10 February 2025
EMA/PRAC/15940/2025
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 10-13 February 2025

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

10 February 2025, 13:00 – 19:30, room 1C

11 February 2025, 08:30 – 19:30, room 1C

12 February 2025, 08:30 – 19:30, room 1C

13 February 2025, 08:30 – 16:00, room 1C

Organisational, regulatory and methodological matters (ORGAM)

27 February 2025, 09:00 – 12:00, via teleconference

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PRAC plenary session to be held 10-13 February 2025. See February 2025 PRAC minutes (to be published post March 2025 PRAC meeting).

1.2. Agenda of the meeting on 10-13 February 2025

Action: For adoption

1.3. Minutes of the previous meeting on 13-16 January 2025

Action: For adoption

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

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

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

3.1. Newly triggered procedures

None

3.2. Ongoing procedures

3.2.1. Dutasteride (NAP); dutasteride, tamsulosin (NAP); finasteride (NAP); finasteride, tadalafil (NAP); finasteride, tamsulosin (NAP) – EMEA/H/A-31/1539

Applicant(s): various

PRAC Rapporteur: Jana Lukacisinova; PRAC Co-rapporteur: Martin Huber

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

Action: For adoption of a list of outstanding issues

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. Clozapine (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of haematological malignant tumours

Action: For adoption of PRAC recommendation

EPITT 20150 – New signal

Lead Member State(s): IT

4.1.2. Ciltacabtagene autoleucel – CARVYKTI (CAP); idecabtagene vicleucel – ABECMA (CAP); tisagenlecleucel - KYMRIAH (CAP)

Applicants: Bristol-Myers Squibb Pharma EEIG (Abecma), Janssen-Cilag International NV (Carvykti), Novartis Europharm Limited (Kymriah), ATMP

PRAC Rapporteur: To be appointed

Scope: Signal of progressive multifocal leukoencephalopathy

Action: For adoption of PRAC recommendation

EPITT 20153 – New signal

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

[1] Re-examination of PRAC recommendation under Article 32 of Directive 2001/83/EC
[2] Each signal refers to a substance or therapeutic class. The route of marketing authorisation is indicated in brackets (CAP for Centrally Authorised Products; NAP for Nationally Authorised Products including products authorised via Mutual Recognition Procedures and Decentralised Procedure). Product names are listed for reference Centrally Authorised Products (CAP) only. PRAC recommendations will specify the products concerned in case of any regulatory action required

4.1.3. Idecabtagene vicleucel – ABECMA (CAP)

Applicant: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Mari Thorn

Scope: Signal of sarcoidosis

Action: For adoption of PRAC recommendation

EPITT 20154 – New signal

Lead Member State(s): SE

4.1.4. Regorafenib - STIVARGA (CAP)

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Signal of hyperammonaemia, hyperammonaemic encephalopathy

Action: For adoption of PRAC recommendation

EPITT 20147 – New signal

Lead Member State(s): NL

4.1.5. Vortioxetine – BRINTELLIX (CAP); NAP

Applicant(s): H. Lundbeck A/S, various

PRAC Rapporteur: To be appointed

Scope: Signal of hallucinations, not related to serotoninergic syndrome

Action: For adoption of PRAC recommendation

EPITT 20152 – New signal

Lead Member State(s): BE

4.2. Signals follow-up and prioritisation

4.2.1. Adagrasib - KRAZATI (CAP) - EMEA/H/C/006013/SDA/003

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Signal of thrombocytopenia

Action: For adoption of PRAC recommendation

EPITT 20112 – Follow-up to October 2024

4.2.2. Mogamulizumab - POTELIGEO (CAP) - EMEA/H/C/004232/SDA/003

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Signal of colitis

Action: For adoption of PRAC recommendation

EPITT 20113 – Follow-up to October 2024

4.3. Variation procedure(s) resulting from signal evaluation

None

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Atropine (CAP MAA) - EMEA/H/C/006385, PUMA[3]

Scope (pre D-180 phase): Treatment of myopia in children aged 3 years and older

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

5.1.2. Denosumab (CAP MAA) - EMEA/H/C/006434

Scope (pre D-180 phase): Treatment of osteoporosis and bone loss

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

5.1.3. Denosumab (CAP MAA) - EMEA/H/C/006435

Scope (pre D-180 phase): Prevention of skeletal related events with advanced malignancies

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

5.1.4. Denosumab (CAP MAA) - EMEA/H/C/006199

Scope (pre D-180 phase): Prevention of skeletal related events with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone

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

5.1.5. Denosumab (CAP MAA) - EMEA/H/C/006376

Scope (pre D-180 phase): Prevention of skeletal related events with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone

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

5.1.6. Denosumab (CAP MAA) - EMEA/H/C/006152

Scope (pre D-180 phase): For the treatment of osteoporosis and bone loss

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

[3] Paediatric Use Marketing Authorisation

5.1.7. Denosumab (CAP MAA) - EMEA/H/C/006377

Scope (pre D-180 phase): For the treatment of osteoporosis and bone loss

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

5.1.8. Deutetrabenazine (CAP MAA) - EMEA/H/C/006371

Scope (pre D-180 phase): Treatment of tardive dyskinesia

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

5.1.9. Deutivacaftor, tezacaftor, vanzacaftor (CAP MAA) - EMEA/H/C/006382, Orphan

Applicant: Vertex Pharmaceuticals (Ireland) Limited

Scope (pre D-180 phase): Indicated for the treatment of cystic fibrosis

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

5.1.10. Inavolisib (CAP MAA) - EMEA/H/C/006353

Scope (pre D-180 phase): Treatment of adult patients with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer

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

5.1.11. L-Acetylleucine (CAP MAA) - EMEA/H/C/006327, Orphan

Applicant: Intrabio Ireland Limited

Scope (pre D-180 phase): Indicated in adults and children from birth for chronic treatment of Niemann-Pick Type C (NPC)

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

5.1.12. Octreotide (CAP MAA) - EMEA/H/C/006322, Orphan

Applicant: Camurus ABScope (pre D-180 phase): Treatment of acromegaly

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

5.1.13. Resminostat (CAP MAA) - EMEA/H/C/006259, Orphan

Applicant: 4Sc AG

Scope (pre D-180 phase): Treatment of patients with advanced stage mycosis fungoides (MF) and Sézary syndrome (SS)

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

5.1.14. Sepiapterin (CAP MAA) - EMEA/H/C/006331, Orphan

Applicant: PTC Therapeutics International Limited

Scope (pre D-180 phase): Treatment of hyperphenylalaninemia (HPA) in adult and

paediatric patients with phenylketonuria (PKU)

