24 November 2023
EMA/PRAC/477373/2023
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 27-30 November 2023

Chair: Sabine Straus – Vice-Chair: Martin Huber

27 November 2023, 13:00 – 19:30, room 1C / via teleconference

28 November 2023, 08:30 – 19:30, room 1C / via teleconference

29 November 2023, 08:30 – 19:30, room 1C / via teleconference

30 November 2023, 08:30 – 16:00, room 1C / via teleconference

Organisational, regulatory and methodological matters (ORGAM)

14 December 2023, 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 27-30 November 2023. See December 2023 PRAC minutes (to be published post January 2024 PRAC meeting).

1.2. Agenda of the meeting on 27-30 November 2023

Action: For adoption

1.3. Minutes of the previous meeting on 23-26 October 2023

Action: For adoption

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

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

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

3.1. Newly triggered procedures

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

3.3.1. Pseudoephedrine (NAP); pseudoephedrine, acetylsalicylic acid (NAP); pseudoephedrine, acetylcysteine, paracetamol (NAP); pseudoephedrine, acrivastine (NAP); pseudoephedrine, ascorbic acid, paracetamol (NAP); pseudoephedrine, cetirizine (NAP); pseudoephedrine, ebastine (NAP); pseudoephedrine, guaifenesin (NAP); pseudoephedrine, ibuprofen (NAP); pseudoephedrine, chlorphenamine (NAP); pseudoephedrine, chlorphenamine, codeine (NAP); pseudoephedrine, chlorphenamine, dextromethorphan (NAP); pseudoephedrine, chlorphenamine, paracetamol (NAP); pseudoephedrine, chlorphenamine, dextromethorphan, paracetamol (NAP); pseudoephedrine, dextromethorphan (NAP); pseudoephedrine, dextromethorphan, paracetamol (NAP); pseudoephedrine, dextromethorphan, ascorbic acid, paracetamol (NAP); pseudoephedrine, dextromethorphan, guaifenesin, paracetamol (NAP); pseudoephedrine, dextromethorphan, guaifenesin, triprolidine (NAP); pseudoephedrine, dextromethorphan, triprolidine (NAP); pseudoephedrine, diphenhydramine, paracetamol (NAP); pseudoephedrine, doxylamine, paracetamol (NAP); pseudoephedrine, loratadine (NAP); pseudoephedrine, paracetamol (NAP); pseudoephedrine, paracetamol, pholcodine (NAP); pseudoephedrine, triprolidine (NAP); pseudoephedrine, triprolidine, guaifenesin (NAP); pseudoephedrine, triprolidine, paracetamol (NAP); pseudoephedrine, desloratadine – AERINAZE (CAP) – EMA/H/A-31/1526

Applicant(s): various

PRAC Rapporteur: Eva Jirsová; PRAC Co-rapporteur: Maia Uusküla

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 (LoOI) or PRAC recommendation to CHMP

3.4. Re-examination procedures[1]

None

3.5. Others

None

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

4. Signals assessment and prioritisation[2]

4.1. New signals detected from EU spontaneous reporting systems

4.1.1. Brolucizumab – BEOVU (CAP)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Signal of scleritis

Action: For adoption of PRAC recommendation

EPITT 20016 – New signal

Lead Member State(s): DE

4.1.2. Doxycycline (NAP)

Applicant: various

PRAC Rapporteur: to be appointed

Scope: Signal of suicidality

Action: For adoption of PRAC recommendation

EPITT 19997 – New signal

Lead Member State(s): NL

4.1.3. Ethambutol (NAP)

Applicant: various

PRAC Rapporteur: to be appointed

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

Action: For adoption of PRAC recommendation

EPITT 20018 – New signal

Lead Member State(s): AT

4.1.4. Glatiramer (NAP)

Applicant: various

PRAC Rapporteur: to be appointed

Scope: Signal of anaphylaxis with a long latency

[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 19990 – New signal

Lead Member State(s): DK

4.1.5. Ivacaftor, tezacaftor, elexacaftor - KAFTRIO (CAP)

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Martin Huber

Scope: Signal of intracranial pressure increased

Action: For adoption of PRAC recommendation

EPITT 20000 – New signal

Lead Member State(s): DE

4.2. New signals detected from other sources

4.2.1. Afatinib - GIOTRIF (CAP)

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Signal of growth of eyelashes

