre D-180 phase): Treatment of age-related macular degeneration (AMD), visual impairment and retinopathy of prematurity (ROP)

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

5.1.4. Belzutifan (CAP MAA) - EMEA/H/C/005636

Scope (pre D-180 phase): Treatment of adult patients with advanced renal cell carcinoma (RCC) and treatment of adult patients with von Hippel-Lindau (VHL) disease

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

5.1.5. Eltrombopag (CAP MAA) - EMEA/H/C/006417

Scope (pre D-180 phase): Treatment of primary immune thrombocytopenia (ITP), chronic hepatitis C virus (HCV) and acquired severe aplastic anaemia (SAA)

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

5.1.6. Filgrastim (CAP MAA) - EMEA/H/C/006400

Scope (pre D-180 phase): for the reduction in the duration of neutropenia and the incidence of febrile neutropenia

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

5.1.7. Garadacimab (CAP MAA) - EMEA/H/C/006116, Orphan

Applicant: CSL Behring GmbH

Scope (pre D-180 phase): Routine prevention of attacks of hereditary angioedema (HAE)

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

5.1.8. Givinostat (CAP MAA) - EMEA/H/C/006079, Orphan

Applicant: Italfarmaco S.p.A.

Scope (pre D-180 phase): Treatment of Duchenne muscular dystrophy (DMD)

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

5.1.9. Insulin human (CAP MAA) - EMEA/H/C/006011

Scope (pre D-180 phase): Treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis

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

5.1.10. Lazertinib (CAP MAA) - EMEA/H/C/006074

Scope (pre D-180 phase): Treatment of adult patients with advanced non-small cell lung cancer (NSCLC)

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

5.1.11. Repotrectinib (CAP MAA) - EMEA/H/C/006005

Scope (pre D-180 phase): Treatment of ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) and for solid tumours

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

5.1.12. Sipavibart (CAP MAA) - EMEA/H/C/006291

Scope (pre D-120 phase, accelerated assessment): Indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older

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

5.1.13. Trabectedin (CAP MAA) - EMEA/H/C/006433,

Scope (pre D-180 phase): Treatment of soft tissue sarcoma and combination with PLD treatment of relapsed platinum-sensitive ovarian cancer

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. Alendronic acid, Colecalciferol - ADROVANCE (CAP) - EMEA/H/C/000759/WS2696/0055; Alendronic acid, Colecalciferol - FOSAVANCE (CAP) - EMEA/H/C/000619/WS2696/0058; Alendronic acid, Colecalciferol - VANTAVO (CAP) - EMEA/H/C/001180/WS2696/0045

Applicant: Organon N.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Submission of an updated RMP version 8.0 following the assessment outcome from procedure WS/2467 to reclassify the risk of atypical femoral fracture from "important potential risk" to "important identified risk" and to extend the risk of "atypical femoral fracture" to "atypical fractures of long bones"

Action: For adoption of PRAC Assessment Report

5.2.2. Amlodipine, Valsartan - AMLODIPINE-VALSARTAN MYLAN (CAP) - EMEA/H/C/004037/II/0021

Applicant: Mylan Pharmaceuticals Limited

PRAC Rapporteur: Karin Erneholm

Scope: Submission of an updated RMP version 4.0 in order to align the safety concerns with the latest version of RMP for Amlodipine/Valsartan available in the public domain and to bring the RMP in line with the latest RMP template

Action: For adoption of PRAC Assessment Report

5.2.3. Alpelisib - PIQRAY (CAP) - EMEA/H/C/004804/II/0024

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Bianca Mulder

Scope: Submission of an updated RMP version 8.0 in order to remove the PASS CBYL719C2404 (Cat. 3) RMP commitment (MEA 002).

Action: For adoption of PRAC Assessment Report

5.2.4. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase (ADA) complementary deoxyribonucleic acid (cDNA) sequence - STRIMVELIS (CAP) - EMEA/H/C/003854/II/0040, Orphan

Applicant: Fondazione Telethon ETS, ATMP

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of an updated RMP version 7.0 in order to propose amendments to the STRIM-005 and STRIM-003 study protocols, as well as revised timelines for completion of both studies. In addition, the Annex II is updated accordingly

Action: For adoption of PRAC Assessment Report

5.2.5. Clopidogrel - GREPID (CAP) - EMEA/H/C/001059/II/0058

Applicant: Pharmathen S.A.

PRAC Rapporteur: Carla Torre

Scope: Submission of an RMP version 0.1 following procedure EMEA/H/C/001059/IB/0057/G to be in line with the updated RMP of the reference product (Plavix).

Action: For adoption of PRAC Assessment Report

5.2.6. Dulaglutide - TRULICITY (CAP) - EMEA/H/C/002825/II/0071

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Submission of an updated RMP version 8.1 in order to add a medullary thyroid cancer (MTC) database linkage study (Study I8F-MC-B014) as an additional pharmacovigilance activity to evaluate the important potential risk of MTC in patients exposed to long-acting glucagon-like peptide-1 receptor agonist (GLP-1 RA) therapies. In addition, the MAH took the opportunity to include an amendment to Study H9X-MC-B013 due to the removal of the United States data source

Action: For adoption of PRAC Assessment Report

5.2.7. Pegcetacoplan - ASPAVELI (CAP) - EMEA/H/C/005553/II/0018, Orphan

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: Submission of an updated RMP version 2.1 in order to revise the category 3 PASS Sobi.PEGCET-301 and Sobi.PEGCET-302

Action: For adoption of PRAC Assessment Report

5.2.8. Rivaroxaban - RIVAROXABAN VIATRIS (CAP); NAP - EMEA/H/C/005600/WS2709/0012

Applicant(s): Viatris Limited, various

PRAC Rapporteur: Mari Thorn

Scope: To provide an updated RMP to remove the following safety concerns (classified as Missing information) in order to align with RMP version 13.4 of the reference product Xarelto:
- Patients with severe renal impairment (CrCl < 30 mL/min)
- Patients receiving concomitant systemic inhibitors of CYP 3A4 or P-gp other than azole antimycotics (e.g. ketoconazole) and HIV-protease inhibitors (e.g. ritonavir)
- Pregnant or breast-feeding women
- Long-term therapy with rivaroxaban in treatment of DVT, PE, SPAF and ACS in real-life setting
- Patients with significant liver diseases (severe hepatic impairment/Child Pugh C)
- Patients < 18 years

Action: For adoption of PRAC Assessment Report

5.2.9. Tadalafil - CIALIS (CAP) - EMEA/H/C/000436/WS2697/0098; Tadalafil - TADALAFIL LILLY (CAP) - EMEA/H/C/004666/WS2697/0012

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: To provide an updated RMP version for Cialis and Tadalafil Lilly to align with the currently approved RMP version of Adcirca. There is only one RMP for all 3 tadalafil products (Adcirca, Cialis and Tadalafil Lilly), however different versions of the same RMP are officially approved in the EMA database (for Adcirca v9.2; for Cialis and Tadalafil Lilly v8.2)

Action: For adoption of PRAC Assessment Report

5.2.10. Tezepelumab - TEZSPIRE (CAP) - EMEA/H/C/005588/II/0013/G

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: A grouped application consisting of:
Type II (C.I.11.b): Submission of an updated RMP version V 3, S 1 in order to remove the SUNRISE study (D5180C00024) from the RMP due to discontinuation of the study. This is a Phase 3, randomised, double-blind, parallel-group, placebo-controlled, multicentre study to evaluate the efficacy and safety of tezepelumab 210 mg Q4W administered SC for 28 weeks using an accessorised pre-filled syringe, compared with placebo in reducing OCS use in OCS-dependent adult asthma participants. In addition, the MAH took the opportunity to implement updates to the Targeted Safety Questionnaires (TSQs) and to the Module SI of the RMP to bring it up to date.

Type IB (C.I.11.z): Submission of an updated RMP version V 3, S 1 in order to remove the DESTINATION study (D5180C00018) following procedure EMEA/H/C/005588/II/0004.

Type IB (C.I.11.z): Submission of an updated RMP version V 3, S 1 in order to propose changes to the study design and objectives for the Pregnancy PASS (D5180R00010), following procedure EMEA/H/C/005588/MEA/001.2.

Type IB (C.I.11.z): Submission of an updated RMP version V 3, S 1 in order to propose changes to the study design and objectives for the Cardiac PASS (D5180R00024), following procedure EMEA/H/C/005588/MEA/005

Action: For adoption of PRAC Assessment Report

5.2.11. Voxelotor - OXBRYTA (CAP) - EMEA/H/C/004869/II/0011, Orphan

Applicant: Pfizer Europe Ma EEIG

PRAC Rapporteur: Jo Robays

Scope: Submission of an updated RMP version 1.2 in order to include the current data for the main existing treatment options and to extend the submission deadline for Study GBT440-0122 (C5341029) and for Study GBT440-034 (C5341022).

Action: For adoption of PRAC Assessment Report

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

5.3.1. Alectinib - ALECENSA (CAP) - EMEA/H/C/004164/II/0048

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jana Lukacisinova

Scope: To update sections 4.4 and 4.6 of the SmPC to update the safety information to amend the duration of the period for which female patients of child-bearing potential must use highly effective contraceptive methods following the last dose of Alecensa, and must be informed of potential harm to the fetus in the event of pregnancy, from 3 months to 5 weeks based on the latest guidelines on contraception requirements for drugs with aneugenic potential. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

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

5.3.2. Amivantamab - RYBREVANT (CAP) - EMEA/H/C/005454/II/0013

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include amivantamab in combination with lazertinib for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 L858R substitution mutations (EGFRm NSCLC), based on results from study 73841937NSC3003 (MARIPOSA). This is a randomized, open-label, Phase 3 study that compares the efficacy and safety of the combination of amivantamab and lazertinib (Arm A) versus osimertinib monotherapy (Arm B) and lazertinib monotherapy (Arm C) in participants with EGFRm NSCLC. The primary objective of the MARIPOSA study

was to assess the efficacy of the combination of amivantamab and lazertinib (Arm A), compared with osimertinib (Arm B), as measured by PFS assessed by BICR in adult participants with EGFRm NSCLC.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1, 5.2, 6.6 and 9 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.3 of the EU RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection

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

5.3.3. Andexanet alfa - ONDEXXYA (CAP) - EMEA/H/C/004108/II/0044

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it 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. Atezolizumab - TECENTRIQ (CAP) - EMEA/H/C/004143/II/0087

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Update of sections 4.2, 4.8 and 5.1 in order to include information regarding switching treatment between Tecentriq intravenous and subcutaneous (and vice versa) and to update safety information, based on primary results from study MO43576 (IMscin002); this is a phase II, randomised, multicenter, open-label cross-over study to evaluate participants and healthcare professional reported reference for subcutaneous atezolizumab compared with intravenous atezolizumab formulation in participants with non-small cell lung cancer. The RMP version 31.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI

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

5.3.5. Avacopan - TAVNEOS (CAP) - EMEA/H/C/005523/II/0015, Orphan

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.5 and 5.2 of the SmPC based on final results from study CL020_168; this is an open-label, phase 1 study to evaluate the effect of repeated oral

doses of avacopan on the pharmacokinetics of a single dose of simvastatin in healthy volunteers; the Package Leaflet is updated accordingly. The updated RMP version 2.0 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

5.3.6. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/II/0028

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Update of section 5.1 of the SmPC in order to update efficacy information based on the final results from study PS0015 (BE RADIANT) listed as a category 3 study in the RMP; this is a multicenter, randomized, double-blind, secukinumab-controlled, parallel-group study to evaluate the efficacy and safety of bimekizumab in adult subjects with moderate to severe chronic plaque psoriasis. In addition, the MAH has taken the opportunity to update the list of local representatives in the Package leaflet and align the PI with the latest QRD template version 10.4 as well as to update wording on polysorbates in the SmPC and the Package leaflet to align with the annex of the guideline related to excipients. The RMP version 2.1 has also been submitted