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

5.1.15. Teprotumumab (CAP MAA) - EMEA/H/C/006396

Scope (pre D-180 phase): Treatment of moderate to severe Thyroid Eye Disease (TED)

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

5.1.16. Teriparatide (CAP MAA) - EMEA/H/C/005687

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

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

5.1.17. Zanidatamab (CAP MAA) - EMEA/H/C/006380, Orphan

Applicant: Jazz Pharmaceuticals Ireland Limited

Scope (pre D-180 phase): Treatment of biliary tract 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. Semaglutide - OZEMPIC (CAP) - EMEA/H/C/004174/WS2819/0053; Semaglutide - WEGOVY (CAP) - EMEA/H/C/005422/WS2819/0029

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: To align the RMPs to the version approved for Rybelsus on 3 October 2024

Action: For adoption of PRAC Assessment Report

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

5.3.1. Acalabrutinib - CALQUENCE (CAP) - EMEA/H/C/005299/II/0026

Applicant: AstraZeneca AB

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Extension of indication to include CALQUENCE as monotherapy for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy based on final results from study ACE-LY-004 (D8225C00002); this is an open-label, phase 2 study of ACP-196 in subjects with Mantle Cell Lymphoma. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI

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

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

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

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

Action: For adoption 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. Avelumab - BAVENCIO (CAP) - EMEA/H/C/004338/II/0046/G

Applicant: Merck Europe B.V.

PRAC Rapporteur: Karin Erneholm

Scope: A grouped application consisting of:
C.I.4: Update of sections 4.2, 4.4, 4.6 and 4.8 of the SmPC in order to add the immune-mediated adverse reactions sclerosing cholangitis, arthritis, polymyalgia rheumatica, and Sjogren's syndrome based on post-marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 7.3 has also been submitted.

C.I.4: Update of section 4.8 of the SmPC in order to update the immunogenicity information based on results from studies EMR100070-003, B9991003 and 100/B9991001. Study EMR100070-003 is a Phase 2, single-arm, open label, multicenter study to investigate the clinical activity and safety of avelumab in patients with mMCC. T. Study B9991003 is a Phase 3 multinational, multicenter, randomized (1:1), open-label, parallel 2 - arm study of avelumab in combination with axitinib versus sunitinib monotherapy in the 1L treatment of participants with aRCC. Study 100/B9991001 is a Phase 3, multicenter, multinational, randomized, open-label, parallel-arm efficacy and safety study of avelumab plus best supportive care (BSC) versus BSC alone as a maintenance treatment in adult participants

with locally advanced or metastatic UC whose disease did not progress after completion of 1L platinum-containing chemotherapy

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

5.3.5. Bempedoic acid - NILEMDO (CAP) - EMEA/H/C/004958/WS2798/0045; Bempedoic acid, ezetimibe - NUSTENDI (CAP) - EMEA/H/C/004959/WS2798/0050

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Kimmo Jaakkola

Scope: Update of sections 4.2, 4.4, and 5.2 of the SmPC in order to amend information concerning renal impairment based on the final results from Study 1002-071 listed as a category 3 study in the RMP; this is a phase 1, open-label, single-dose study to evaluate the pharmacokinetics of bempedoic acid in healthy subjects with normal renal function and subjects with end-stage renal disease receiving haemodialysis; the Package Leaflet is updated accordingly. The RMP version 7.0 has also been submitted

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

5.3.6. Chikungunya virus, strain delta5nsP3, live attenuated - IXCHIQ (CAP) - EMEA/H/C/005797/II/0001

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in adolescents 12 years and older for IXCHIQ, based on interim 6 months results from study VLA1553-321; this is a randomized, double-blinded, multicentre study to evaluate the immunogenicity and safety of the adult dose of VLA1553 6 months following vaccination in adolescents from 12 years to less than 18 years of age after a single immunization. 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. 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

5.3.7. Ciltacabtagene autoleucel - CARVYKTI (CAP) - EMEA/H/C/005095/II/0036, Orphan

Applicant: Janssen-Cilag International NV, ATMP

PRAC Rapporteur: Jo Robays

Scope: Update of sections 4.8, and 5.1 of the SmPC in order to update the list of adverse drug reactions (ADRs), and update clinical efficacy and safety information based on second interim analysis from study 68284528MMY3002 (CARTITUDE-4); this is a phase 3 randomized study comparing ciltacabtagene autoleucel, a chimeric antigen receptor T cell (CAR-T) therapy directed against BCMA, versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in subjects with relapsed and lenalidomide-refractory multiple myeloma; The RMP version 5.3 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 CAT and CHMP

5.3.8. Covid-19 Vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - EMEA/H/C/005808/II/0096/G

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Grouped quality variations; RMP version 6.1 has also been submitted

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

5.3.9. Daratumumab - DARZALEX (CAP) - EMEA/H/C/004077/II/0077, Orphan

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include daratumumab for the treatment of adult patients with smouldering multiple myeloma (SMM) at high risk of developing multiple myeloma based on results from studies 54767414SMM3001 (AQUILA) and 54767414SMM2001 (CENTAURUS). SMM3001 (AQUILA) is a Phase 3 Randomized, Multicenter Study of Subcutaneous Daratumumab Versus Active Monitoring in Subjects with High-risk Smoldering Multiple Myelom. SMM2001 (CENTAURUS) is a Randomized Phase 2 Trial to Evaluate Three Daratumumab Dose Schedules in Smoldering Multiple Myeloma.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the PI in accordance with the latest EMA excipients guideline

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

5.3.10. Ebola vaccine (rDNA[4], replication-incompetent) - MVABEA (CAP) - EMEA/H/C/005343/II/0021

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy based on final results from study VAC52150EBL3010 listed as a category 3 study in the RMP as well as study VAC52150EBL3008 and two post-authorization vaccination campaigns. Study VAC52150EBL3010 is a phase 3 open-label randomized clinical trial to evaluate the safety, reactogenicity and immunogenicity of a 2-dose Ebola vaccine regimen of Ad26.ZEBOV followed by MVA-BN-Filo in healthy pregnant women. The Package Leaflet is updated accordingly. The RMP version 3.3 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

[4] Ribosomal deoxyribonucleic acid

5.3.11. Ebola vaccine (rDNA[5], replication-incompetent) - ZABDENO (CAP) - EMEA/H/C/005337/II/0019

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy based on final results from study VAC52150EBL3010 listed as a category 3 study in the RMP as well as study VAC52150EBL3008 and two post-authorisation vaccination campaigns. Study VAC52150EBL3010 is a phase 3 open-label randomized clinical trial to evaluate the safety, reactogenicity and immunogenicity of a 2-dose Ebola vaccine regimen of Ad26.ZEBOV followed by MVA-BN-Filo in healthy pregnant women. The Package Leaflet is updated accordingly. The RMP version 3.3 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information