Action: For adoption of PRAC recommendation

EPITT 19987 – New signal

Lead Member State(s): SE

4.3. Signals follow-up and prioritisation

4.3.1. Axicabtagene ciloleucel – YESCARTA (CAP) - EMEA/H/C/004480/SDA/014

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Signal of progressive multifocal leukoencephalopathy (PML)

Action: For adoption of PRAC recommendation

EPITT 19940 – follow up to July 2023

4.3.2. Dabrafenib - TAFINLAR (CAP) - EMEA/H/C/002604/SDA/022; Trametinib - MEKINIST (CAP) - EMEA/H/C/002643/SDA/017

Applicant: Novartis Europharm Limited

PRAC Rapporteur: David Olsen

Scope: Signal of peripheral neuropathy

Action: For adoption of PRAC recommendation

EPITT 19947 – follow up to July 2023

4.3.3. Exenatide - BYDUREON (CAP) - EMEA/H/C/002020/SDA/030, BYETTA (CAP) - EMEA/H/C/000698/SDA/050; Dulaglutide - TRULICITY (CAP) - EMEA/H/C/002825/SDA/010; Insulin glargine, lixisenatide - SULIQUA (CAP) - EMEA/H/C/004243/SDA/009; Lixisenatide - LYXUMIA (CAP) - EMEA/H/C/002445/SDA/017; liraglutide – SAXENDA (CAP) - EMEA/H/C/003780/SDA/020, VICTOZA (CAP) - EMEA/H/C/001026/SDA/040, XULTOPHY (CAP) - EMEA/H/C/002647/SDA/006; Semaglutide – OZEMPIC (CAP) - EMEA/H/C/004174/SDA/008, RYBELSUS (CAP) - EMEA/H/C/004953/SDA/013, WEGOVY (CAP) - EMEA/H/C/005422/SDA/007;

Applicant: AstraZeneca AB (Bydureon, Byetta), Eli Lilly Nederland B.V. (Trulicity, Novo Nordisk A/S (Ozempic, Rybelsus, Saxenda, Victoza, Wegovy, Xultophy), Sanofi Winthrop Industrie (Lyxumia, Suliqua)

PRAC Rapporteur: Menno van der Elst

Scope: Signal of suicidal ideation and self-injurious ideation

Action: For adoption of PRAC recommendation

EPITT 19946 – follow up to July 2023

4.3.4. Pirfenidone – ESBRIET (CAP) - EMEA/H/C/002154/SDA/016, PIRFENIDONE AXUNIO (CAP), PIRFENIDONE VIATRIS (CAP)

Applicant: Axunio Pharma GmbH (Pirfenidone Axunio), Roche Registration GmbH (Esbriet), Viatris Limited (Pirfenidone Viatris)

PRAC Rapporteur: Rhea Fitzgerald

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

Action: For adoption of PRAC recommendation

EPITT 19920 – follow up to May 2023

4.4. Variation procedure(s) resulting from signal evaluation

None

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Apremilast - - EMEA/H/C/006208

Scope: treatment of psoriatic arthritis, psoriasis, Behçet's disease

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

5.1.2. Aprocitentan - - EMEA/H/C/006080

Scope: treatment of resistant hypertension

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

5.1.3. Aumolertinib - - EMEA/H/C/006069

Scope: treatment of non-small cell lung cancer

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

5.1.4. Aztreonam, Avibactam - - EMEA/H/C/006113

Scope (accelerated assessment): treatment of infections (complicated intra-abdominal infection (cIAI), hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) and complicated urinary tract infection (cUTI), including pyelonephritis, and aerobic Gram-negative infections with limited treatment options

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

5.1.5. Buprenorphine - - EMEA/H/C/006188

Scope: treatment of opioid drug dependence

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

5.1.6. Flortaucipir (^{18}F) - - EMEA/H/C/006064

Scope: indicated for Positron Emission Tomography (PET) imaging of the brain

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

5.1.7. Nintedanib - - EMEA/H/C/006179

Scope: treatment of idiopathic pulmonary fibrosis (IPF), chronic fibrosing interstitial lung diseases (ILDs) and lung diseases (ILDs) systemic sclerosis associated interstitial lung disease (SSc-ILD)

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

5.1.8. Omecamtiv mecarbil - - EMEA/H/C/006112

Scope: treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction less than 30%

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

5.1.9. Retifanlimab - - EMEA/H/C/006194, Orphan

Applicant: Incyte Biosciences Distribution B.V.