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

5.3.7. Bulevirtide - HEPCLUDEX (CAP) - EMEA/H/C/004854/II/0034, Orphan

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Adam Przybylkowski

Scope: Update of section 4.8 of the SmPC in order to update safety information based on final results from study MYR204 listed as a category 3 study in the RMP; this is a multicenter, open-label, randomized Phase 2b clinical study to assess efficacy and safety of bulevirtide in combination with pegylated interferon alfa-2a in patients with chronic hepatitis delta. The RMP version 4.2 has also been submitted

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

5.3.8. Cabotegravir - APRETUDE (CAP) - EMEA/H/C/005756/II/0004

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Update of sections 4.8, 5.1 and 5.2 of the SmPC to include data from clinical studies in HIV-1 uninfected adolescents (HPTN 083-01 and HPTN 084-01), updated data from the MOCHA study and updated PK data based on a population PK analysis of cabotegravir in adolescents in MOCHA, HPTN 083-01 and HPTN 084-01. In addition, the MAH took the opportunity to update section 4.2 of the SmPC to clarify the wording related to missed doses of oral PrEP and renal impairment, and to implement editorial changes in the SmPC. Furthermore, the MAH took the opportunity to align the PI with the latest QRD template version 10.4. The RMP version 1.1 has also been submitted

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

5.3.9. Cabotegravir - VOCABRIA (CAP) - EMEA/H/C/004976/II/0022

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include in combination with rilpivirine injection, the treatment of adolescents (at least 12 years of age and weighing at least 35 kg) for Vocabria, based on interim results from study 208580 (Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents). This is an ongoing Phase 1/Phase 2 multicenter, open-label, non-comparative study evaluating the safety, acceptability, tolerability, and PK of oral and LA injectable CAB and LA injectable RPV in virologically suppressed HIV-infected adolescents 12 to <18 years of age and weighing at least 35 kg who are receiving stable cART consisting of 2 or more drugs from 2 or more classes of ARV drugs. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes. Furthermore, the PI is brought in line with the latest QRD template version 10.4

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

5.3.10. Canagliflozin - INVOKANA (CAP) - EMEA/H/C/002649/WS2619/0066/G; Canagliflozin, Metformin - VOKANAMET (CAP) - EMEA/H/C/002656/WS2619/0073/G

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Martin Huber

Scope: A grouped application consisting of two Type II variations, as follows:
C.I.4: Update of section 4.4 of the SmPC in order to amend an existing warning on Diabetic Ketoacidosis based on literature. The Package Leaflet is updated accordingly.
C.I.4: Update of sections 4.6 and 5.3 of the SmPC in order to update information on pregnancy based on literature.
The RMP version 11.1 has also been submitted

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

5.3.11. Canakinumab - ILARIS (CAP) - EMEA/H/C/001109/II/0085

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Gabriele Maurer

Scope: 1. Type II (B.II.e.1.b.2)
The updated RMP version 14.0 has also been submitted to introduce changes related to the addition of the PFS presentation

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

5.3.12. Ceftazidime, Avibactam - ZAVICEFTA (CAP) - EMEA/H/C/004027/II/0035

Applicant: Pfizer Ireland Pharmaceuticals

PRAC Rapporteur: Rugile Pilviniene

Scope: Extension of indication to include treatment of paediatric patients from birth to less than 3-months of age in the following infections: complicated intra-abdominal infection (cIAI), complicated urinary tract infection (cUTI), including pyelonephritis, hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) and in the treatment of infections due to aerobic Gram-negative organisms in patients with limited treatment options, for ZAVICEFTA, based on final results from study C3591024 and the population PK modelling/simulation analyses. Study C3591024 is a Phase 2a, 2-part, open-label, non-randomized, multicenter, single and multiple dose trial to evaluate pharmacokinetics, safety and tolerability of ceftazidime and avibactam in neonates and infants from birth to less than 3 months of age with suspected or confirmed infections due to gram-negative pathogens requiring intravenous antibiotic treatment. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.3 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI

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

5.3.13. Ceritinib - ZYKADIA (CAP) - EMEA/H/C/003819/II/0055

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: Submission of the final report from PAES study LDK378A2303; this is a Phase III, multicenter, randomized, open-label study of oral LDK378 versus standard chemotherapy in adult patients with ALK rearranged (ALK-positive) advanced non-small cell lung cancer who have been treated previously with chemotherapy (platinum doublet) and crizotinib. The RMP (version 18.0) is updated accordingly

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

5.3.14. Dapagliflozin - EDISTRIDE (CAP) - EMEA/H/C/004161/WS2733/0068; Dapagliflozin - FORXIGA (CAP) - EMEA/H/C/002322/WS2733/0089

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Submission of the post-treatment week 104 safety results from study D1680C00019 (T2NOW) listed as a category 3 study in the RMP. This is a randomised, placebo-controlled, double-blind, parallel-group, phase 3 trial with a 26-week safety extension period evaluating the safety and efficacy of dapagliflozin 5 and 10 mg, and saxagliptin 2.5 and 5 mg in paediatric patients with type 2 diabetes mellitus who are between 10 and below 18 years of age. The RMP version 31,s1 has also been submitted

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

5.3.15. Daratumumab - DARZALEX (CAP) - EMEA/H/C/004077/II/0072, Orphan

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include, in combination with bortezomib, lenalidomide and dexamethasone, the treatment of adult patients with newly diagnosed multiple myeloma, who are eligible for autologous stem cell transplant for Darzalex, based on the primary analysis results from the pivotal study 54767414MMY3014 (PERSEUS) and the results from study 54767414MMY2004 (GRIFFIN) and the D-VRd cohort of study 54767414MMY2040 (PLEIADES).
MMY3014 (PERSEUS) is a randomised, open-label, active-controlled, multicentre phase 3 study in adult subjects with newly diagnosed multiple myeloma, who are eligible for high dose therapy (as required for autologous stem cell transplant). The primary objective is to compare the efficacy of (subcutaneous) daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) versus bortezomib, lenalidomide and dexamethasone (VRd) in terms of progression free survival (PFS).
MMY2004 (GRIFFIN) is a randomised, open-label, active controlled, multicentre phase 2 study in adult subjects with newly diagnosed multiple myeloma, who are eligible for high dose therapy and autologous stem cell transplant. The primary objective is to compare the efficacy of daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) versus bortezomib, lenalidomide and dexamethasone (VRd), in terms of stringent complete response (sCR) rate.
MMY2040 (PLEIADES) is a randomised, open-label, multicentre phase 2 study to evaluate subcutaneous daratumumab in combination with standard multiple myeloma treatment regimens. The D-VRd cohort included adult subjects with newly diagnosed multiple myeloma, who were evaluated for clinical benefit in terms of very good partial response or better (VGPR) rate.
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 10.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet

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

5.3.16. Dengue tetravalent vaccine (live, attenuated) - DENGUE TETRAVALENT VACCINE (LIVE, ATTENUATED) TAKEDA (Art 58) - EMEA/H/W/005362/WS2593/0012; Dengue tetravalent vaccine (live, attenuated) - QDENGA (CAP) - EMEA/H/C/005155/WS2593/0013

Applicant: Takeda GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Update of section 4.5 of the SmPC in order to add co-administration information with HPV vaccine based on final results from study DEN-308 listed as a category 3 study in the RMP (MEA003/MEA004); this is a Phase 3, open-label, randomized trial to investigate the immunogenicity and safety of the co-administration of a subcutaneous dengue tetravalent vaccine (live, attenuated) (TDV) and an intramuscular recombinant 9-valent human papillomavirus (9vHPV) vaccine in subjects aged ≥9 to <15 years in an endemic country for dengue; the Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took this opportunity to introduce editorial

changes and to update the text on PSUR submissions in Annex II for Dengue tetravalent vaccine

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

5.3.17. Dostarlimab - JEMPERLI (CAP) - EMEA/H/C/005204/II/0032

Applicant: GlaxoSmithKline (Ireland) Limited

PRAC Rapporteur: Carla Torre

Scope: Extension of indication for JEMPERLI to include, in combination with carboplatin and paclitaxel, the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy based on Interim Analysis 1 and 2 from study RUBY Part 1 (213361). This is a phase 3, randomized, double-blind, controlled study evaluating the efficacy and safety of dostarlimab plus carboplatin and paclitaxel in primary advanced or recurrent EC versus placebo plus carboplatin and paclitaxel.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted.
In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC and to align the PI with the latest QRD template version 10.4

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

5.3.18. Dupilumab - DUPIXENT (CAP) - EMEA/H/C/004390/II/0083

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents 12 years and older, who are symptomatic despite treatment with H1 antihistamines and who are intolerant to or inadequately controlled by anti-IgE therapy for Dupixent, based on the results from studies EFC16461 (CUPID) study B (pivotal) and study A (supportive); EFC16461 Study B was a 24-week, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of dupilumab in adult and adolescent participants with CSU who remained symptomatic despite the use of H1-antihistamine and who were intolerant or incomplete responders to omalizumab and EFC16461 Study A was a 24-week, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of dupilumab in participants with CSU who remained symptomatic despite the use of H1-antihistamine and who were naïve to omalizumab. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11.0 of the RMP has also been submitted

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

5.3.19. Efgartigimod alfa - VYVGART (CAP) - EMEA/H/C/005849/II/0020, Orphan

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include the treatment of adult patients with chronic

inflammatory demyelinating polyneuropathy (CIDP) with active disease despite treatment with corticosteroids or immunoglobulins for VYVGART, based on final results from study ARGX-113-1802; this is a pivotal study to investigate the efficacy, safety and tolerability of efgartigimod PH20 SC in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP); and based on interim results from study ARGX-113-1902; this is an open-label extension study of the ARGX-113-1802 trial to investigate the long-term safety, tolerability and efficacy of efgartigimod PH20 SC in patients with (CIDP).
As a consequence, sections 4.1, 4.2. 4.4, 4.8, 5.1 and 5.2 of the SmPC has been updated. The Package Leaflet has been updated in accordance with the SmPC. 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

5.3.20. Everolimus - VOTUBIA (CAP) - EMEA/H/C/002311/II/0089

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Martin Huber

Scope: Submission of the final report from study CRAD001M2305 listed as a category 3 study in the RMP. This is an interventional PASS study to monitor the growth and development of pediatric patients previously treated with everolimus in study CRAD001M2301 (EXIST-LT). The RMP version 15.0 has also been submitted

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

5.3.21. Faricimab - VABYSMO (CAP) - EMEA/H/C/005642/II/0011/G

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: 1.Type II (B.II.e.1.b.2)
2.Type II (B.II.b.1.c)
3.Type IB (B.II.b.2.a)
4.Type IB (B.II.b.2.a)
5.Type IB (B.II.b.2.a.
6. Type II (B.II.b.1.c)
7.Type IB (B.II.b.2.z)
8.Type IB (B.IV.1.a.1)
9.Type IA (B.II.d.1.c)

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

5.3.22. Fenofibrate, Pravastatin sodium - PRAVAFENIX (CAP) - EMEA/H/C/001243/II/0037

Applicant: Laboratoires SMB s.a.