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

5.3.12. Glofitamab - COLUMVI (CAP) - EMEA/H/C/005751/II/0010, Orphan

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jana Lukacisinova

Scope: Submission of the updated 2-year follow-up report from study NP30179 listed as a Specific Obligation in the Annex II of the Product Information. This is a multicenter, open-label Phase I/II study to evaluate the safety, efficacy, tolerability, and pharmacokinetics of escalating doses of glofitamab in patients with relapsed/refractory B-cell Non-Hodgkin's Lymphoma (NHL). The Annex II and the RMP version 4.0 are updated accordingly. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation

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

5.3.13. 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

[5] Ribosomal deoxyribonucleic acid

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

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

Applicant: Horizon Therapeutics Ireland DAC

PRAC Rapporteur: Amelia Cupelli

Scope: Extension of indication to include treatment of adult patients with Immunoglobulin G4-Related Disease (IgG4-RD) for UPLIZNA, based on primary analysis results from study MITIGATE (VIB0551.P3.S2) for all subjects from the completed 52-week randomised-controlled period. This is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adult subjects with IgG4-RD. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to bring it in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection

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

5.3.15. Influenza quadrivalent vaccine (rDNA[6]) - SUPEMTEK TETRA (CAP) - EMEA/H/C/005159/II/0021/G

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur:

Scope: Grouped application comprising two type II variations as follows:
C.I.6.a – Extension of indication to include the treatment of children 9 years of age and older for Supemtek, based on final results from study VAP00027; this is a Phase III, non-randomized, open-label, uncontrolled study to demonstrate the non-inferior HAI immune response of RIV4 for the 4 strains in participants aged 9 to 17 years vs participants aged 18 to 49 years; As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted.
C.I.4 - Update of sections 4.8 and 5.1 of the SmPC in order to update paediatric information based on final results from study VAP00026; this is a Phase III, randomized, modified double-blind, active-controlled 2-arm to demonstrate the non-inferior HAI immune response of RIV4 vs licensed IIV4 for the 4 strains based on the egg-derived antigen in all participants. Version 2.0 of the RMP has also been submitted

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

[6] Ribosomal deoxyribonucleic acid

5.3.16. Liraglutide - SAXENDA (CAP) - EMEA/H/C/003780/II/0042

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include the use of SAXENDA for weight management in children from the age of 6 years to less than 12 years based on results from study NN8022-4392; this is a 56-week, double-blind, randomised, placebo-controlled study investigating safety and efficacy of liraglutide on weight management in children with obesity aged 6 to <12 years. 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 34.0 of the RMP has also been submitted

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

5.3.17. Maralixibat - LIVMARLI (CAP) - EMEA/H/C/005857/X/0015, Orphan

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to introduce a new pharmaceutical form (tablet) associated with new strengths 10 mg, 15 mg, 20 mg and 30 mg.
The RMP (version 5.0) is updated in accordance

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

5.3.18. Odevixibat - KAYFANDA (CAP) - EMEA/H/C/006462/II/0001/G

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application consisting of:
C.I.4: Update of sections 4.4, 4.8, and 5.1 of the SmPC based on results from Study A4250-015 listed as a category 3 study in the RMP; this is a Phase 3, multicentre, open-label extension study to evaluate the long-term safety and efficacy of odevixibat in patients with ALGS. The Package Leaflet is updated accordingly. The RMP version 6.2 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

C.I.13: Submission of the 72 week report from study A4250-008. This is a Phase 3, multicentre, open-label extension study to investigate the long-term efficacy and safety of odevixibat in patients with Progressive Familial Intrahepatic Cholestasis Types 1 and 2 (PEDFIC 2)

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

5.3.19. Pregabalin - LYRICA (CAP) - EMEA/H/C/000546/X/0127

Applicant: Upjohn EESV

PRAC Rapporteur: Liana Martirosyan

Scope: Extension application to introduce a new pharmaceutical form (orodispersible tablet)

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

5.3.20. Riociguat - ADEMPAS (CAP) - EMEA/H/C/002737/X/0041

Applicant: Bayer AG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength (0.15 mg/ml granules for oral suspension) for the Pulmonary arterial hypertension (PAH) paediatric indication. As a consequence, the film coated tablets presentations are updated to accommodate the new pharmaceutical form. In addition, contact details for local representatives of Belgium, Luxembourg, Greece and Ireland, have also been updated

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

5.3.21. Ritlecitinib - LITFULO (CAP) - EMEA/H/C/006025/II/0007

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Adam Przybylkowski

Scope: Update of section 4.8 of the SmPC in order to update of the long-term efficacy and safety information based on interim results from study B7981032 listed as a category 3 study in the RMP; this is a Phase 3 Open-Label, Multi-Center, Long-Term Study Investigating the Safety and Efficacy of PF-06651600 in Adult and Adolescent Participants With Alopecia Areata. The RMP version 2 has also been submitted

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

5.3.22. Selpercatinib - RETSEVMO (CAP) - EMEA/H/C/005375/X/0031

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension application to introduce a new pharmaceutical form (film-coated tablets) associated with new strengths (40 mg, 80 mg, 120 mg and 160 mg).
The RMP (version 7.1) is updated in accordance

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

5.3.23. Sorafenib - NEXAVAR (CAP) - EMEA/H/C/000690/II/0059, Orphan

Applicant: Bayer AG

PRAC Rapporteur: Mari Thorn

Scope: Update of section 5.3 of the SmPC in order to update preclinical safety data on carcinogenicity studies based on final results from studies T4079666 - Carcinogenicity Study in CD-1 Mice (2 Years Administration by Diet) and T8076320 - Carcinogenicity Study in Wistar Rats (2 Years Administration in the Diet with Dose Adjustment). In addition, the MAH took the opportunity to introduce editorial changes to the PI and 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

5.3.24. Spesolimab - SPEVIGO (CAP) - EMEA/H/C/005874/X/0011

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Zoubida Amimour

Scope: Extension application to add a new strength of 300 mg (150 mg/ml) for solution for injection in a pre-filled syringe.
The RMP (version 3.0) is updated in accordance.
In addition, the applicant has updated SmPC (Annex I) and Package Leaflet (Annex IIIB) for both 450 mg concentrate for solution for infusion and 150 mg and 300 mg solution for injection in line with the new excipient guideline