Scope: Treatment of Merkel cell carcinoma (MCC)

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

5.1.10. Serplulimab - - EMEA/H/C/006170, Orphan

Applicant: Henlius Europe GmbH

Scope: first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)

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

5.1.11. Sugemalimab - - EMEA/H/C/006088

Scope: treatment of adults with metastatic non-small-cell lung cancer (NSCLC)

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

5.1.12. Ustekinumab - - EMEA/H/C/006183

Scope: treatment of Crohn's disease and Ulcerative colitis, treatment of Crohn's disease, Ulcerative colitis, Plaque psoriasis, Paediatric plaque psoriasis and Psoriatic arthritis (PsA)

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. Aflibercept - ZALTRAP (CAP) - EMEA/H/C/002532/II/0071

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Submission of an updated RMP version 5.0 in order to update the Risk Minimization Measures and List of Safety Concerns removing "Nephrotic syndrome", "Cardiac failure and ejection fraction decreased", "Posterior reversible encephalopathy syndrome", "Thrombotic microangiopathy" and "Osteonecrosis of jaw" of the important identified risks, "Reproductive and developmental toxicity" as an important potential risk and "Safety in patients with severe hepatic impairment" of the missing information, following the assessment of PSUSA/00010019/202108

Action: For adoption of PRAC Assessment Report

5.2.2. Baricitinib - OLUMIANT (CAP) - EMEA/H/C/004085/II/0043

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Submission of an updated RMP version 22.1 in order to remove existing additional pharmacovigilance activities (category 3 studies): Study I4V-MC-JAJA (JAJA) and Study I4V-MC-JAJD (JAJD)

Action: For adoption of PRAC Assessment Report

5.2.3. Dasatinib - SPRYCEL (CAP) - EMEA/H/C/000709/II/0090

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Submission of an updated RMP version 18.0 in order to reflect the proposed revised commitments to assess the growth and development disorders and bone mineral metabolism disorders in paediatric subjects

Action: For adoption of PRAC Assessment Report

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

Applicant: Baxter Holding B.V.

PRAC Rapporteur: Eva Jirsová

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

Action: For adoption of PRAC Assessment Report

5.2.5. Ivabradine - CORLENTOR (CAP) - EMEA/H/C/000598/WS2569/0059; IVABRADINE ANPHARM (CAP) - EMEA/H/C/004187/WS2569/0019; PROCORALAN (CAP) - EMEA/H/C/000597/WS2569/0058

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Menno van der Elst

Scope: C.I.11.z - To update the RMP to delete the obsolete products (Ivabradine Egis and Ivabradine Proterapia) that are still mentioned in the RMP

Action: For adoption of PRAC Assessment Report

5.2.6. Meningococcal group A, C, W135 and Y conjugate vaccine - NIMENRIX (CAP) - EMEA/H/C/002226/II/0127

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: David Olsen

Scope: Submission of an updated RMP version 9.0 in order to remove the important potential risks 'Change in meningococcal epidemiology/serogroup replacement' and 'Lack of Efficacy' from the list of the safety concerns, to remove 'Long-term persistence of the vaccine response and need for a booster dose' as missing information and to remove 'Use during pregnancy' from the list of safety concerns

Action: For adoption of PRAC Assessment Report

5.2.7. Sildenafil - REVATIO (CAP) - EMEA/H/C/000638/II/0107

Applicant: Upjohn EESV

PRAC Rapporteur: Menno van der Elst

Scope: Submission of an updated RMP version 8.0 in order to remove "Long-term Mortality" as missing information based on the completion of Study A1481324 - A multinational, multicentre study to assess the effects of oral sildenafil on mortality in adults with pulmonary arterial hypertension (PAH). In addition, the MAH took the opportunity to reflect the completion of the Studies A1481324 and A1481319