PRAC Rapporteur: Nathalie Gault

Scope: Extension of indication to include treatment of mixed hyperlipidaemia in adult patients while on a treatment with pravastatin 40 mg monotherapy or on another moderate-intensity statin regimen for PRAVAFENIX, based on final results from the non-interventional PASS: POSE (Pravafenix Observational Study in Europe); this is a European,

observational, three-year cohort comparative study on the safety of the fixed dose combination pravastatin 40 mg/fenofibrate 160 mg (Pravafenix) versus statin alone in real clinical practice. As a consequence, sections 4.1 and 4.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 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. Guselkumab - TREMFYA (CAP) - EMEA/H/C/004271/II/0044

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication for TREMFYA to include treatment of adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic treatment, based on results from GALAXI Phase 2/3 program and the GRAVITI Phase 3 study. GALAXI is a Phase 2/3, randomized, double-blind, placebo- and active-controlled, parallel-group, multicenter protocol to evaluate the efficacy and safety of guselkumab in participants with moderately to severely active CD who have demonstrated an inadequate response or failure to tolerate previous conventional or biologic therapy. GRAVITI is a Phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the efficacy and safety of guselkumab SC induction therapy in participants with moderately to severely active CD.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection

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

5.3.24. Guselkumab - TREMFYA (CAP) - EMEA/H/C/004271/X/0043/G

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Extension application to:
- introduce a new pharmaceutical form (concentrate for solution for infusion), a new strength (200 mg) and a new route of administration (intravenous use)
- add a new strength of 200 mg for solution for injection (in pre-filled syringe / pre-filled pen) for subcutaneous use
This application is grouped with a type II variation (C.I.6.a) to include the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor for Tremfya, based on results of a Phase 2b/3 clinical development programme (CNTO1959UCO3001) consisting of 3 separate studies, an Induction dose finding Study 1 Phase 2b, an Induction Study 2 Phase 3 and a Phase 3 Maintenance Study. These studies were randomized, double-blind, placebo-controlled, parallel-group, multicenter studies that evaluated the efficacy and safety of guselkumab in participants with moderately to severely active UC. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC of the already approved form 100

mg solution for injection are updated. The Package Leaflet and Labelling are updated in accordance. Version 10.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI

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

5.3.25. Herpes zoster vaccine (recombinant, adjuvanted) - SHINGRIX (CAP) - EMEA/H/C/004336/II/0076

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Sonja Hrabcik

Scope: Update of sections 4.8 and 5.1 of the SmPC to include the final results of study ZOSTER-049, listed as a category 3 study in the RMP. This is a Phase 3b, open label, multi-country, long-term follow-up study that assessed the prophylactic efficacy, safety, and immunogenicity persistence of Shingrix in adults ≥50 years of age at the time of primary vaccination in studies ZOSTER 006 and ZOSTER-022. The study also assessed 1 or 2 additional doses of Shingrix on a 0 or 0, 2-month schedule in two subgroups of older adults. The updated RMP version 8.0 is also included. In addition, the MAH took the opportunity to implement editorial changes to the SmPC, Labelling and Package Leaflet; and to bring the PI in line with the latest QRD template version 10.4

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

5.3.26. Inotuzumab ozogamicin - BESPONSA (CAP) - EMEA/H/C/004119/II/0029, Orphan

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of the final report from study B1931030 listed as a category 3 study in the RMP. Phase 4, open-label, randomized study of two Inotuzumab Ozogamicin dose levels in adult patients with relapsed or refractory B-cell acute lymphoblastic leukemia eligible for hematopoietic stem cell transplantation and who have risk factor(s) for veno-occlusive disease. The RMP version 3.1 has also been submitted

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

5.3.27. Linzagolix choline - YSELTY (CAP) - EMEA/H/C/005442/II/0013

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include treatment of endometriosis-associated pain in adult women of reproductive age for YSELTY, based on final results from studies Edelweiss 3 (18-OBE2109-003) and Edelweiss 6 (19-OBE2109-006) as well as additional supporting studies. Edelweiss 3 is a pivotal phase 3, randomised, double-blind, placebo-controlled, safety and efficacy study to evaluate linzagolix with add-back therapy as a therapy for pain associated with endometriosis, while Edelweiss 6 is an open-label extension study including patients who completed Edelweiss 3 pivotal study regardless of their previous treatment assignment and met the eligibility criteria. 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. As part of the application, the MAH is requesting a 1-year extension of the market protection

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

5.3.28. Lutetium (^{177}Lu) oxodotreotide - LUTATHERA (CAP) - EMEA/H/C/004123/II/0052, Orphan

Applicant: Advanced Accelerator Applications

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include the treatment of newly diagnosed, unresectable or metastatic, well-differentiated (G2 and G3), somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) adult patients for LUTATHERA, based on primary analysis results from study CAAA601A22301 (NETTER-2); NETTER-2 study is a Phase III, multicenter, stratified, open-label, randomized, comparator-controlled study comparing treatment with Lutathera plus octreotide LAR 30 mg (Lutathera arm) to treatment with high-dose octreotide LAR 60 mg (control arm). The main purpose of the NETTER-2 study was to determine if treatment in the Lutathera arm prolongs PFS in subjects with newly diagnosed SSTR-positive, G2 and G3 advanced GEP-NET when compared with treatment in the control arm.
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. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes in the SmPC. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection

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

5.3.29. Mavacamten - CAMZYOS (CAP) - EMEA/H/C/005457/II/0011/G

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Grouped application comprised of 2 Type II Variations as follows:

C.I.4: Update of section 4.2 of the SmPC to change the echocardiography monitoring frequency once a patient is on a stable dose of mavacamten. The proposed update is supported by the clinical data from interim Clinical study report of MAVA-LTE (CV027-003) study: "A Long-term Safety Extension Study of Mavacamten in Adults with Hypertrophic Cardiomyopathy who have completed the MAVERICK-HCM (MYK-461-006) or EXPLORER-HCM (MYK-461-005) trials", modelling & simulation results and safety data from post-approval safety database. The Package Leaflet is updated accordingly.

C.I.4: Update of section 4.2 of the SmPC to introduce the optional use of the Left ventricular outflow track (LVOT) gradient by post-exercise testing to guide dose titration for patient with specific characteristics. The proposed update is supported by the exposure-response modeling and simulation report with LVOT post-exercise gradient, based on the previously developed model with the data from the following studies: MYK-461-004 (PIONEER), MYK-461-005 (EXPLORER), MYK-461-007, MYK-461-008 (MAVA-LTE) and MYK-461-017

(VALOR).

The RMP version 4.0 has also been submitted

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

5.3.30. Melatonin - SLENYTO (CAP) - EMEA/H/C/004425/II/0028

Applicant: RAD Neurim Pharmaceuticals EEC SARL

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension of indication to include treatment of insomnia in children and adolescents aged 2-18 with Attention-Deficit Hyperactivity Disorder (ADHD), where sleep hygiene measures have been insufficient, based on results from phase III study NEU_CH_7911 and literature. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted

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

5.3.31. Meningococcal group B vaccine (recombinant, adsorbed) - TRUMENBA (CAP) - EMEA/H/C/004051/II/0053

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.4 and 5.1 of the SmPC in order to amend an existing warning on immunocompromised individuals and to add immunogenicity data in individuals 10 years of age and above with complement deficiencies or splenic dysfunction based on final results from study B1971060 (A Phase 4, Open-Label, Single-Arm Trial to Describe the Safety, Tolerability, and Immunogenicity of Trumenba When Administered to Immunocompromised Participants ≥10 Years of Age) listed as a category 3 study in the RMP. This was an open-label, single-arm, multicenter trial in which up to 50 immunocompromised participants ≥10 years of age with asplenia (anatomic or functional) or complement deficiency have been enrolled and received bivalent rLP2086 on a 2-dose, 0- and 6-month schedule. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.4

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

5.3.32. Midazolam - BUCCOLAM (CAP) - EMEA/H/C/002267/II/0061

Applicant: Neuraxpharm Pharmaceuticals S.L.

PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include treatment of adults to Buccolam 10 mg, based on the results from study 2023-504903-10-00; this is an Interventional Study, Relative Bioavailability to investigate the pharmacokinetics of a single dose of midazolam oromucosal solution (Buccolam) compared to midazolam solution for intramuscular injection (Hypnovel) in healthy volunteers under fasting conditions. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 6.5 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are

updated in accordance. Version 8.1 of the RMP has also been submitted

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

5.3.33. Mirikizumab - OMVOH (CAP) - EMEA/H/C/005122/X/0006/G

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Sonja Hrabcik

Scope: Extension application to add a new strength of 200 mg grouped with an extension of indication (C.I.6) to include treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment, for Omvoh, based mainly on final results from study I6T-MC-AMAM; this is a phase 3, multicenter, randomized, double-blind, placebo- and active-controlled, treat-through study to evaluate the efficacy and safety of mirikizumab in patients with moderately to severely active Crohn's disease. As a consequence, sections 1, 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.1, 6.5, 6.6 and 8 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. Version 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and to update the list of local representatives in the Package Leaflet. As part of the application, the MAH is requesting a 1-year extension of the market protection.

The following Quality variations are also included as part of this application:

Type IA, A.5.b

Type II, B.II.a.3.b.5

Type IB, B.II.b.4.a

Type II, B.I.a.2.c

Type IB, B.I.a.2.z

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

5.3.34. Nintedanib - OFEV (CAP) - EMEA/H/C/003821/X/0057/G

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Extension application to add a new strength of 25 mg hard capsules, grouped with an extension of indication (C.I.6.a) to include treatment of fibrosing Interstitial Lung Diseases (ILDs) in children and adolescents from 6 to 17 years of age for Ofev, following the assessment of procedure X/0052/G, based on final results from study 1199-0337 (A Double Blind, Randomised, Placebo-controlled Trial to Evaluate the Dose-exposure and Safety of Nintedanib Per os on Top of Standard of Care for 24 Weeks, Followed by Open Label Treatment With Nintedanib of Variable Duration, in Children and Adolescents (6 to 17 Year-old) With Clinically Significant Fibrosing Interstitial Lung Disease), which is supplemented by

the currently ongoing prospective Phase III extension trial 1199-0378 (An Open-label Trial of the Long-term Safety and Tolerability of Nintedanib Per os, on Top of Standard of Care, Over at Least 2 Years, in Children and Adolescents With Clinically Significant Fibrosing Interstitial Lung Disease). The main objective of the study 1199-0337 was to evaluate dose-exposure and safety of nintedanib in children and adolescents with fibrosing Interstitial Lung Disease (ILD). 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 and Labelling are updated in accordance. Version 12.0 of the RMP has also been submitted

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

5.3.35. Nusinersen - SPINRAZA (CAP) - EMEA/H/C/004312/II/0034/G, Orphan

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: A grouped application consisting of:
C.I.4: Update of sections 5.1 and 5.2 of the SmPC based on final results from study CS11 (SHINE) listed as a PAES in the Annex II. The Annex II and the RMP v12.1 are updated accordingly. SHINE is a phase III, open-label extension study for patients with Spinal Muscular Atrophy (SMA) who previously participated in investigational studies of ISIS 396443.
C.I.4: Update of section 5.1 of the SmPC based on interim results from study CS5 (NURTURE, 232SM201). NURTURE is a Phase II, open-label study to assess the efficacy, safety, tolerability, and pharmacokinetics of multiple doses of nusinersen delivered intrathecally to patients with genetically diagnosed and presymptomatic SMA.
C.I.4: Update of section 5.1 of the SmPC in order to relocate the updated information regarding immunogenicity from SmPC section 4.8 to section 5.1 as per applicable CHMP guidance. The data has been revised based on an updated integrated analysis across several studies.
C.I.4: Update of section 5.1 of the SmPC based on the outcome of a systematic literature review (SLR) and Natural History data from an International SMA registry (ISMAR)