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

5.3.25. Tasimelteon - HETLIOZ (CAP) - EMEA/H/C/003870/X/0039, Orphan

Applicant: Vanda Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (4 mg/ml oral solution). The new formulation is indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in paediatric patients 3 to 15 years of age. The RMP (version 5.0) is updated in accordance

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

5.3.26. Tirzepatide - MOUNJARO (CAP) - EMEA/H/C/005620/II/0038

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of symptomatic chronic heart failure with preserved ejection fraction (HFpEF) in adults with obesity for MOUNJARO, based on results from the Phase 3 trial I8F-MC-GPID (SUMMIT). SUMMIT was a randomized, multicenter, international, placebo-controlled, double-blind, parallel-arm study in participants with HFpEF and obesity. The study was designed to evaluate the effect of tirzepatide compared with placebo on both clinical and symptomatic or functional outcomes. As a consequence, sections 4.1, 4.8, and 5.1 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

5.3.27. Tislelizumab - TEVIMBRA (CAP) - EMEA/H/C/005919/II/0017

Applicant: Beigene Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include, in combination with gemcitabine and cisplatin, the first-line treatment of adult patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) for TEVIMBRA based on final results from study BGB-A317-309 (study 309). Study 309 was a Phase 3 randomised, double-blind, placebo-controlled, Asia-only study that compared the efficacy and safety of tislelizumab combined with gemcitabine plus cisplatin

(GC) versus placebo combined with GC as 1L treatment for recurrent or metastatic NPC. 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 2.6 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial and administrative changes to the PI as well as to update the PI in line with the Excipients Guideline

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

5.3.28. Trabectedin - YONDELIS (CAP) - EMEA/H/C/000773/II/0070

Applicant: Pharma Mar, S.A.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Update of sections 4.4 and 4.6 of the SmPC in order to update the contraceptive precautions when receiving Yondelis, in line with EMA recommendations. The Package Leaflet is updated accordingly. The RMP version 11.1 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

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

5.3.29. Trastuzumab deruxtecan - ENHERTU (CAP) - EMEA/H/C/005124/II/0048

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include treatment of adult patients with unresectable or metastatic HER2-low or HER2-ultralow breast cancer (BC) who have received at least one endocrine therapy in the metastatic setting for ENHERTU, based on results from study D9670C00001 (DESTINY-Breast06); this is a phase 3, randomized, multicentre, open-label study of trastuzumab deruxtecan (DS-8201a) compared with investigator's choice chemotherapy in, hormone receptor-positive, HER2-low and HER2-ultralow BC patients whose disease has progressed on endocrine therapy in the metastatic setting. 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 8.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI, to update the list of local representatives in the Package Leaflet and to update the PI according to the Excipients Guideline

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

5.3.30. Ustekinumab - PYZCHIVA (CAP) - EMEA/H/C/006183/X/0006

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension application to introduce a new strength (45 mg solution for injection in a vial) for partial use in paediatric patients

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

5.3.31. Valoctocogene roxaparvovec - ROCTAVIAN (CAP) - EMEA/H/C/005830/II/0014, Orphan

Applicant: BioMarin International Limited, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Update of the Annex II in order to propose changes to the current marketing authorisation obligations for ROCTAVIAN. The RMP version 1.3 has also been submitted

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

6. Periodic safety update reports (PSURs)

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

6.1.1. Aclidinium bromide - BRETARIS GENUAIR (CAP); EKLIRA GENUAIR (CAP) - PSUSA/00009005/202407

Applicant: Covis Pharma Europe B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.2. Anifrolumab - SAPHNELO (CAP) - PSUSA/00010980/202407

Applicant: AstraZeneca AB

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.3. Ataluren - TRANSLARNA (CAP) - PSUSA/00010274/202407

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.4. Atazanavir - REYATAZ (CAP) - PSUSA/00000258/202406

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.5. Avapritinib - AYVAKYT (CAP) - PSUSA/00010878/202407

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.6. Beclometasone, formoterol, glycopyrronium bromide - RIARIFY (CAP); TRIMBOW (CAP); TRYDONIS (CAP) - PSUSA/00010617/202407

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.7. Birch bark extract[7] - FILSUVEZ (CAP) - PSUSA/00010446/202407

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.8. Brexpiprazole - RXULTI (CAP) - PSUSA/00010698/202407

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Miroslava Gocova

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.9. Brexucabtagene autoleucel - TECARTUS (CAP) - PSUSA/00010903/202407

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

6.1.10. Budesonide[8] - JORVEZA (CAP) - PSUSA/00010664/202407

Applicant: Dr. Falk Pharma GmbH

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

[7] Centrally authorised product(s) only
[8] For centrally authorised product(s) indicated for eosinophilic esophagitis only

Action: For adoption of recommendation to CHMP

6.1.11. Canakinumab - ILARIS (CAP) - PSUSA/00000526/202406

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.12. Casirivimab, imdevimab - RONAPREVE (CAP) - PSUSA/00010963/202407

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.13. Cenegermin - OXERVATE (CAP) - PSUSA/00010624/202407

Applicant: Dompe' Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.14. Cladribine[9] - MAVENCLAD (CAP) - PSUSA/00010634/202407

Applicant: Merck Europe B.V.

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.15. Danicopan - VOYDEYA (CAP) - PSUSA/00011056/202407

Applicant: Alexion Europe

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.16. Darolutamide - NUBEQA (CAP) - PSUSA/00010843/202407

Applicant: Bayer AG

PRAC Rapporteur: Jan Neuhauser

[9] Multiple sclerosis indication only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.17. Decitabine, cedazuridine - INAQOVI (CAP) - PSUSA/00000118/202407

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

6.1.18. Eptacog beta (activated) - CEVENFACTA (CAP) - PSUSA/00011006/202407

Applicant: Laboratoire Francais du Fractionnement et des Biotechnologies

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.19. Faricimab - VABYSMO (CAP) - PSUSA/00011016/202407

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. Finerenone - KERENDIA (CAP) - PSUSA/00010978/202407

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.21. Gefapixant - LYFNUA (CAP) - PSUSA/00000132/202407

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.22. Glucagon[10] - BAQSIMI (CAP); OGLUO (CAP) - PSUSA/00010826/202407

Applicant(s): Amphastar France Pharmaceuticals (BAQSIMI), Tetris Pharma B.V. (Ogluo)

[10] For centrally authorised product(s) only

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.23. Glucarpidase - VORAXAZE (CAP) - PSUSA/00010968/202407

Applicant: SERB S.A.S.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.24. Guselkumab - TREMFYA (CAP) - PSUSA/00010652/202407