Action: For adoption of PRAC Assessment Report

5.2.8. Tocofersolan - VEDROP (CAP) - EMEA/H/C/000920/II/0047

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Melinda Palfi

Scope: Submission of an updated RMP version 10.1 in order to remove all important potential risks and missing information from the list of safety concerns, to align with the new RMP format according to Good Pharmacovigilance Practices Module V Revision 2 and to remove one closed PASS of category 2 (Recordati Rare Diseases's Vedrop registry) from the pharmacovigilance plan

Action: For adoption of PRAC Assessment Report

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

5.3.1. Abrocitinib - CIBINQO (CAP) - EMEA/H/C/005452/II/0010

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Extension of indication to include treatment of adolescents 12 to < 18 years of age with moderate to severe atopic dermatitis for CIBINQO based on final results from non-clinical study 00655292 [21GR211] and interim results from clinical study B7451015; this is a Phase III multi-center, long-term extension study investigating the efficacy and safety of abrocitinib, with or without topical medications, administered to subjects aged 12 years and older with moderate to severe atopic dermatitis. 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 4.1 of the RMP has also been submitted

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

5.3.2. Afamelanotide - SCENESSE (CAP) - EMEA/H/C/002548/II/0044, Orphan

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

Scope: Extension of indication for the prevention of phototoxicity in adolescent patients (12 to under 18 years of age) with erythropoietic protoporphyria (EPP), based on the analysis of the safety and efficacy data available. As a consequence, sections 4.1, 4.2 and 4.4 of the SmPC are updated. The package leaflet is updated in accordance. Version 9.4 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial correction to the product information

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

5.3.3. Agomelatine - VALDOXAN (CAP) - EMEA/H/C/000915/II/0051

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Pernille Harg

Scope: Extension of indication to include new therapeutic indication in adolescents aged 12 to 17 years for the treatment of moderate to severe major depressive episodes, if depression is unresponsive to psychological therapy alone, for Valdoxan, further to the results of the phase 2 (CL2-20098-075) and phase 3 (CL3-20098-076) paediatric clinical studies included in the Paediatric Investigation Plan number EMEA-001181-PIP-11; As a consequence the sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated accordingly. The updated RMP version 25.1 has also been submitted

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

5.3.4. Alendronic acid, colecalciferol - ADROVANCE (CAP) - EMEA/H/C/000759/WS2467/0051; FOSAVANCE (CAP) - EMEA/H/C/000619/WS2467/0054; VANTAVO (CAP) - EMEA/H/C/001180/WS2467/0041

Applicant: Organon N.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Update of sections 4.4 and 4.8 the SmPC in order to include information on the risk of low-energy fractures in bones other than femur based on post-marketing case reports and the literature. The package leaflet and Labelling are updated accordingly. In addition, the MAH 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 and to introduce editorial changes. A justification for not submitting the RMP was provided

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

5.3.5. Alpelisib - PIQRAY (CAP) - EMEA/H/C/004804/II/0022/G

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Menno van der Elst

Scope: Grouped application comprising two type II variations (C.I.4) as follows:
- Update of sections 4.2, 4.4, 4.8 of the SmPC in order to update information on prophylactic use of metformin for hyperglycaemia based on the results from study

CBYL719CES01T (METALLICA). METALLICA is a Phase II study aimed to evaluate the effect of prophylactic use of metformin for hyperglycaemia in HR-positive, HER2-negative, PIK3CA-mutated advanced breast cancer patients treated with alpelisib plus endocrine therapy.
- Update of section 4.8 of the SmPC in order to add "uveitis" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on a cumulative review of the MAH safety database and literature.
The package leaflet and Annex II are 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. Apixaban - ELIQUIS (CAP) - EMEA/H/C/002148/X/0089/G