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

5.3.36. Pegzilarginase - LOARGYS (CAP) - EMEA/H/C/005484/II/0002/G, Orphan

Applicant: Immedica Pharma AB

PRAC Rapporteur: Martin Huber

Scope: Grouped application comprising two type II variations as follows:
C.I.4 – Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study CAEB1102-300A (SOB 003), listed as a specific obligation in Annex II. Study 300A was a Phase 3, randomized, double blind, placebo-controlled study of the efficacy and safety of pegzilarginase in adults, adolescents and children with arginase 1 deficiency (ARG1 D).
C.I.4 – Update of section 4.8 of the SmPC in order to update efficacy and safety information based on final results from study CAEB1102-102A (SOB 004), listed as a specific obligation in Annex II.
Study 102A was an open label extension study to evaluate the long-term safety, tolerability,

and efficacy of pegzilarginase in adults, adolescents and children with arginase 1 deficiency (ARG1 D).
The Package Leaflet and Annex II are updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes

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

5.3.37. Respiratory syncytial virus vaccine (bivalent, recombinant) - ABRYSVO (CAP) - EMEA/H/C/006027/II/0007

Applicant: Pfizer Europe Ma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include active immunization of individuals 18 through 59 years of age for ABRYSVO, based on final results from C3671023 Substudy A; this is a Phase 3 double-blinded, randomised, placebo-controlled study of safety, tolerability and immunogenicity of Abrysvo in participants ≥18 to <60 years of age at high risk of severe RSV disease due to certain chronic medical conditions. 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 1.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, as part of the application the MAH is requesting a 1-year extension of the market protection

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

5.3.38. Rilpivirine - REKAMBYS (CAP) - EMEA/H/C/005060/II/0022

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include in combination with cabotegravir injection, the treatment of adolescents (at least 12 years of age and weighing at least 35 kg) for Rekambys, based on interim results from study 208580 (Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents). This is an ongoing Phase 1/Phase 2 multicenter, open-label, non-comparative study evaluating the safety, acceptability, tolerability, and PK of oral and LA injectable CAB and LA injectable RPV in virologically suppressed HIV-infected adolescents 12 to <18 years of age and weighing at least 35 kg who are receiving stable cART consisting of 2 or more drugs from 2 or more classes of ARV drugs.Consequently, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update a local representative in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4

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

5.3.39. Sarilumab - KEVZARA (CAP) - EMEA/H/C/004254/X/0043/G

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Monica Martinez Redondo

Scope: Extension application to add a new strength of 175 mg/ml solution for injection in vial, grouped with an Extension of indication to include treatment of active polyarticular-course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older for KEVZARA, based on results from study DRI13925; this is a multinational, multi-center, open-label, 2 phase, 3 portions study to describe the PK profile as well as safety and efficacy of sarilumab. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI

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

5.3.40. Somatrogon - NGENLA (CAP) - EMEA/H/C/005633/II/0016, Orphan

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include the long-term replacement of endogenous growth hormone of adults with growth hormone deficiency for Ngenla, based on supplemental results from study CP-4-005 and the Phase 2 supportive study CP-4-003. CP-4-005 is a Phase 3, multicenter study designed to evaluate the efficacy and safety of a Long Acting hGH Product (MOD-4023) in adult subjects with Growth Hormone Deficiency. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes

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

5.3.41. Tislelizumab - TEVIMBRA (CAP) - EMEA/H/C/005919/II/0003

Applicant: Beigene Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include in combination with platinum-based chemotherapy the first-line treatment of adult patients with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma (OSCC) for TEVIMBRA, based on results from study BGB-A317-306; this is a multi-regional, randomized, placebo-controlled, double-blind phase 3 study evaluating the efficacy and safety of tislelizumab in combination with chemotherapy compared to placebo in combination with chemotherapy as first-line treatment in patients with unresectable or locally advanced recurrent or metastatic OSCC. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI

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

5.3.42. Turoctocog alfa pegol - ESPEROCT (CAP) - EMEA/H/C/004883/II/0023

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include children below 12 years of age for treatment and prophylaxis of bleeding with haemophilia A for Esperoct, including previously untreated patients (PUPs) based on the final results from studies 3776, 4410, 3908, 3859, 3885, 3860, 4033 and 4595. As a consequence, section 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 3.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4

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

5.3.43. Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - AFLUNOV (CAP) - EMEA/H/C/002094/II/0086

Applicant: Seqirus S.r.l

PRAC Rapporteur: Amelia Cupelli

Scope: Extension of indication to include treatment of individuals 6 months of age and older for AFLUNOV, based on final results from study V87_30. This is a Phase 2, Randomized, Observer-Blind, Multicentre Study to Evaluate the Immunogenicity and Safety of Several Doses of Antigen and MF59 Adjuvant Content in a Monovalent H5N1 Pandemic Influenza Vaccine in Healthy Paediatric Subjects 6 Months to < 9 Years of Age.
As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 5.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (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

6. Periodic safety update reports (PSURs)

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

6.1.1. Albutrepenonacog alfa - IDELVION (CAP) - PSUSA/00010497/202401

Applicant: CSL Behring GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.2. Anifrolumab - SAPHNELO (CAP) - PSUSA/00010980/202401

Applicant: AstraZeneca AB

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.3. Apalutamide - ERLEADA (CAP) - PSUSA/00010745/202402

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.4. Asparaginase[3] - SPECTRILA (CAP) - PSUSA/00010445/202401

Applicant: medac Gesellschaft fur klinische Spezialpraparate mbH

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.5. Ataluren - TRANSLARNA (CAP) - PSUSA/00010274/202401

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.6. Avalglucosidase alfa - NEXVIADYME (CAP) - PSUSA/00011002/202402

Applicant: Sanofi B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.7. Avapritinib - AYVAKYT (CAP) - PSUSA/00010878/202401

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

[3] For centrally authorised products only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.8. Baricitinib - OLUMIANT (CAP) - PSUSA/00010578/202402

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.9. Besilesomab - SCINTIMUN (CAP) - PSUSA/00000385/202401

Applicant: CIS BIO International

PRAC Rapporteur: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.10. Birch bark extract[4] - FILSUVEZ (CAP) - PSUSA/00010446/202401

Applicant: Chiesi Farmaceutici S.p.A

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.11. Botulinum toxin type A[5] - NUCEIVA (CAP) - PSUSA/00010796/202401

Applicant: Evolus Pharma B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.12. Brexucabtagene autoleucel - TECARTUS (CAP) - PSUSA/00010903/202401

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

[4] For centrally authorised products only
[5] For centrally authorised products only

6.1.13. Brivaracetam - BRIVIACT (CAP) - PSUSA/00010447/202401

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.14. Bulevirtide - HEPCLUDEX (CAP) - PSUSA/00010873/202401

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.15. Ceftolozane, tazobactam - ZERBAXA (CAP) - PSUSA/00010411/202312

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.16. Clofarabine - EVOLTRA (CAP) - PSUSA/00000805/202312

Applicant: Sanofi B.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.17. Dapagliflozin, metformin - EBYMECT (CAP); XIGDUO (CAP) - PSUSA/00010294/202401

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.18. Dapivirine - DAPIVIRINE VAGINAL RING 25 MG (Art 58[6]) - EMEA/H/W/002168/PSUV/0026

Applicant: International Partnership for Microbicides Belgium AISBL

PRAC Rapporteur: Jan Neuhauser;

Scope: Evaluation of a PSUR procedure

Action: For adoption of recommendation to CHMP

6.1.19. Daridorexant - QUVIVIQ (CAP) - PSUSA/00010993/202401

Applicant: Idorsia Pharmaceuticals Deutschland GmbH

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. Darolutamide - NUBEQA (CAP) - PSUSA/00010843/202401

Applicant: Bayer AG

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.21. Darunavir - PREZISTA (CAP) - PSUSA/00000934/202312

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.22. Decitabine, cedazuridine - INAQOVI (CAP) - PSUSA/00000118/202401

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

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

6.1.23. Defatted powder of arachis hypogaea l., semen (peanuts) - PALFORZIA (CAP) - PSUSA/00010902/202401

Applicant: Aimmune Therapeutics Ireland Limited

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.24. Elranatamab - ELREXFIO (CAP) - PSUSA/00000225/202402

Applicant: Pfizer Europe Ma EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.25. Epoetin zeta - RETACRIT (CAP); SILAPO (CAP) - PSUSA/00001241/202312

Applicants: Pfizer Europe MA EEIG (Retacrit), STADA Arzneimittel AG (Silapo), various

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.26. Ertugliflozin - STEGLATRO (CAP); ertugliflozin, metformin hydrochloride - SEGLUROMET (CAP); ertugliflozin, sitagliptin - STEGLUJAN (CAP); - PSUSA/00010784/202312

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.27. Evinacumab - EVKEEZA (CAP) - PSUSA/00010945/202402

Applicant: Ultragenyx Germany GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.28. Faricimab - VABYSMO (CAP) - PSUSA/00011016/202401

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.29. Fedratinib - INREBIC (CAP) - PSUSA/00010909/202402

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.30. Fostemsavir - RUKOBIA (CAP) - PSUSA/00010911/202402

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.31. Gefapixant - LYFNUA (CAP) - PSUSA/00000132/202401

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.32. Glucarpidase - VORAXAZE (CAP) - PSUSA/00010968/202401

Applicant: SERB S.A.S.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.33. Liraglutide - SAXENDA (CAP); VICTOZA (CAP) - PSUSA/00001892/202312

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. Lisocabtagene maraleucel- BREYANZI (CAP) - PSUSA/00010990/202402

Applicant: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.35. Melphalan flufenamide - PEPAXTI (CAP) - PSUSA/00011013/202402

Applicant: Oncopeptides AB

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.36. Meningococcal group-B vaccine (rDNA[7], component, adsorbed) - BEXSERO (CAP) - PSUSA/00010043/202401

Applicant: GSK Vaccines S.r.l

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.37. Mercaptamine[8] - CYSTADROPS (CAP) - PSUSA/00010574/202401

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.38. Metreleptin - MYALEPTA (CAP) - PSUSA/00010700/202401

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. Odevixibat - BYLVAY (CAP) - PSUSA/00010949/202401

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

[7] Recombinant deoxyribonucleic acid
[8] Indicated for the treatment of corneal cystine crystal deposit only

Action: For adoption of recommendation to CHMP

6.1.40. Osilodrostat - ISTURISA (CAP) - PSUSA/00010820/202401

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. Pirtobrutinib - JAYPIRCA (CAP) - PSUSA/00000155/202401

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.42. Pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) - VAXNEUVANCE (CAP) - PSUSA/00010975/202401

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.43. Quadrivalent influenza vaccine (recombinant, prepared in cell culture) - SUPEMTEK (CAP) - PSUSA/00010886/202401

Applicant: Sanofi Pasteur

PRAC Rapporteur: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Ranolazine - RANEXA (CAP) - PSUSA/00002611/202401

Applicant: Menarini International Operations Luxembourg S.A.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Regdanvimab - REGKIRONA (CAP) - PSUSA/00010964/202402

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Relugolix - ORGOVYX (CAP) - PSUSA/00010994/202401

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Remimazolam - BYFAVO (CAP) - PSUSA/00010924/202401

Applicant: Paion Pharma GmbH

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. Risdiplam - EVRYSDI (CAP) - PSUSA/00010925/202402

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.49. Roflumilast - DAXAS (CAP) - PSUSA/00002658/202401

Applicant: AstraZeneca AB

PRAC Rapporteur: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.50. Romosozumab - EVENITY (CAP) - PSUSA/00010824/202401

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.51. Salmeterol, fluticasone propionate[9] - BROPAIR SPIROMAX (CAP); SEFFALAIR SPIROMAX (CAP) - PSUSA/00010928/202401

Applicant: Teva B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.52. Secukinumab - COSENTYX (CAP) - PSUSA/00010341/202312

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.53. Selexipag - UPTRAVI (CAP) - PSUSA/00010503/202312

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.54. Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara) - IMVANEX (CAP) - PSUSA/00010119/202401

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.55. Sutimlimab - ENJAYMO (CAP) - PSUSA/00011023/202402