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.25. Ibandronic acid - BONDRONAT (CAP); BONVIVA (CAP) - PSUSA/00001702/202406

Applicant(s): Atnahs Pharma Netherlands B.V. (Bondronat, Bonviva)

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.26. Icatibant - FIRAZYR (CAP) - PSUSA/00001714/202407

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.27. Icosapent ethyl - VAZKEPA (CAP) - PSUSA/00010922/202407

Applicant: Amarin Pharmaceuticals Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.28. Imipenem, cilastatin, relebactam - RECARBRIO (CAP) - PSUSA/00010830/202407

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.29. Inotersen - TEGSEDI (CAP) - PSUSA/00010697/202407

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.30. Lomitapide - LOJUXTA (CAP) - PSUSA/00010112/202407

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.31. Mirabegron - BETMIGA (CAP) - PSUSA/00010031/202406

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.32. Nivolumab - OPDIVO (CAP) - PSUSA/00010379/202407

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.33. Odevixibat - BYLVAY (CAP) - PSUSA/00010949/202407

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. Opicapone - ONGENTYS (CAP); ONTILYV (CAP) - PSUSA/00010516/202406

Applicant(s): Bial - Portela & Cª, S.A. (Ongentys), Bial Portela & Companhia S.A. (Ontilyv)

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.35. Paliperidone - BYANNLI (CAP); INVEGA (CAP); TREVICTA (CAP); XEPLION (CAP) - PSUSA/00002266/202406

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.36. Palivizumab - SYNAGIS (CAP) - PSUSA/00002267/202406

Applicant: AstraZeneca AB

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.37. Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - INCELLIPAN (CAP); zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - CELLDEMIC (CAP) - PSUSA/00011057/202407

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.38. Pirtobrutinib - JAYPIRCA (CAP) - PSUSA/00000155/202407

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. Remimazolam - BYFAVO (CAP) - PSUSA/00010924/202407

Applicant: Paion Pharma GmbH

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.40. Sacubitril, valsartan - ENTRESTO (CAP); NEPARVIS (CAP) - PSUSA/00010438/202407

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. Smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara) - IMVANEX (CAP) - PSUSA/00010119/202407

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.42. Spheroids of human autologous matrix-associated chondrocytes - SPHEROX (CAP) - PSUSA/00010630/202407

Applicant: Co.Don GmbH, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.43. Tafasitamab - MINJUVI (CAP) - PSUSA/00010951/202407

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Tebentafusp - KIMMTRAK (CAP) - PSUSA/00010991/202407

Applicant: Immunocore Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Tobramycin[11] - TOBI PODHALER (CAP) - PSUSA/00009315/202406

Applicant: Viatris Healthcare Limited

PRAC Rapporteur: Liana Martirosyan

[11] Inhalation powder, capsules only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Tocofersolan - VEDROP (CAP) - PSUSA/00002981/202407

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Voclosporin - LUPKYNIS (CAP) - PSUSA/00011020/202407

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. Voretigene neparvovec - LUXTURNA (CAP) - PSUSA/00010742/202407

Applicant: Novartis Europharm Limited, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

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

6.2.1. Cabazitaxel - CABAZITAXEL ACCORD (CAP); JEVTANA (CAP); NAP - PSUSA/00000476/202406

Applicant(s): Accord Healthcare S.L.U. (Cabazitaxel Accord), Sanofi Winthrop Industrie (Jevtana), various

PRAC Rapporteur: Tiphaine Vaillant

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. Acenocoumarol (NAP) - PSUSA/00000027/202407

Applicant(s): various

PRAC Lead: Maria Popova-Kiradjieva

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.2. Benzalkonium chloride, ethyl alcohol (NAP); benzalkonium chloride, isopropyl alcohol (NAP) - PSUSA/00000342/202407

Applicant(s): various

PRAC Lead: Guðrún Stefánsdóttir

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Brivudine (NAP) - PSUSA/00000434/202407

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.4. Busulfan (NAP) - PSUSA/00000464/202407

Applicant(s): various

PRAC Lead: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. Clebopride (NAP) - PSUSA/00000789/202406

Applicant(s): various

PRAC Lead: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.6. Dexchlorpheniramine (NAP) - PSUSA/00000989/202406

Applicant(s): various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.7. Glibenclamide, metformin hydrochloride (NAP) - PSUSA/00002002/202406

Applicant(s): various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. Human fibrinogen (NAP) - PSUSA/00001624/202406

Applicant(s): various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.9. Human plasma proteins with no less than 95% albumin (NAP) - PSUSA/00010605/202407

Applicant(s): various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. Manidipine (NAP) - PSUSA/00001932/202406

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. Nilutamide (NAP) - PSUSA/00002163/202407

Applicant(s): various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. Nimesulide[12] (NAP) - PSUSA/00009236/202406

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. Phentermine, topiramate (NAP) - PSUSA/00010956/202407

Applicant(s): various

[12] Systemic formulation(s) only

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.14. Propranolol[13] (NAP) - PSUSA/00010251/202406

Applicant(s): various

PRAC Lead: Guðrún Stefánsdóttir

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.15. Rabbit anti-human T-lymphocyte immunoglobulin (NAP) - PSUSA/00010252/202406

Applicant(s): various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.16. Rabbit anti-human thymocyte immunoglobulin (NAP) - PSUSA/00010184/202406

Applicant(s): various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.17. Thiocolchicoside (NAP); paracetamol, thiocolchicoside (NAP) - PSUSA/00010464/202407

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.18. Tiagabine (NAP) - PSUSA/00002942/202406

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

[13] All except centrally authorised product(s) only

6.3.19. Tianeptine (NAP) - PSUSA/00002943/202406

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.4. Follow-up to PSUR/PSUSA procedures

None

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. 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

6.5.2. 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

6.5.3. Secukinumab - COSENTYX (CAP) - EMEA/H/C/003729/II/0127

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Monica Martinez Redondo

Scope: Update section 4.4 of the SmPC to update the safety information following PSUSA/00010341/202312 procedure in order to assess the safety topics of tuberculosis and hepatitis C virus with secukinumab. The Package Leaflet is updated accordingly

Action: For adoption of PRAC Assessment Report

6.6. Expedited summary safety reviews[14]

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[15]

7.1.1. Exagamglogene autotemcel – CASGEVY (CAP) - EMEA/H/C/PSA/S/0113.2

Applicant: Vertex Pharmaceuticals (Ireland), ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Substantial amendment to a protocol for a long-term registry-based study of patients with transfusion-dependent β-thalassemia (TDT) or sickle cell disease (SCD) treated with exagamglogene autotemcel (exa-cel) [MAH's response to PSA/S/0113.1]