Applicant: Bristol-Myers Squibb / Pfizer EEIG

PRAC Rapporteur: Menno van der Elst

Scope: Extension application to:
1) Introduce a new pharmaceutical form (granules in single-dose container) associated with a new strength (0.15 mg).
2) Introduce a new pharmaceutical form (coated granules in sachet) associated with 3 new strengths (0.5 mg, 1.5 mg and 2 mg);
The above two line extensions are grouped with a type II - C.I.6.a variation:
Extension of indication to include the treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to less than 18 years of age for Eliquis (all strengths), based on a pre-specified interim analysis from Study CV185325; this is an open-label, multi-centre, randomised, active controlled trial to provide PK data and data on anti-Xa activity to support the extrapolation of efficacy to children, to evaluate safety and efficacy of apixaban in children who require anticoagulation for a venous thromboembolism; As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPCs are updated. The package leaflet and Annex II are updated in accordance. Version 21.0 of the RMP has also been submitted

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

5.3.7. Atezolizumab - TECENTRIQ (CAP) - EMEA/H/C/004143/II/0081

Applicant: Roche Registration GmbH

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension of indication to include, in combination with bevacizumab, adjuvant treatment of adult patients with hepatocellular carcinoma at high risk of recurrence after surgical resection or ablation for TECENTRIQ, based on final results from study WO41535 (IMbrave050); this is a phase III, randomised, multi-centre, international, open-label study, conducted to evaluate the efficacy and safety of adjuvant therapy of atezolizumab in combination with bevacizumab in patients with completely resected or ablated HCC who were at high risk for disease recurrence. 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 28.0 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

5.3.8. Atezolizumab - TECENTRIQ (CAP) - EMEA/H/C/004143/II/0082

Applicant: Roche Registration GmbH

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension of indication to include first-line treatment of adult patients with non-small cell lung cancer (NSCLC) who are ineligible for platinum-based chemotherapy and who do not have EGFR mutant or ALK-positive disease, who have: locally advanced unresectable NSCLC not amenable for definitive chemoradiotherapy, or metastatic NSCLC, for TECENTRIQ, based on final results from study MO29872 (IPSOS); this is a phase 3, open-label, multicenter, randomised study to investigate the efficacy and safety of atezolizumab compared with chemotherapy in patients with treatment naive advanced or recurrent (stage IIIB not amenable for multimodality treatment) or metastatic (stage IV) non-small cell lung cancer who are deemed unsuitable for platinum-containing therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. Version 29.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the product information

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

5.3.9. Bezlotoxumab - ZINPLAVA (CAP) - EMEA/H/C/004136/II/0037

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of the paediatric population (1 to 18 years of age) for ZINPLAVA, based on final results from study MK-6072-001 (MODIFY III) listed as a category 3 study in the RMP; this is a phase 3, randomised, placebo-controlled, parallel-group, multi-site, double-blind trial evaluating the safety, tolerability, pharmacokinetics (PK) and efficacy of a single infusion of bezlotoxumab in paediatric participants from 1 to <18 years of age receiving antibacterial drug treatment for Clostridioides difficile infection (CDI). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 2.3 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the product information

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

5.3.10. Burosumab - CRYSVITA (CAP) - EMEA/H/C/004275/II/0035/G, Orphan

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Grouped variation consisting of: 1) Addition of prefilled syringe presentation for the 10 mg strength; addition of prefilled syringe presentation for the 20 mg strength; addition of prefilled syringe presentation for the 30 mg strength; 2) other quality variations

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

5.3.11. Ciltacabtagene autoleucel - CARVYKTI (CAP) - EMEA/H/C/005095/II/0021, Orphan

Applicant: Janssen-Cilag International NV, ATMP

PRAC Rapporteur: Jo Robays

Scope: Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 1 prior therapy, including an IMiD and a product information, have demonstrated disease progression on or after the last therapy and are refractory to lenalidomide for CARVYKTI, based on interim results from study MMY3002 listed as a specific obligation (SOB/006) in the Annex II. This is an ongoing, Phase 3, randomised, open-label, multicentre study to determine whether treatment with cilta-cel provides an efficacy benefit compared to standard therapy in participants with relapsed and lenalidomide-refractory multiple myeloma. As a consequence, sections 4.1, 4.4, 4.5, 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 MAH took the opportunity to update Annex II of the product information. 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 CAT and CHMP