Applicant: Sanofi B.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[9] For centrally authorised products only

6.1.56. Tafasitamab - MINJUVI (CAP) - PSUSA/00010951/202401

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.57. Talquetamab - TALVEY (CAP) - PSUSA/00000099/202402

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.58. Tebentafusp - KIMMTRAK (CAP) - PSUSA/00010991/202401

Applicant: Immunocore Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.59. Tecovirimat - TECOVIRIMAT SIGA (CAP) - PSUSA/00010971/202401

Applicant: SIGA Technologies Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.60. Tezacaftor, ivacaftor - SYMKEVI (CAP) - PSUSA/00010730/202402

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.61. Ticagrelor - BRILIQUE (CAP) - PSUSA/00002948/202312

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.62. Upadacitinib - RINVOQ (CAP) - PSUSA/00010823/202402

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.63. Vericiguat - VERQUVO (CAP) - PSUSA/00010950/202401

Applicant: Bayer AG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.64. Voclosporin - LUPKYNIS (CAP) - PSUSA/00011020/202401

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.65. Voxelotor - OXBRYTA (CAP) - PSUSA/00010983/202402

Applicant: Pfizer Europe Ma EEIG

PRAC Rapporteur: Jo Robays

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. Estradiol, nomegestrol acetate - ZOELY (CAP); NAP - PSUSA/00002182/202401

Applicants: Theramex Ireland Limited (Zoely), various

PRAC Rapporteur: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.2. Lutetium (^{177}Lu) chloride - ENDOLUCINBETA (CAP); LUMARK (CAP); LUTETIUM (^{177}LU) CHLORIDE BILLEV (CAP); NAP - PSUSA/00010391/202312

Applicants: Billev Pharma ApS (Lutetium (177Lu) chloride Billev), I.D.B. Holland B.V. (Lumark), ITM Medical Isotopes GmbH (EndolucinBeta), various

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.3. Rasagiline - AZILECT (CAP); RASAGILINE RATIOPHARM (CAP); NAP - PSUSA/00002612/202401

Applicants: Teva B.V. (Azilect, Rasagiline ratiopharm), various

PRAC Rapporteur: Ana Sofia Diniz Martins

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. 5 fluorouracil[10] (NAP) - PSUSA/00000007/202312

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.2. Alitretinoin[11] (NAP) - PSUSA/00010710/202401

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Allopurinol (NAP) - PSUSA/00000095/202312

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

[10] Intravenous use only
[11] Oral use only

Action: For adoption of recommendation to CMDh

6.3.4. Altizide, spironolactone (NAP) - PSUSA/00002781/202401

Applicant(s): various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. Amantadine (NAP) - PSUSA/00000126/202401

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.6. Amiodarone (NAP) - PSUSA/00000166/202312

Applicant(s): various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.7. Amitriptyline, perphenazine (NAP) - PSUSA/00000170/202401

Applicant(s): various

PRAC Lead: Georgia Gkegka

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. Amitriptyline (NAP), amitriptyline, amitriptylinoxide (NAP), amitriptylinoxide (NAP) - PSUSA/00010374/202401

Applicant(s): various

PRAC Lead: Georgia Gkegka

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.9. Amlodipine, losartan (NAP) - PSUSA/00010512/202401

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. Azelastine (NAP) - PSUSA/00000277/202312

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. Balsalazide (NAP) - PSUSA/00009074/202401

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. Bendroflumethiazide (NAP); bendroflumethiazide, potassium chloride (NAP) - PSUSA/00010583/202401

Applicant(s): various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. Betahistine (NAP) - PSUSA/00000389/202312

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.14. Caffeine, drotaverine hydrochloride, metamizole sodium (NAP) - PSUSA/00001996/202401

Applicant(s): various

PRAC Lead: Anna Mareková

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.15. Celecoxib (NAP) - PSUSA/00000616/202312

Applicant(s): various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.16. Cyproheptadine (NAP) - PSUSA/00000902/202312

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.17. Dapoxetine (NAP) - PSUSA/00000928/202312

Applicant(s): various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.18. Desmopressin (NAP) - PSUSA/00000964/202312

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.19. Dexpanthenol (NAP) - PSUSA/00000999/202401

Applicant(s): various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.20. Doxazosin (NAP) - PSUSA/00001169/202312

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.21. Ferric carboxymaltose[12] (NAP) - PSUSA/00010865/202401

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.22. Ferric derisomaltose[13] (NAP) - PSUSA/00010866/202401

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.23. Hepatitis A vaccines (inactivated, adsorbed) (NAP) - PSUSA/00001596/202401

Applicant(s): various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.24. Hydrochlorothiazide, spironolactone (NAP) - PSUSA/00001662/202401

Applicant(s): various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.25. Iron dextran (NAP) - PSUSA/00010696/202401

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

[12] Parenteral use only
[13] Parenteral use only

6.3.26. Iron sucrose[14] (NAP) - PSUSA/00010864/202401

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.27. Levodropropizine (NAP) - PSUSA/00001853/202401

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.28. Levonorgestrel, ethinylestradiol (NAP); ethinylestradiol[15] (NAP) - PSUSA/00010442/202401

Applicant(s): various

PRAC Lead: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.29. Liothyronine (NAP) - PSUSA/00001890/202401

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.30. Lormetazepam (NAP) - PSUSA/00001910/202312

Applicant(s): various

PRAC Lead: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.31. Macrogol 3350 combinations[16] (NAP) - PSUSA/00010705/202401

Applicant(s): various

[14] Parenteral use only
[15] Combination pack
[16] Oral use only

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.32. Omega-3-acid ethyl esters (NAP) - PSUSA/00010312/202401

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.33. Pentoxyverine (NAP) - PSUSA/00002345/202312

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.34. Povidone iodinated (NAP) - PSUSA/00002487/202401

Applicant(s): various

PRAC Lead: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.35. Protirelin (NAP) - PSUSA/00009273/202401

Applicant(s): various

PRAC Lead: Jana Lukačišinová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.36. Pseudoephedrine, triprolidine (NAP) - PSUSA/00003047/202312

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.37. Rupatadine (NAP) - PSUSA/00002673/202312

Applicant(s): various

PRAC Lead: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.38. Sodium iron gluconate[17] (NAP) - PSUSA/00010867/202401

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.39. Tobramycin[18] [19] (NAP) - PSUSA/00009316/202312

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.40. Valproic acid; sodium valproate (NAP), valproate pivoxil (NAP), valproate semisodium (NAP), valpriomide (NAP), valproate bismuth (NAP), calcium valproate (NAP), valproate magnesium (NAP) - PSUSA/00003090/202401

Applicant(s): various

PRAC Lead: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.41. Zofenopril (NAP) - PSUSA/00003147/202401

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

[17] Parenteral use only
[18] Nebuliser solution only
[19] Non-centrally authorised product(s) only

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Burosumab - CRYSVITA (CAP) - EMEA/H/C/004275/LEG 008.1

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: MAH's responses to LEG 008 [Safety Review on Craniosynostosis cases] as adopted in March 2024

Action: For adoption of advice to CHMP

6.4.2. Dolutegravir - TIVICAY (CAP) - EMEA/H/C/002753/LEG 015.5

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: From EMEA/H/C/PSUSA/00010075/202101:
Third Annual RESPOND Study Report (from 2023)
In view of the new data regarding diabetes mellitus and the use of INSTIs as well as new data on virologic outcomes and LeXTO, the MAH should discuss these issues as soon as corresponding publications are available(no later than 30 days after the receipt of these data).
Upcoming annual RESPOND study reports should be submitted no later than two months after they are available. Upcoming submissions should also include a discussion of the different results by the MAH

Action: For adoption of advice to CHMP

6.4.3. Dolutegravir, abacavir, lamivudine - TRIUMEQ (CAP) - EMEA/H/C/002754/LEG 010.5

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: From EMEA/H/C/PSUSA/00010075/202101:
Third Annual RESPOND Study Report (from 2023)
In view of the new data regarding diabetes mellitus and the use of INSTIs as well as new data on virologic outcomes and LeXTO, the MAH should discuss these issues as soon as corresponding publications are available(no later than 30 days after the receipt of these data).
Upcoming annual RESPOND study reports should be submitted no later than two months after they are available. Upcoming submissions should also include a discussion of the different results by the MAH

Action: For adoption of advice to CHMP

6.4.4. Dolutegravir, lamivudine - DOVATO (CAP) - EMEA/H/C/004909/LEG 005.5

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: David Olsen

Scope: From EMEA/H/C/PSUSA/00010075/202101:
Third Annual RESPOND Study Report (from 2023)
In view of the new data regarding diabetes mellitus and the use of INSTIs as well as new data on virologic outcomes and LeXTO, the MAH should discuss these issues as soon as corresponding publications are available(no later than 30 days after the receipt of these data).
Upcoming annual RESPOND study reports should be submitted no later than two months after they are available. Upcoming submissions should also include a discussion of the different results by the MAH

Action: For adoption of advice to CHMP

6.4.5. Fluciclovine (^{18}F) - AXUMIN (CAP) - EMEA/H/C/004197/LEG 002

Applicant: Blue Earth Diagnostics Ireland Limited

PRAC Rapporteur: Rugile Pilviniene

Scope: From EMEA/H/C/PSUSA/00010594/202305:
A Cumulative Safety Review of case reports of PET imaging interpretation errors with a focus on false positive and false negative results, as well as a discussion of related literature and further evidence available. Implementation of the self-training programme in the EU member states

Action: For adoption of advice to CHMP

6.4.6. Nirsevimab - BEYFORTUS (CAP) - EMEA/H/C/005304/LEG 007

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: From PSUSA /00011026/202310:
The MAH is requested, in view of the available data regarding hypotonic-hyporesponsive episode (HHE) and apnoea case reports, either to submit a variation in accordance with Articles 16 and 17 of Regulation (EC) No 726/2004 or provide a justification for not doing so. The MAH should discuss the need for updating the product information and/or RMP. This should be provided without any delay and no later than 16th June 2024

Action: For adoption of advice to CHMP

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Efavirenz, emtricitabine, tenofovir disoproxil - EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL MYLAN (CAP) - EMA/VR/0000179367

Applicant: Mylan Pharmaceuticals Limited

PRAC Lead: Martin Huber

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning

on Bone effects and to add 'bone mineral density decreased' to the list of adverse drug reactions (ADRs) with frequency common, based on the PRAC conclusions from the PSUSA for Emtricitabine/Tenofovir disoproxil (PSUSA/1210/202304). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet

Action: For adoption of PRAC Assessment Report

6.5.2. Fenfluramine - FINTEPLA (CAP) - EMEA/H/C/003933/II/0025, Orphan

Applicant: UCB Pharma SA

PRAC Rapporteur: Martin Huber

Scope: Update of section 4.8 of the SmPC in order to propose a combined Adverse Drug Reaction table for Dravet Syndrome and Lennox-Gastaut syndrome following PSUSA procedure EMEA/H/C/PSUSA/00010907/202306. The package leaflet is updated accordingly

Action: For adoption of PRAC Assessment Report

6.5.3. Ivacaftor, tezacaftor, elexacaftor - KAFTRIO (CAP) - EMEA/H/C/005269/II/0052/G, Orphan

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Martin Huber

Scope: Grouped application comprising two type II variations as follows:
Type II (C.I.3.b) – Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on rash and to add hypersensitivity to the list of adverse drug reactions (ADRs) with frequency "not known" following the outcome of procedure PSUSA/00010868/202310. The Package Leaflet is updated accordingly.
Type II (C.I.z) – Submission of post-marketing breast-feeding case reports

Action: For adoption of PRAC Assessment Report

6.5.4. Meningococcal group A, C, W135 and Y conjugate vaccine - NIMENRIX (CAP) - EMEA/H/C/002226/II/0137

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: David Olsen

Scope: Update of section 4.8 of the SmPC in order to add 'hypersensitivity' to the list of adverse drug reactions (ADRs) with frequency uncommon, following PRAC's recommendation for procedure EMEA/H/002226/PAM/LEG/058.