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

7.1.2. Voretigene neparvovec – LUXTURNA (CAP) - EMEA/H/C/PSA/S/0114.1

Applicant: Novartis Europharm Limited, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Substantial amendment to a post-authorization observational study to collect long-term safety information (i.e., for 5 years after treatment) associated with voretigene neparvovec (vector and/or transgene), its subretinal injection procedure, the concomitant use of corticosteroids, or a combination of these procedures and products [MAH's response to PSA/S/0114]

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

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[16]

7.2.1. Abrocitinib - CIBINQO (CAP) - EMEA/H/C/005452/MEA 006.1

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: From II-0010
Revised Protocol for PASS B7451120
Title: A Prospective Active Surveillance Study to Monitor Growth, Development, and Maturation Among Adolescents with Atopic Dermatitis Exposed to Abrocitinib" (as listed in PART III of the EU Risk Management Plan (Version 4.4)

Action: For adoption of advice to CHMP

[14] 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
[15] In accordance with Article 107n of Directive 2001/83/EC
[16] In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

7.2.2. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/MEA 003.4

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: PASS Study No. PS0036 (non-imposed/non-interventional)
Bimekizumab pregnancy exposure and outcome registry. An OTIS Autoimmune Diseases in Pregnancy Study.
The objective of this study is to assess maternal, foetal and infant outcomes among people who become pregnant while exposed to bimekizumab relative to the outcomes in 2 matched comparator populations.
Revised Protocol (Version 3, Amendment #2) / Study No. PS0036

Action: For adoption of advice to CHMP

7.2.3. Cannabidiol - EPIDYOLEX (CAP) - EMEA/H/C/004675/MEA 012

Applicant: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: From initial MAA
Proposal for change in data collection for PASS GWEP21042
A Prospective, Observational Cohort Study to Assess Long-Term Safety in Patients Prescribed Epidyolex with a Focus on Drug-induced Liver Injury (DILI).

Action: For adoption of advice to CHMP

7.2.4. Covid-19 Vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - EMEA/H/C/005808/MEA 004.8

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: ***Updated Protocol / Study 2019nCoV-402*** Protocol version 5.0
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

Action: For adoption of advice to CHMP

7.2.5. Covid-19 Vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - EMEA/H/C/005808/MEA 006.5

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: ***Updated Protocol / Study 2019nCoV-404*** Protocol version 5.0
US Post-authorisation safety study to evaluate the pooled of risk of selected AESI within specified time periods after vaccination with Nuvaxovid using a claim and/or EHR database

Action: For adoption of advice to CHMP

7.2.6. Crovalimab - PIASKY (CAP) - EMEA/H/C/006061/MEA 002

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: From initial MAA
Protocol for PASS MO45473 (Cat. 3/non-imposed/RMP)
Crovalimab safety study to characterise safety events and special conditions including pregnancy and infant outcomes in the IPIG registry

Action: For adoption of advice to CHMP

7.2.7. Delgocitinib - ANZUPGO (CAP) - EMEA/H/C/006109/MEA 003

Applicant: LEO Pharma A/S

PRAC Rapporteur: Liana Martirosyan

Scope: From initial MAA
PASS Protocol (Cat. 3/NI/NI)
Delgocitinib cream 20 mg/g in moderate to severe chronic hand eczema and risk of non-melanoma skin cancer: a nationwide registry based long-term post-authorization safety study

Action: For adoption of advice to CHMP

7.2.8. Eptinezumab - VYEPTI (CAP) - EMEA/H/C/005287/MEA 004.6

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Liana Martirosyan

Scope: **Revised Protocol for PASS No 19756N**
Observational, historical cohort study of patients initiating eptinezumab in routine clinical practice and is investigating the long-term cardiovascular safety and real-world use of Eptinezumab.

Action: For adoption of advice to CHMP

7.2.9. Etrasimod - VELSIPITY (CAP) - EMEA/H/C/006007/MEA 001.1

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Bolin

Scope: From Initial MAA:
PASS Revised 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

7.2.10. Filgotinib - JYSELECA (CAP) - EMEA/H/C/005113/MEA 018.1

Applicant: Alfasigma S.p.A.

PRAC Rapporteur: Petar Mas

Scope: From initial MAA
Amended Protocol for PASS GLPG0634-CL-408
Evalutation of the effectiveness of the additional risk minimization measures for filgotinib (Jyseleca) use in patients with moderate to severe active rheumatoid arthritis within European registries

Action: For adoption of advice to CHMP

7.2.11. Lebrikizumab - EBGLYSS (CAP) - EMEA/H/C/005894/MEA 001.1

Applicant: Almirall, S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: From Initial MAA:
Revised Protocol for PASS J2T-MC-B003 (non-imposed)
Title: Observational Database Study of Pregnancy and Infant Outcomes among Women Exposed to Lebrikizumab During Pregnancy

Action: For adoption of advice to CHMP

7.2.12. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 001.11

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: From initial MAA
Revised Protocol for PASS Study No. OP0005 (NINI)
European non-interventional post-authorisation safety study (PASS) related to the adherence to the cardiovascular risk minimization measures for romosozumab, by the EU-ADR Alliance

Action: For adoption of advice to CHMP

7.2.13. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 002.12

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: From Initial MAA:
Revised Protocol for PASS Study No. OP0004:
European non-interventional post-authorisation safety study (PASS) related to serious cardiovascular adverse events of myocardial infarction and stroke for romosozumab by the EU-ADR Alliance to evaluate potential differences in terms of serious cardiovascular adverse events between romosozumab and currently available therapies used in comparable patients in real-world conditions

Action: For adoption of advice to CHMP

7.2.14. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 003.11

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: From Initial MAA:
Revised Protocol for PASS Study No. OP0006
European non-interventional post-authorisation safety study (PASS) related to serious infections risk for romosozumab by the EU-ADR Alliance to evaluate potential differences in terms of serious infection between romosozumab and currently available therapies used in comparable patients in real-world conditions

Action: For adoption of advice to CHMP

7.2.15. Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation - MRESVIA (CAP) - EMEA/H/C/006278/MEA 003.1

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

Scope: ***Updated Study Protocol / mRNA-1345-P902 and mRNA-1345-P903***(RMP (v. 0.4))
mRNA-1345-P902: Post-Authorization Active Surveillance Safety Study Using Secondary Data to Monitor Real-World Safety of the mRNA-1345 Vaccine for respiratory syncytial virus (RSV) in the United States.