5.3.12. Cladribine - MAVENCLAD (CAP) - EMEA/H/C/004230/II/0027

Applicant: Merck Europe B.V.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Update of sections 4.5 and 4.6 of the SmPC in order to add information regarding the use of Mavenclad with oral contraceptives based on the final study results from the drug-drug interaction study (MS 700568-0031). This is a randomised, double-blind, 2-period, 2-sequence, crossover Phase I study with a 1-month run-in period to examine the effect of cladribine tablets on the pharmacokinetics of a monophasic oral contraceptive containing ethinyl estradiol and levonorgestrel (microgynon) in pre-menopausal women with Relapsing Multiple Sclerosis (RMS). The Annex II and package leaflet are updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity implement editorial changes to sections 4.2 and 4.4 of the SmPC

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

5.3.13. Defatted powder of Arachis hypogaea L., semen (peanuts) - PALFORZIA (CAP) - EMEA/H/C/004917/II/0014/G

Applicant: Aimmune Therapeutics Ireland Limited

PRAC Rapporteur: Kirsti Villikka

Scope: Grouped variation consisting of:
C.I.6.a (Extension of indication): Extension of indication to include treatment of patients 1 to 3 years old for PALFORZIA, based on final results from study ARC005; this is a Phase 3 randomised, double-blind, placebo-controlled Peanut Oral Immunotherapy Study of Early Intervention for Desensitization (POSEIDON) to evaluate the safety and efficacy of peanut powder in terms of superiority of placebo in children of 1 year to less than 4 years of age with peanut allergy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 6.5 and 8 of the

SmPC are updated. The package leaflet and Labelling were updated accordingly. Version 1.1 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 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.
B.II.e.5.a

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

5.3.14. Enzalutamide - XTANDI (CAP) - EMEA/H/C/002639/II/0063

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include treatment of adult men with high-risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer (nmHSPC) who are unsuitable for salvage-radiotherapy, for Xtandi, based on final results from study MDV3100-13 (EMBARK); this is a phase 3, randomised, efficacy and safety study of enzalutamide plus leuprolide, enzalutamide monotherapy, and placebo plus leuprolide in men with high-risk non-metastatic prostate cancer progressing after definitive therapy. 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 18.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the product information 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

5.3.15. Fexinidazole - FEXINIDAZOLE WINTHROP (Art 58[3]) - EMEA/H/W/002320/II/0016

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Extension of indication to include treatment of both first stage (haemo-lymphatic) and second stage (meningo-encephalitic) of human African trypanosomiasis (HAT) due to Trypanosoma brucei rhodesiense for FEXINIDAZOLE WINTHROP based final results from study DNDI-FEX-07-HAT - Efficacy and safety of fexinidazole in patients with Human African Trypanosomiasis (HAT) due to Trypanosoma brucei rhodesiense: a multicentre, open-label clinical trial; this is a phase-II/III, multicenter, open-label, non-randomised, single-arm clinical trial to assess the efficacy and safety of fexinidazole in patients with r-HAT. As a consequence, sections 4.1, 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

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

5.3.16. Human fibrinogen, human thrombin - VERASEAL (CAP) - EMEA/H/C/004446/II/0027

Applicant: Instituto Grifols, S.A.

[3] 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)

PRAC Rapporteur: Amelia Cupelli

Scope: Extension of indication to include treatment of children for VeraSeal, based on final results from study IG1405; this is a prospective, randomised, active-controlled, single-blind, parallel group clinical trial to evaluate the safety and efficacy of VeraSeal as an adjunct to haemostasis during surgery in paediatric subjects. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. Version 6.0 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. Human normal immunoglobulin - HYQVIA (CAP) - EMEA/H/C/002491/II/0087

Applicant: Baxalta Innovations GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in adults for HyQvia, based on final results from studies 161403 and ABV-771-1001; and interim results from study 161505. 161403 and 161505 are interventional Phase III efficacy and safety studies respectively, while ABV-771-1001 is an interventional Phase I safety study. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet and labelling are updated in accordance. Version 14.0 of the RMP has also been submitted

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

5.3.18. Inotersen - TEGSEDI (CAP) - EMEA/H/C/004782/II/0038, Orphan

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to modify the warning on liver monitoring and drug-induced liver injury and to add 'drug-induced liver injury' to the list of adverse drug reactions (ADRs) with frequency 'not known', following the request in the assessment report for PAM procedure EMEA/H/C/004782/LEG/008. The Annex II and package leaflet are updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor updates to the product information