Action: For adoption of PRAC Assessment Report

6.5.5. Naltrexone hydrochloride, bupropion hydrochloride - MYSIMBA (CAP) - EMEA/H/C/003687/II/0063

Applicant: Orexigen Therapeutics Ireland Limited

Re-examination PRAC Rapporteur: To be appointed

Scope: Request for re-examination of variation II/63 concluded with negative PRAC recommendation in July 2024

Action: For appointment of re-examination of PRAC Rapporteur

6.6. Expedited summary safety reviews[20]

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[21]

7.1.1. Ketoconazole - KETOCONAZOLE HRA (CAP) - EMEA/H/C/PSA/S/0109.2

Applicant: HRA Pharma Rare Diseases

PRAC Rapporteur: Petar Mas

Scope: Substantial amendment to a 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 [MAH's response to PSA/S/0109.1]

Action: For adoption of recommendation to CHMP

7.1.2. Pegzilarginase - LOARGYS (CAP) - EMEA/H/C/PSP/S/0105.1

Applicant: Immedica Pharma AB

PRAC Rapporteur: Martin Huber

Scope: MAH's response to PSP/0105 [A European, non-interventional, multicentre, registry-based post-authorisation safety study to evaluate the long-term safety of Loargys treatment in arginase 1 deficiency patients in standard clinical care] as per the request to supplementary information (RSI) adopted in May 2024

Action: For adoption of recommendation to CHMP

7.1.3. Tabelecleucel - EBVALLO (CAP) - EMEA/H/C/PSA/S/0115

Applicant: Pierre Fabre Medicament, ATMP

PRAC Rapporteur: Amelia Cupelli

Scope: Substantial amendment to an observational, Post-Authorisation Safety Study (PASS)

[20] 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

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

to describe the safety and effectiveness of tabelecleucel in patients with Epstein-Barr Virus positive (EBV+) Post-Transplant Lymphoproliferative Disease (PTLD) in a real-world setting in Europe

Action: For adoption of recommendation to CAT and CHMP

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[22]

7.2.1. Anifrolumab - SAPHNELO (CAP) - EMEA/H/C/004975/MEA 001.3

Applicant: AstraZeneca AB

PRAC Rapporteur: Liana Martirosyan

Scope: ***REVISED PROTOCOL v. 4 / Study D3461R00028****
Ttile: A non-interventional multi-database post-authorisation study to assess pregnancy-related safety data from women with Systemic Lupus Erythematosus exposed to anifrolumab

Action: For adoption of advice to CHMP

7.2.2. Atogepant - AQUIPTA (CAP) - EMEA/H/C/005871/MEA 002.1

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: ***Revised Protocol*** /Study no.: P24433
Title: Post-authorisation safety study to evaluate the utilisation and safety of atogepant in patients with migraine and significant cardiovascular or cerebrovascular disease in Europe

Action: For adoption of advice to CHMP

7.2.3. Deucravacitinib - SOTYKTU (CAP) - EMEA/H/C/005755/MEA 001.2

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: MAH's responses to MEA 001.1 [revised protocol no PASS IM011194] as adopted in April 2024.
Long-term, observational cohort study of adults with plaque psoriasis, who are new users of deucravacitinib, non-TNFi (tumor necrosis factor inhibitor) biologics, TNFi biologics, or non-biologic systemic therapy in the real-world clinical setting (IM011194). To evaluate the long-term safety of deucravacitinib in patients with psoriasis in the real-world setting

Action: For adoption of advice to CHMP

7.2.4. Diroximel fumarate - VUMERITY (CAP) - EMEA/H/C/005437/MEA 001.3

Applicant: Biogen Netherlands B.V.

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

PRAC Rapporteur: Martin Huber

Scope: ***Updated Protocol Version 6 / Study 272MS401***
A prospective observational pregnancy exposure registry to characterise how DRF may affect pregnancy and infant outcomes

Action: For adoption of advice to CHMP

7.2.5. Dulaglutide - TRULICITY (CAP) - EMEA/H/C/002825/MEA 006.6

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: ***REVISED PROTOCOL / H9X-MC-B013***
Title: Dulaglutide and Potential Risks of Pancreatic Cancer and Thyroid Cancer: A Non-Interventional PASS

Action: For adoption of advice to CHMP

7.2.6. Eptinezumab - VYEPTI (CAP) - EMEA/H/C/005287/MEA 004.5

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Liana Martirosyan

Scope: MAH's response to MEA 004.4 [REVISED PROTOCOL / PASS No. 19756N] as adopted in March 2024.
Title: Long-term cardiovascular safety and real-world use of eptinezumab - An observational, historical cohort study of patients initiating eptinezumab in routine clinical practice.
Regarding the alternative proxy as proposed by MAH to identify severe migraine patients for the subgroup analyses, there are some remaining issues:
a. The MAH is requested to discuss the validity of this proxy to define the severity of migraine and to describe any potential limitations with this regard in the protocol.
b. The MAH should specify per database which acute pain medications are used in migraine treatment and these should be used in the proxy, since this could differ per region

Action: For adoption of advice to CHMP

7.2.7. Etrasimod - VELSIPITY (CAP) - EMEA/H/C/006007/MEA 001

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Mari Thorn

Scope: From Initial MAA:
PASS Protocol / Study C5041046
Title: An Active Surveillance, Post-Authorization Safety Study to Characterize the Safety of Etrasimod in Patients with Ulcerative Colitis Using Real-World Data in the European Union (C5041046)

Action: For adoption of advice to CHMP

7.2.8. Hydroxycarbamide - XROMI (CAP) - EMEA/H/C/004837/MEA 006

Applicant: Nova Laboratories Ireland Limited

PRAC Rapporteur: Jo Robays

Scope: ***Protocol v1.0 / Study NOVDD-001***
Title: A comparative observational study to evaluate the safety and effectiveness of Xromi (hydroxycarbamide oral solution 100mg/ml) for the prevention of vaso-occlusive complications of sickle cell disease in children under 2 years of age

Action: For adoption of advice to CHMP

7.2.9. Lebrikizumab - EBGLYSS (CAP) - EMEA/H/C/005894/MEA 001

Applicant: Almirall, S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: From Initial MAA:
Protocol of study J2T-MC-B003
Title: Observational Database Study of Pregnancy and Infant Outcomes among Women Exposed to Lebrikizumab During Pregnancy

Action: For adoption of advice to CHMP

7.2.10. Mogamulizumab - POTELIGEO (CAP) - EMEA/H/C/004232/MEA 001.5

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: MAH's response to MEA 001.4 [REVISED PROTOCOL 0.3 FOR PASS EUPAS31436] as adopted in March 2024
To Characterise the Safety of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) in Patients with Cutaneous T-Cell Lymphoma (CTCL) treated with Mogamulizumab

Action: For adoption of advice to CHMP

7.2.11. Neratinib - NERLYNX (CAP) - EMEA/H/C/004030/MEA 003.4

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Bianca Mulder

Scope: Revised protocol + MAH's responses to MEA 003.3 [***Amended Protocol /Study PUMA-NER-7402*** (version 4.0)] RSI as adopted in May 2024.
Title: Multicentre, multi-country, prospective, observational, post authorisation safety study to describe the incidence of discontinuation due to diarrhoea within the first 3 months of a treatment with neratinib, in adult breast cancer patients treated in extended adjuvant in a real world setting: the NERLYFE study

Action: For adoption of advice to CHMP

7.2.12. Niraparib, Abiraterone acetate - AKEEGA (CAP) - EMEA/H/C/005932/MEA 001.3

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jan Neuhauser

Scope: ***Revised PASS Protocol (ver. 3)/ Study no.: PCSONCA0485***
Study title: Post authorization safety study to characterize 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

7.2.13. Zilucoplan - ZILBRYSQ (CAP) - EMEA/H/C/005450/MEA 001

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Karin Erneholm

Scope: From initial MAA
DRAFT PROTOCOL / PASS MG0026 (NI/NI, RMP)
A Multi-National Cohort Study to Assess the Implementation of the Risk Minimization Measures to Prevent Meningococcal Infection in Patients with
Generalized Myasthenia Gravis Initiating Zilucoplan, and Zilucoplan Safety in Real-World Settings

Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)[23]

7.3.1. Lenalidomide - REVLIMID (CAP) - EMEA/H/C/PSR/S/0049

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Final study report for a post-authorisation, non-interventional, retrospective, drug-utilisation study to describe the pattern of use of lenalidomide in patients with myelodysplastic syndromes (MDS)

Action: For adoption of recommendation to CHMP

7.3.2. Umeclidinium bromide, vilanterol - ANORO ELLIPTA (CAP); LAVENTAIR ELLIPTA (CAP); INCRUSE ELLIPTA (CAP); ROLUFTA ELLIPTA (CAP) - EMEA/H/C/PSR/S/0048

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Final study report for a post-authorisation safety observational cohort study to quantify the incidence and comparative safety of selected cardiovascular and cerebrovascular events in chronic obstructive pulmonary disease (COPD) patients using

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

inhaled umeclidinium/vilanterol (UMEC/VI) combination, or inhaled UMEC versus tiotropium

Action: For adoption of recommendation to CHMP

7.4. Results of PASS non-imposed in the marketing authorisation(s)[24]

7.4.1. Baricitinib - OLUMIANT (CAP) - EMEA/H/C/004085/II/0047

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Submission of the final report from non-interventional Study I4V-MC-B012 listed as a category 3 study in the RMP. This is a post-marketing safety surveillance of baricitinib in three European registries. The RMP version 23.1 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.2. Canagliflozin - INVOKANA (CAP) - EMEA/H/C/002649/WS2719/0068; Canagliflozin, metformin - VOKANAMET (CAP) - EMEA/H/C/002656/WS2719/0075

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of the final report from study PCSCVM003617, listed as a category 3 study in the RMP. This is a Real-World Database Study of Canagliflozin Utilization in Type 1 Diabetes Patients Over Time among European Countries. The RMP version 12.1 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.3. Dengue tetravalent vaccine (live, attenuated) - DENGVAXIA (CAP) - EMEA/H/C/004171/II/0031

Applicant: Sanofi Pasteur

PRAC Rapporteur: Sonja Hrabcik

Scope: Submission of final study report of DNG15, listed in the RMP as category 3. DNG15 was a prospective, multinational, non-interventional, observational study aiming to assess the risk of AEs associated with CYD dengue vaccine in the real-world immunization setting

Action: For adoption of PRAC Assessment Report

7.4.4. Dimethyl fumarate - TECFIDERA (CAP) - EMEA/H/C/002601/WS2587/0085; Diroximel fumarate - VUMERITY (CAP) - EMEA/H/C/005437/WS2587/0015

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Submission of the final report from study 109MS401, a multicenter, global,

[24] 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

observational study to collect information on safety and to document the drug utilization of Tecfidera (Dimethyl Fumarate) when used in routine medical practice in the treatment of Multiple Sclerosis (ESTEEM), listed as a category 3 study in the RMP (MEA007.6). The RMPs version 16.1 for Tecfidera and version 2.1 for Vumerity, have also been submitted

Action: For adoption of PRAC Assessment Report

7.4.5. Empagliflozin - JARDIANCE (CAP) - EMEA/H/C/002677/WS2713/0089; Empagliflozin, linagliptin - GLYXAMBI (CAP) - EMEA/H/C/003833/WS2713/0062; Empagliflozin, metformin - SYNJARDY (CAP) - EMEA/H/C/003770/WS2713/0080