mRNA-1345-P903: Post-Authorization Active Surveillance Safety Study Using Secondary Data to Monitor Real-World Safety of the mRNA-1345 Vaccine for respiratory syncytial virus (RSV) in Europe

Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)[17]

None

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

7.4.1. Adalimumab - HUMIRA (CAP) - EMEA/H/C/000481/II/0219

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Karin Bolin

Scope: Submission of the final report from study P10-262 listed as a category 3 study in the RMP. This is a long-term, multi-center, longitudinal, post-marketing observational registry to assess long-term safety and effectiveness of Humira (adalimumab) in children with moderately to severely active polyarticular or polyarticular-course juvenile idiopathic arthritis (JIA). The RMP version 16.1 has also been submitted

Action: For adoption of PRAC Assessment Report

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

7.4.2. Benralizumab - FASENRA (CAP) - EMEA/H/C/004433/II/0054

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Submission of the final report from study D3250R00042 listed as a category 3 study in the RMP. This is a noninterventional, descriptive post authorisation safety study of the incidence of malignancy in severe asthma patients receiving benralizumab and other therapies. The RMP version 7.1 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.3. Human C1-esterase inhibitor - CINRYZE (CAP) - EMEA/H/C/001207/II/0104

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Gabriele Maurer

Scope: Update of sections 4.6, 5.1 and 5.3 of the SmPC based on final results from the Icatibant Outcome Survey (IOS), listed as an imposed PASS in the Annex II. This is a prospective, observational disease registry. The Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the product information in line with the latest QRD template version 10.4 and to update Annex II of the PI

Action: For adoption of PRAC Assessment Report

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

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Mari Thorn

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

Action: For adoption of PRAC Assessment Report

7.4.5. Lenalidomide - REVLIMID (CAP) - EMEA/H/C/000717/II/0130

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of the final report from study CC-5013-MCL-005 listed as a category 3 study in the RMP. This is a non-interventional, post-authorization safety study of patients with relapsed or refractory mantle cell lymphoma to further investigate and characterize the association of lenalidomide with tumor flare reaction and high tumor burden. The RMP version 42.0 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.6. Nivolumab - OPDIVO (CAP) - EMEA/H/C/003985/II/0149

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of the final clinical study report (CSR) for the PASS study CA209234 listed as a category 3 study in the RMP. This is an observational, multicenter, prospective study in patients treated with nivolumab for melanoma and lung cancer in order assess the safety experience, survival, adverse event management, and outcomes of adverse events associated with nivolumab (monotherapy or with ipilimumab) in routine oncology care facilities. The RMP version 42.0 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.7. Sacubitril, valsartan - ENTRESTO (CAP) - EMEA/H/C/004062/WS2802/0070; Sacubitril, valsartan - NEPARVIS (CAP) - EMEA/H/C/004343/WS2802/0067

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the final report for study CLCZ696B2014 listed as a category 3 study in the RMP; this is a non-interventional post-authorization multi-database safety study to characterize the risk of angioedema and other specific safety events of interest in association with use of Entresto (sacubitril/valsartan) in adult patients with heart failure. The RMP version 9.0 for Entresto and Neparvis has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.8. Sacubitril, valsartan - ENTRESTO (CAP) - EMEA/H/C/004062/WS2803/0071; Sacubitril, valsartan - NEPARVIS (CAP) - EMEA/H/C/004343/WS2803/0068

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the final report for study CLCZ696B2015 listed as a category 3 study in the RMP for Entresto and Neparvis; this is a non-interventional post-authorization multi-database safety study to assess the risk of myotoxicity, hepatotoxicity and acute pancreatitis in statin-exposed heart failure patients with or without concomitant use of sacubitril/valsartan. The RMP version 9.0 for Entresto and Neparvis 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. Abatacept - ORENCIA (CAP) - EMEA/H/C/000701/MEA 043.1

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: MAH Response to MEA 043 Study No. IM101240 as adopted in October 2024: Responses to the questions raised during assessment of the third interim report for Study IM101240, An Observational Registry of Abatacept in Patients with Juvenile Idiopathic

Arthritis (JIA).

From R/55:
An Observational Registry of Abatacept in Patients with Juvenile Idiopathic Arthritis is ongoing. The primary objective is to describe the long-term safety of abatacept treatment for JIA in routine clinical practice by quantifying the incidence rates of serious infections, autoimmune disorders, and malignancies. The data in these studies do not change the safety profile of abatacept

Action: For adoption of advice to CHMP

7.5.2. Axicabtagene ciloleucel - YESCARTA (CAP) - EMEA/H/C/004480/ANX 002.7

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: From initial MAA
Fourth Annual Interim Report for PASS KT-EU-471-0117
Title: Long-term, non-interventional study of recipients of Yescarta for treatment of relapsed or refractory Diffuse Large B-cell Lymphoma and Primary Mediastinal B-cell Lymphoma (EU PAS Register no.: EUPAS32539)

Action: For adoption of advice to CAT and CHMP

7.5.3. Cladribine - MAVENCLAD (CAP) - EMEA/H/C/004230/MEA 003.5

Applicant: Merck Europe B.V.

PRAC Rapporteur: Carla Torre

Scope: From initial MAA
PASS study protocol (Study MS700568-0004: Pregnancy outcomes in women exposed to oral cladribine: a multi-country cohort database study - CLEAR)
FIRST INTERIM REPORT

Action: For adoption of advice to CHMP

7.5.4. Inotersen - TEGSEDI (CAP) - EMEA/H/C/004782/MEA 007.6

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: PASS No TG4005 (non-imposed/non-interventional)
Pregnancy surveillance program of women and infants exposed to Tegsedi during pregnancy.
Fourth Interim Report

Action: For adoption of advice to CHMP

7.5.5. Linaclotide - CONSTELLA (CAP) - EMEA/H/C/002490/MEA 009.10

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Martin Huber

Scope: [MAH Response to MEA 009.8 as adopted in October 2024]

PASS Study EVM-18888
Title: Linaclotide Safety Study for the Assessment of Diarrhoea Complications and Associated Risk Factors in Selected European Populations with Irritable Bowel Syndrome with Constipation (IBS-C)

Action: For adoption of advice to CHMP

7.5.6. Ocrelizumab - OCREVUS (CAP) - EMEA/H/C/004043/MEA 004.3

Applicant: Roche Registration GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: ***INTERIM STUDY REPORT*** / PASS Study BA39730:
Long-term surveillance of ocrelizumab-treated patients with Multiple Sclerosis (MANUSCRIPT study; Category 3, non-interventional, multi-source, multi-country, longitudinal cohort study to assess and characterise the long-term safety data, including malignancies, from the use of ocrelizumab in patients with MS)