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

5.3.19. Inotuzumab ozogamicin - BESPONSA (CAP) - EMEA/H/C/004119/II/0026, Orphan

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Update of sections 4.2, 4.6, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric information based on final results from studies ITCC-059 (WI203581) and INO-Ped-ALL-1 (WI235086). Study WI203581 is a Phase 1/2, multicenter, European, multi-cohort, open-label study in pediatric patients (⩾1 and <18 years of age) with R/R CD22-positive Acute Lymphoblastic Leukemia (ALL); and study WI235086 is an open-label, multi-

center Phase 1 study to assess safety and tolerability of InO in Japanese pediatric patients with R/R CD22-positive ALL. The package leaflet is updated accordingly. The RMP version 2.0 has also been submitted

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

5.3.20. Ivacaftor, tezacaftor, elexacaftor - KAFTRIO (CAP) - EMEA/H/C/005269/II/0039, Orphan

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Martin Huber

Scope: Update of sections 4.8 and 5.1 of the SmPC based on interim results from study VX19-445-107 (Study 107) listed as a category 3 study in the RMP; this is a Phase III, open-label study evaluating the long-term safety and efficacy of VX445/TEZ/IVA combination therapy in subjects with cystic fibrosis who 6 years of age and older. The RMP version 7.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes in the SmPC

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

5.3.21. Maralixibat - LIVMARLI (CAP) - EMEA/H/C/005857/II/0003/G, Orphan

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Grouped variation consisting of: 1) Extension of indication to include treatment of Progressive Familial Intrahepatic Cholestasis (PFIC) in patients 2 months of age and older for LIVMARLI, based on results from studies MRX-502, LUM001-501, MRX-503, MRX-800 and MRX-801; MRX-502 is an international, multicenter, randomised, double-blind, placebo-controlled, parallel group Phase 3 study that evaluated the efficacy and safety of maralixibat in PFIC participants aged >12 months to <18 years on a proposed dosage of up to 600 µg/kg BID over 6 months. 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 Annex II are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes; 2) B.I.b.1.b

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

5.3.22. Osilodrostat - ISTURISA (CAP) - EMEA/H/C/004821/II/0017/G, Orphan

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Grouped application comprising two type II variations (C.I.4) as follows:
- 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 LINC4 (study CLCI699C2302 - A Phase III, multi-center, randomised, double-blind, 48 week study with an initial 12 week placebo-controlled period to evaluate the safety and efficacy of osilodrostat in patients with Cushing's disease).
- 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 LINC3 (study CLCI699C2301 - A Phase III, multi-center, double-blind, randomised withdrawal study of LCI699 following a 24 week, single-arm, open-label dose titration and treatment period to evaluate the safety and efficacy of LCI699 for the treatment of patients with Cushing's disease).
The package leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce some minor editorial changes to the product information

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

5.3.23. Osimertinib - TAGRISSO (CAP) - EMEA/H/C/004124/II/0053

Applicant: AstraZeneca AB

PRAC Rapporteur: Menno van der Elst

Scope: Extension of indication to include TAGRISSO in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations, based on final results from study FLAURA2 (D5169C00001); this is a Phase III, open-label, randomised study of osimertinib with or without platinum plus pemetrexed chemotherapy, multicentre study to assess the efficacy and safety of TAGRISSO as first-line treatment in patients with EGFR mutation-positive, locally advanced or metastatic NSCLC. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.3 of the SmPC are updated. The package leaflet is updated in accordance. Version 16 of the RMP has also been submitted

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

5.3.24. Pralsetinib - GAVRETO (CAP) - EMEA/H/C/005413/II/0017

Applicant: Roche Registration GmbH

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of sections 4.2 and 5.2 of the SmPC in order to include information regarding moderate and severe hepatic impairment based on final results from study GP43163 listed as a category 3 study in the RMP; this is a Phase I, open-label, single-dose study to evaluate the pharmacokinetics and safety of pralsetinib in subjects with moderate or severe hepatic impairment compared to healthy subjects. The RMP version 1.8 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the package leaflet and to update the marketing authorisation renewal date in Annex I