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the final report from study 1245-0097. This is a post-authorisation safety study (PASS) to assess the risk of urinary tract malignancies in relation to empagliflozin exposure in patients with type 2 diabetes: a multi-database European study. The RMP versions 23.0, 17.0 and 11.0 are also submitted for Jardiance, Synjardy and Glyxambi, respectively

Action: For adoption of PRAC Assessment Report

7.4.6. Influenza quadrivalent vaccine (rDNA) - SUPEMTEK (CAP) - EMEA/H/C/005159/II/0020

Applicant: Sanofi Pasteur

PRAC Rapporteur: Nathalie Gault

Scope: Update of section 4.6 of the SmPC in order to update pregnancy information based on final results from study VAP00007 (non-interventional PASS); this is a Phase IV, observational retrospective post-authorization, descriptive, safety surveillance study to evaluate the safety of RIV4 in pregnant women and their offspring exposed during pregnancy or up to 28 days preceding the estimated date of conception with regards to pregnancy, birth, and neonatal/infant outcomes

Action: For adoption of PRAC Assessment Report

7.4.7. Inotuzumab ozogamicin - BESPONSA (CAP) - EMEA/H/C/004119/II/0028, Orphan

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of the final report from study B1931028; this is a non-interventional post-authorization safety study (PASS) of inotuzumab ozogamicin to characterize complications post-hematopoietic stem cell transplantation (HSCT) following inotuzumab ozogamicin treatment in adult and pediatric patients with B-cell precursor acute lymphoblastic leukemia (ALL). The RMP version 3.0 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.8. Piperaquine tetraphosphate, Artenimol - 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

7.4.9. Pregabalin - LYRICA (CAP) - EMEA/H/C/000546/WS2708/0136; Pregabalin - PREGABALIN PFIZER (CAP) - EMEA/H/C/003880/WS2708/0057

Applicant: Upjohn EESV

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final report from study A0081096 listed as a category 3 study in the RMP. This is a prospective randomized 12-week controlled study of visual field change in subjects with partial seizures receiving pregabalin or placebo

Action: For adoption of PRAC Assessment Report

7.4.10. Tacrolimus - ADVAGRAF (CAP) - EMEA/H/C/000712/WS2519/0071/G; Tacrolimus - MODIGRAF (CAP) - EMEA/H/C/000954/WS2519/0046/G

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eamon O'Murchu

Scope: A grouped application consisting of:

Type II (C.I.13): Submission of the final report from study F506-PV-0001 listed as a category 3 study in the RMP for Advagraf and Modigraf. This is a non-interventional post-authorization safety study (NI-PASS) of outcomes associated with the use of tacrolimus around conception, or during pregnancy or lactation using data from Transplant Pregnancy Registry International (TPRI). The RMP version 5.0 has also been submitted.

Type IB (C.I.11.z): To include the feasibility assessment of using alternative secondary-use data sources to replicate the Transplant Pregnancy Registry International (TPRI) study as a category 3 additional pharmacovigilance activity in the RMP, including the milestones for the progress report and the final report of the feasibility assessment, related to EMEA/H/C/000712/MEA/032 and EMEA/H/C/000954/MEA/024

Action: For adoption of PRAC Assessment Report

7.4.11. 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 post-authorization safety study (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

7.4.12. Zanamivir - DECTOVA (CAP) - EMEA/H/C/004102/II/0020

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Mari Thorn

Scope: Submission of the final report from study 208140 listed as a category 3 PASS in the RMP. This is an observational study of the safety of zanamivir 10 mg/ml solution for infusion exposure in pregnant women with complicated influenza and their offspring. The RMP version 8.0 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. Aflibercept - EYLEA (CAP) - EMEA/H/C/002392/MEA 022.1

Applicant: Bayer AG

PRAC Rapporteur: Nathalie Gault

Scope: ***3rd Interim Study Report***
FIREFLEYE NEXT Study # 20275 (non-imposed/interventional/RMP)
An extension study to evaluate the long-term outcomes of subjects who received teatment for retinopathy of prematurity in Study 20090

Action: For adoption of advice to CHMP

7.5.2. Apremilast - OTEZLA (CAP) - EMEA/H/C/003746/MEA 008.6

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Monica Martinez Redondo

Scope: ***5 Year Study Report / Study BSRBR-PsA (CC-10004-PSA-012)***
Title: British Society for Rheumatology Psoriatic Arthritis Register (BSR - PsA)

Action: For adoption of advice to CHMP

7.5.3. Apremilast - OTEZLA (CAP) - EMEA/H/C/003746/MEA 008.5

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Monica Martinez Redondo

Scope: MAH's response to MEA 008.4 [4th interim report of the Apremilast PsA Registry in the UK - BSRBR-PsA] RSI as adopted in April 2024.
1. The MAH is requested to provide, the reason for which most patients receiving apremilast in UK for PsA are illegible for the inclusion in the study and if it is related to the inclusion criteria (CASPAR score), the calculation of this score in the patients included and not included in the study should be presented

Action: For adoption of advice to CHMP

7.5.4. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - STRIMVELIS (CAP) - EMEA/H/C/003854/ANX 004.5

Applicant: Fondazione Telethon ETS, ATMP

PRAC Rapporteur: Liana Martirosyan

Scope: MAH Response to ANX 004.4 [Patient Registry / STRIM-0003] as adopted in June 2023:
Based on the PRAC Rapporteur review of the PASS interim study report, dated 21 March 2023, the PRAC considers that the risk-benefit balance of medicinal products containing the active substance Strimvelis concerned by the PASS interim report is subject to a request for supplementary information detailed in Section 12 in the Annex, before a recommendation can be made. The responses timetable to the Request for Supplementary Information will be 60 days

Action: For adoption of advice to CAT and CHMP

7.5.5. Beclometasone, formoterol, glycopyrronium bromide - RIARIFY (CAP) - EMEA/H/C/004836/MEA 002.1

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: ***1st interim report / CLI-05993BA1-05 (TRIBE)***
Multinational database cohort study to assess adverse cardiovascular and cerebrovascular outcomes in patients with chronic obstructive pulmonary disease initiating a fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via dry powder inhaler (DPI) compared to pressurized metered dose inhaler (pMDI)

Action: For adoption of advice to CHMP

7.5.6. Beclometasone, formoterol, glycopyrronium bromide - TRIMBOW (CAP) - EMEA/H/C/004257/MEA 002.5

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: ***1st interim report / CLI-05993BA1-05 (TRIBE)***
Multinational database cohort study to assess adverse cardiovascular and cerebrovascular outcomes in patients with chronic obstructive pulmonary disease initiating a fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via dry powder inhaler (DPI) compared to pressurized metered dose inhaler (pMDI)

Action: For adoption of advice to CHMP

7.5.7. Beclometasone, formoterol, glycopyrronium bromide - TRYDONIS (CAP) - EMEA/H/C/004702/MEA 002.1

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

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

Action: For adoption of advice to CHMP

7.5.8. Brexucabtagene autoleucel - TECARTUS (CAP) - EMEA/H/C/005102/ANX 002.4

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Bianca Mulder

Scope: ***First Annual Interim Safety Report of Study KTE-EU-472-6036***
Title: Long-term, non-interventional study of recipients of Tecartus (brexucabtagene autoleucel) for treatment of adult patients with relapsed or refractory Mantle Cell Lymphoma (MCL)

Action: For adoption of advice to CAT and CHMP

7.5.9. Brodalumab - KYNTHEUM (CAP) - EMEA/H/C/003959/MEA 002.8

Applicant: LEO Pharma A/S

PRAC Rapporteur: Monica Martinez Redondo

Scope: **INTERIM STUDY REPORT / Study NIS-KYNTHEUM-1345 - On suicidal behaviour, serious infections, MACE and malignancy**
Title: The BRodalumab Assessment of Hazards: A Multinational Safety (BRAHMS) study in electronic healthcare databases

Action: For adoption of advice to CHMP

7.5.10. Covid-19 Vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - EMEA/H/C/005808/MEA 004.7

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: From Initial MAA:
Study 2019nCoV-402:
UK Post-Authorisation Safety Study Using the Clinical Practice Research Datalink (CPRD): A surveillance study to characterise the safety profile of Nuvaxovid in adults aged 18 years and older in the real-world setting using the UK CPRD
Second Interim report, study no. 2019nCoV-402

Action: For adoption of advice to CHMP

7.5.11. Covid-19 Vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - EMEA/H/C/005808/MEA 005.3

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: From Initial MAA:
Second Interim Report, 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

7.5.12. Dimethyl fumarate - SKILARENCE (CAP) - EMEA/H/C/002157/MEA 001.8

Applicant: Almirall S.A

PRAC Rapporteur: Mari Thorn

Scope: ***Sixth Annual Interim Results*** for a non-imposed (category 3) PASS. Study no.: M-41008-40
Study Title: An Observational Post-Authorisation Safety Study of Skilarence in European Psoriasis Registers

Action: For adoption of advice to CHMP

7.5.13. Drospirenone, estetrol - DROVELIS (CAP) - EMEA/H/C/005336/MEA 001.4

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Martin Huber

Scope: ***1st Interim Study Report / Study INAS-NEES***
Title: International Active Surveillance Study: Native Estrogen Estetrol (E4) Safety Study

Action: For adoption of advice to CHMP

7.5.14. Drospirenone, estetrol - LYDISILKA (CAP) - EMEA/H/C/005382/MEA 001.4

Applicant: Estetra SRL

PRAC Rapporteur: Martin Huber

Scope: ***1st Interim Study Report / Study INAS-NEES***
Title: International Active Surveillance Study: Native Estrogen Estetrol (E4) Safety Study (INAS-NEES)

Action: For adoption of advice to CHMP

7.5.15. Lutetium (^{177}Lu) oxodotreotide - LUTATHERA (CAP) - EMEA/H/C/004123/MEA 001.13

Applicant: Advanced Accelerator Applications

PRAC Rapporteur: Adam Przybylkowski

Scope: MAH's response to MEA 001.12 [Study No. A-LUT-T-E02-402] as adopted in September 2023.
Title: An International, Non-Interventional, Post-Authorization Long-Term Safety Study of Lutathera, in Patients with Unresectable or Metastatic, Well-Differentiated, Somatostatin Receptor Positive, Gastroenteropancreatic Neuroendocrine Tumours (SALUS study)
SEVENTH PROGRESS REPORT

Action: For adoption of advice to CHMP

7.5.16. Luspatercept - REBLOZYL (CAP) - EMEA/H/C/004444/MEA 002.3

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Jo Robays

Scope: ***4th annual report / Study No. ACE-536-LTFU-001***
To evaluate the long-term safety, including TEEs (only in the β thalassaemia population with splenectomy) and progression to AML and/or other malignancies/ pre malignancies, of luspatercept in patients who have participated in Acceleron or Celgene sponsored luspatercept clinical trials

Action: For adoption of advice to CHMP

7.5.17. Mavacamten - CAMZYOS (CAP) - EMEA/H/C/005457/MEA 005

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: From initial MAA:
PASS (RMP/non-imposed) CV027012 (DISCOVER-HCM)
Deliver Insights on Safety in Hypertrophic Cardiomyopathy and Observe Endpoints in Real-world
First Annual Study Progress Report / CV027012 (DISCOVER-HCM)

Action: For adoption of advice to CHMP

7.5.18. Octocog alfa - KOVALTRY (CAP) - EMEA/H/C/003825/MEA 005.6

Applicant: Bayer AG

PRAC Rapporteur: Gabriele Maurer

Scope: ***Study 15689*** / Annual PedNet report of 2023
Evaluation of AEs of special interest in the PedNet registry (European Paediatric Network for Haemophilia Management) (Epidemiological Study).
Submission of the annual PedNet report of 2021 containing data for Kovaltry as interim results for Study 15689, epidemiological study, category 3

Action: For adoption of advice to CHMP

7.5.19. Pegvaliase - PALYNZIQ (CAP) - EMEA/H/C/004744/MEA 003.7

Applicant: BioMarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 003.6 [SECOND INTERIM REPORT for Study 165-501] RSI as adopted in March 2024.
A prospective, global observational exposure study. Title: A Multi-Center, Observational Study to Evaluate the Long Term Safety of Subcutaneous Injections of Pegvaliase in Patients with Phenylketonuria

Action: For adoption of advice to CHMP

7.5.20. Pegvaliase - PALYNZIQ (CAP) - EMEA/H/C/004744/MEA 005.10

Applicant: BioMarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 005.8 [***Second Interim Report / study number: 165-504***] RSI as adopted in February 2024.
Study 165-504 - A global multicentre study to assess maternal, fetal and infant outcomes of exposure to Palynziq (pegvaliase) during pregnancy and breastfeeding

Action: For adoption of advice to CHMP

7.5.21. Ravulizumab - ULTOMIRIS (CAP) - EMEA/H/C/004954/MEA 009.1

Applicant: Alexion Europe SAS

PRAC Rapporteur: Kimmo Jaakkola

Scope: ***Second aHUS Registry Biennial Interim Report / PASS Study number: M07-001***
AN OBSERVATIONAL, NON-INTERVENTIONAL MULTI-CENTER, MULTI-NATIONAL STUDY OF PATIENTS WITH ATYPICAL HEMOLYTICUREMIC SYNDROME (AHUS REGISTRY).