Action: For adoption of advice to CHMP

7.5.7. Rimegepant - VYDURA (CAP) - EMEA/H/C/005725/MEA 003.2

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Erneholm

Scope: ***First Annual Progress Report, Updated Protocol & SAP*** / Study C4951017 (CV PASS)
(Formerly Biohaven Protocol Number BHV3000-408)
Post-Authorisation Safety Study of Rimegepant in Patients with Migraine and History of Cardiovascular Disease in European Countries

Action: For adoption of advice to CHMP

7.5.8. Turoctocog alfa pegol - ESPEROCT (CAP) - EMEA/H/C/004883/ANX 001.4

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Gabriele Maurer

Scope: From Initial MAA:
Post-authorisation safety study (PASS):
In order to investigate the potential effects of PEG accumulation in the choroid plexus of the brain and other tissues/organs, the MAH should conduct and submit the results of a post-authorisation safety study according to an agreed protocol.

Study ID: NN7088-4029 A multinational, prospective, open labelled, non-controlled, non-interventional post-authorisation study of turoctocog alfa pegol (N8-GP) during long-term routine prophylaxis and treatment of bleeding episodes in patients with haemophilia A.

PASS Fourth Progress Report, Study ID: NN7088-4029

MAH also includes the interim results of the study with the data cut-off date 23-Apr-2023

Action: For adoption of advice to CHMP

7.5.9. Vamorolone - AGAMREE (CAP) - EMEA/H/C/005679/MEA 001.1

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 001 [***Feasibility Interim Study Results / No. SNT-IV-VAM-10***] RSI as adopted in August 2024.
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

None

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. Cholic acid - ORPHACOL (CAP) - EMEA/H/C/001250/S/0056 (without RMP)

Applicant: Theravia

PRAC Rapporteur: Maria Poulianiti

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.2. Eladocagene exuparvovec - UPSTAZA (CAP) - EMEA/H/C/005352/S/0025 (without RMP)

Applicant: PTC Therapeutics International Limited, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CAT and CHMP

8.1.3. Fosdenopterin - NULIBRY (CAP) - EMEA/H/C/005378/S/0012 (without RMP)

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Martin Huber

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.4. Idebenone - RAXONE (CAP) - EMEA/H/C/003834/S/0041 (without RMP)

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Amelia Cupelli

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.5. Tocofersolan - VEDROP (CAP) - EMEA/H/C/000920/S/0050 (without RMP)

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Melinda Palfi

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. Lorlatinib - LORVIQUA (CAP) - EMEA/H/C/004646/R/0040 (with 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

8.2.2. Mosunetuzumab - LUNSUMIO (CAP) - EMEA/H/C/005680/R/0014 (without RMP)

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.3. Pemigatinib - PEMAZYRE (CAP) - EMEA/H/C/005266/R/0019 (without RMP)

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.4. Selumetinib - KOSELUGO (CAP) - EMEA/H/C/005244/R/0019 (without RMP)

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.5. Volanesorsen - WAYLIVRA (CAP) - EMEA/H/C/004538/R/0029 (without RMP)

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Apixaban - APIXABAN ACCORD (CAP) - EMEA/H/C/005358/R/0012 (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. Bevacizumab - AYBINTIO (CAP) - EMEA/H/C/005106/R/0022 (without RMP)

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Insulin aspart - INSULIN ASPART SANOFI (CAP) - EMEA/H/C/005033/R/0020 (without RMP)

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Phenylephrine, Ketorolac - OMIDRIA (CAP) - EMEA/H/C/003702/R/0030 (without RMP)

Applicant: Rayner Surgical (Ireland) Limited

PRAC Rapporteur: Jan Neuhauser

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

None

10.4. Scientific Advice

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

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

11.1. Safety related variations of the marketing authorisation

11.1.1. Levonorgestrel (NAP) - DE/H/xxxx/WS/1803

Applicant: Jenapharm GmbH & Co. KG (subsidiary of Bayer) (Mirena, Jaydess, Kyleena)

PRAC Lead: Martin Huber

Scope: PRAC consultation on a worksharing variation procedure (DE/H/xxxx/WS/1803) to update the product information in order to emphasize the need for ultrasound examination after levonorgestrel-intrauterine system (LNG-IUS) insertion to assure correct location of the IUS and to prevent (partial) perforation, following the conclusion of the PSUSA procedure on levonorgestrel (PSUSA/00010828/202305) concluded in January 2024, at request of Germany

Action: For adoption of advice to Member States

11.2. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC membership

Action: For information

12.1.2. Vote by proxy

Action: For information

12.1.3. Committee Meeting Dates for 2027-2028

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 – Q4 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. PRAC strategic review and learning meeting (SRLM) under the Polish presidency of the European Union (EU) Council – Warsaw, Poland, 1 - 2 April 2025 - agenda

PRAC lead: Adam Przybylkowski

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

None

12.8. Planning and reporting

12.8.1. EU Pharmacovigilance system - quarterly workload measures and performance indicators – Q4 2024 and predictions

Action: For discussion

12.8.2. PRAC workload statistics – Q4 2024

Action: For discussion

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

PRAC lead: Lukacisinova

Action: For discussion

12.10.3. PRAC workload in 2025 based on new PSUR frequencies predicted by the EURD Tool

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.10.4. PSURs repository

None

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

Action: For adoption

12.11. Signal management

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

PRAC lead: Martin Huber

Action: For discussion

12.11.2. Signals and safety analytics project – update on activities

PRAC lead: Martin Huber

Action: For discussion

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.13.2. Guideline on masking of personal data in Individual Case Safety Reports (ICSRs) submitted to EudraVigilance

Action: For adoption

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

None

12.21. Others

12.21.1. Concept paper on clinical evaluation of therapeutic radiopharmaceuticals in oncology (EMA/CHMP/451705/2024)

Action: For discussion

12.21.2. Good Pharmacovigilance Practice (GVP) Guideline on product or population specific considerations III: pregnancy and breastfeeding

PRAC lead: Ulla Wändel Liminga

Action: For discussion

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

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.21.4. HES court case - key points from the General Court's judgment

Action: For discussion

12.21.5. IRIS training - demo

Action: For discussion

12.21.6. Revision of the procedural advice on CHMP/CAT/PRAC Rapporteur/Co-Rapporteur appointment principle

Action: For adoption

12.21.7. US-FDA-EMA collaboration on gene therapies for (ultra) rare diseases (CoGenT) pilot

Action: For information

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.

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