The MAH has provided the first interim safety report of the aHUS registry study (Protocol

M07-001). This study is a category 3 study, that is part of the additional pharmacovigilance activities included in the risk management plan (RMP) of ravulizumab. Based on the data presented in this report, no new safety concerns were identified.
To better contextualize the ravulizumab data regarding the safety concerns that are addressed by this PASS, the MAH should provide in the next update relevant comparisons of ravulizumab event rates to other patients in the registry (especially eculizumab only-treated patients).
The MAH has adequately fullfilled the commitment to provide the first interim safety report for aHUS registry study. However, all commitments are not fulfilled until the study is finalised.

Next Interim Report should be provided according to the RMP every 2 years until the study is finalised

Action: For adoption of advice to CHMP

7.5.22. Reslizumab - CINQAERO (CAP) - EMEA/H/C/003912/MEA 005.8

Applicant: Teva B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: ***Updated Feasibility Assessment and Interim Safety Report*** [Study number C38072-AS-50027]
Considering the difficulties in the collection of data of a sufficient number of patients, the MAH is asked provide an updated feasibility assessment within two years and an interim safety report, when at least 200-300 study eligible patients treated with reslizumab have been accumulated in one of the databases

Action: For adoption of advice to CHMP

7.5.23. Rurioctocog alfa pegol - ADYNOVI (CAP) - EMEA/H/C/004195/ANX 002.4

Applicant: Baxalta Innovations GmbH

PRAC Rapporteur: Bianca Mulder

Scope: MAH's response to MEA 002.3 [*Fourth Progress Report*/ PASS TAK-660-403] as adopted in April 2024.
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 post-authorisation safety study according to an agreed protocol

Action: For adoption of advice to CHMP

7.5.24. Vamorolone - AGAMREE (CAP) - EMEA/H/C/005679/MEA 001

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: ***Feasibility Interim Study Results / No. SNT-IV-VAM-10***
Feasibility Report for a Registry-Based Post-authorisation Safety Study (PASS) to Evaluate the Safety of Vamorolone (AGAMREE®) in Patients with Duchenne Muscular Dystrophy

(DMD)

Action: For adoption of advice to CHMP

7.6. Others

7.6.1. Tozinameran - COMIRNATY (CAP) - EMEA/H/C/005735/MEA 064.3

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: ***Justification for termination of study C4591051***
Title: A Non-Interventional Post-Approval Safety Study of Pfizer-BioNTech Bivalent COVID-19 Vaccine in the United States to ensure comprehensive understanding of real-world safety of the Pfizer-BioNTech COVID-19 bivalent Omicron-modified vaccine in large samples of general US populations

Action: For adoption of advice to CHMP

7.6.2. Velaglucerase alfa - VPRIV (CAP) - EMEA/H/C/001249/MEA 029.1

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Martin Huber

Scope: ***Gaucher Disease Outcome Survey Annual Report 2024 + MAH's responses to MEA 029 [Gaucher Disease Outcome Survey Annual Report 2023] RSI as adopted in March 2024***
Title: Gaucher Disease Outcome Survey (GOS): An Observational, International, Multi-center, Long-term Registry of Patients with Gaucher Disease
Request for GOS discontinuation

Action: For adoption of advice to CHMP

7.7. New Scientific Advice

7.8. Ongoing Scientific Advice

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

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Evinacumab - EVKEEZA (CAP) - EMEA/H/C/005449/S/0018 (without RMP)

Applicant: Ultragenyx Germany GmbH

PRAC Rapporteur: Mari Thorn

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. Adagrasib - KRAZATI (CAP) - EMEA/H/C/006013/R/0006 (without RMP)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.2. Brexucabtagene autoleucel - TECARTUS (CAP) - EMEA/H/C/005102/R/0047 (with RMP)

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CAT and CHMP

8.2.3. Elranatamab - ELREXFIO (CAP) - EMEA/H/C/005908/R/0003 (without RMP)

Applicant: Pfizer Europe Ma EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.4. Loncastuximab tesirine - ZYNLONTA (CAP) - EMEA/H/C/005685/R/0018 (without RMP)

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Eva Jirsová

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.5. Sotorasib - LUMYKRAS (CAP) - EMEA/H/C/005522/R/0018 (without RMP)

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.6. Spesolimab - SPEVIGO (CAP) - EMEA/H/C/005874/R/0008 (without RMP)

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Nathalie Gault

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.7. Trastuzumab - ENHERTU (CAP) - EMEA/H/C/005124/R/0047 (without RMP)

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Azacitidine - AZACITIDINE ACCORD (CAP) - EMEA/H/C/005147/R/0019 (without RMP)

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.2. Azacitidine - AZACITIDINE MYLAN (CAP) - EMEA/H/C/004984/R/0019 (without RMP)

Applicant: Mylan Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Bempedoic acid - NILEMDO (CAP) - EMEA/H/C/004958/R/0042 (without RMP)

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Kimmo Jaakkola

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Bempedoic acid, Ezetimibe - NUSTENDI (CAP) - EMEA/H/C/004959/R/0047 (without RMP)

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Kimmo Jaakkola

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.5. Darolutamide - NUBEQA (CAP) - EMEA/H/C/004790/R/0021 (without RMP)

Applicant: Bayer AG

PRAC Rapporteur: Jan Neuhauser

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.6. Dexmedetomidine - DEXMEDETOMIDINE ACCORD (CAP) - EMEA/H/C/005152/R/0013 (without RMP)

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.7. Deferasirox - DEFERASIROX ACCORD (CAP) - EMEA/H/C/005156/R/0011 (without RMP)

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.8. Fostamatinib - TAVLESSE (CAP) - EMEA/H/C/005012/R/0018 (with RMP)

Applicant: Instituto Grifols, S.A.

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.9. Givosiran - GIVLAARI (CAP) - EMEA/H/C/004775/R/0020 (without RMP)

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.10. Insulin lispro - LYUMJEV (CAP) - EMEA/H/C/005037/R/0019 (without RMP)

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.11. Rituximab - RUXIENCE (CAP) - EMEA/H/C/004696/R/0017 (without RMP)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.12. Semaglutide - RYBELSUS (CAP) - EMEA/H/C/004953/R/0042 (without RMP)

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.13. Treprostinil sodium - TREPULMIX (CAP) - EMEA/H/C/005207/R/0020 (without RMP)

Applicant: SciPharm Sarl

PRAC Rapporteur: Zane Neikena

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

None

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

None

10.3. Other requests

10.3.1. Azithromycin[25] (NAP) - EMEA/H/A-31/1532

Applicant: various

PRAC Rapporteur: Kimmo Jaakkola

Scope: PRAC consultation regarding the use of azithromycin-containing products (for systemic use only) during pregnancy in the context of a referral procedure under Article 31 of Directive 2001/83/EC upon CHMP's request

[25] For systemic use only

Action: For adoption of advice to CHMP

10.4. Scientific Advice

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

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

11.1. Safety related variations of the marketing authorisation

None

11.2. Other requests

11.2.1. Brivaracetam

PRAC Lead: Guðrún Þengilsdóttir

Scope: PRAC consultation on the evaluation of initial marketing authorisation application(s) under the decentralised procedure for generic brivaracetam-containing medicinal products in order to consider the need to add the EURAP registry study as category 3 additional pharmacovigilance activity in the RMP, on request of Iceland

Action: For adoption of advice to Member States

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. Election of PRAC Vice-Chair

Action: For adoption

12.1.2. PRAC membership

Action: For information

12.1.3. Vote by proxy

Action: For information

12.1.4. PRAC working group - Best practice guide on using PRAC plenary time efficiently and effectively – update on the implementation of quantitative goals – Q2 2024

Action: For discussion

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

12.4.2. EU Network Training Centre (EU NTC) – update on supporting capacity and capability building in the EU Medicines Regulatory Network

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.4.3. European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) steering group – update and call for expression of interest for a PRAC representative

PRAC lead: Ulla Wändel Liminga

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 - update

PRAC lead: Ulla Wändel Liminga, Martin Huber

Action: For discussion

12.8. Planning and reporting

12.8.1. EU Pharmacovigilance system - quarterly workload measures and performance indicators – Q2 2024 and predictions

Action: For discussion

12.8.2. PRAC workload statistics – Q2 2024

Action: For discussion

12.9. For discussion 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: **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

None

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

12.20.1. Strategy on measuring the impact of pharmacovigilance – PRAC interest group (IG) Impact – revision of the PRAC criteria to prioritise impact research (revision 1)

PRAC lead: Liana Martirosyan

Action: For adoption

12.20.2. Proposal for an impact study to measure the effectiveness of risk minimisation measures implemented for medicines containing nomegestrol or chlormadinone in order to minimise the risk of meningioma - DARWIN EU pilot

PRAC lead: Petar Mas

Action: For discussion

12.21. Others

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

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.21.2. Good Pharmacovigilance Practice (GVP) – status update and planning for 2025

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.21.3. Committee meetings in Microsoft Teams and new tool for voting

Action: For discussion

13. Any other business

None

14. Explanatory notes

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

EU Referral procedures for safety reasons: Urgent EU procedures and Other EU referral procedures
(Items 2 and 3 of the PRAC agenda)

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

Signals assessment and prioritisation
(Item 4 of the PRAC agenda)

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

The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.
The evaluation of safety signals may not necessarily conclude that the medicine caused the adverse event in question. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary and this usually takes the form of an update of the summary of product characteristics and the package leaflet.

Risk Management Plans (RMPs)
(Item 5 of the PRAC agenda)

The RMP describes what is known and not known about the side effects of a medicine and states how these risks will be prevented or minimised in patients. It also includes plans for studies and other activities to gain more knowledge about the safety of the medicine and risk factors for developing side effects.
RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available.

Assessment of Periodic Safety Update Reports (PSURs)
(Item 6 of the PRAC agenda)

A PSUR is a report providing an evaluation of the benefit-risk balance of a medicine, which is submitted by marketing authorisation holders at defined time points following a medicine's authorisation.
PSURs summarises data on the benefits and risks of a medicine and includes the results of all studies carried out with this medicine (in the authorised and unauthorised indications).

Post-authorisation Safety Studies (PASS)
(Item 7 of the PRAC agenda)

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

Product related pharmacovigilance inspections
(Item 9 of the PRAC agenda)

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

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/