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

5.3.25. Ribociclib - KISQALI (CAP) - EMEA/H/C/004213/II/0045

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-

negative, Stage II or Stage III early breast cancer, irrespective of nodal status, in combination with an aromatase inhibitor (AI) for Kisqali based on study CLEE011O12301C (NATALEE); This is a global, Phase III, multicenter, randomised, open-label trial to evaluate efficacy and safety of ribociclib with endocrine therapy (ET) versus ET alone as adjuvant treatment in patients with HR-positive, HER2-negative, early breast cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The package leaflet is updated in accordance. Version 8.0 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

5.3.26. Rilpivirine - EDURANT (CAP) - EMEA/H/C/002264/X/0042/G

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Grouped application consisting of: 1) Extension application to introduce a new pharmaceutical form associated with new strength (2.5 mg dispersible tablets). The new presentation is indicated, in combination with other antiretroviral medicinal products, for the treatment of HIV-1 infection in patients ≥2 to <18 years of age and weighing at least 10 kg to less than 25 kg. The product information and RMP have been updated in accordance. 2) Type II variation (C.I.6.a) to modify the approved therapeutic indication of the already authorised 25 mg film-coated tablets presentation to include, in combination with other antiretroviral medicinal products, treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve and virologically suppressed (HIV-1 RNA less than 50 copies per ml) paediatric patients from 2 to less than 12 years weighing at least 25 kg, based on final results from study studies TMC278-TiDP38-C213 Cohort 2. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The package leaflet and Labelling are updated in accordance. The updated RMP version 10.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to Annex II 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

5.3.27. Sotorasib - LUMYKRAS (CAP) - EMEA/H/C/005522/II/0010/G

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Update of sections 4.2, 4.4, 4.8, 5.2 and 5.3 of the SmPC in order to change in the recommended dose and to update safety and efficacy information based on results from study 20190009 (CodeBreaK 200) listed as a specific obligation in the Annex II, in order to fulfil SOB/001; and results from study 20170543 (CodeBreak 100) phase 2 part B. Study 20190009 is a phase 3 multicentre, randomised, open-label, active-controlled study of AMG 510 versus docetaxel for the treatment of previously treated locally advanced and unresectable or metastatic non-small cell lung cancer (NSCLC) subjects with mutated KRAS p.G12C; while study 20170543 is a phase 1/2, open-label study evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of AMG 510 monotherapy in subjects with advanced solid tumours with KRAS p.G12C mutation and AMG 510

combination therapy in subjects with advanced NSCLC with KRAS p.G12C mutation. The package leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the SmPC

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

5.3.28. Teriflunomide - TERIFLUNOMIDE ACCORD (CAP) - EMEA/H/C/005960/X/0002

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Martin Huber

Scope: Extension application to add a new strength of 7 mg film-coated tablets. The bioequivalence study data were submitted

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

5.3.29. Velaglucerase alfa - VPRIV (CAP) - EMEA/H/C/001249/II/0063

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Martin Huber

Scope: Update of section 4.2 of the SmPC in order to add information to support at-home self-administration of VPRIV by a trained patient and/or a caregiver based on post-marketing data and literature. The package leaflet and Annex IID are updated accordingly. The updated RMP version 13.0 has also been submitted

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. Abaloparatide - ELADYNOS (CAP) - PSUSA/00011029/202304

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.2. Alogliptin; alogliptin, metformin; alogliptin, pioglitazone - INCRESYNC (CAP); VIPDOMET (CAP); VIPIDIA (CAP) - PSUSA/00010061/202304

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.3. Andexanet alfa - ONDEXXYA (CAP) - PSUSA/00010764/202304

Applicant: AstraZeneca AB

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.4. Asciminib - SCEMBLIX (CAP) - PSUSA/00011008/202304

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.5. Atezolizumab - TECENTRIQ (CAP) - PSUSA/00010644/202305

Applicant: Roche Registration GmbH

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.6. Brigatinib - ALUNBRIG (CAP) - PSUSA/00010728/202304

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.7. Bupivacaine[4] - EXPAREL LIPOSOMAL (CAP) - PSUSA/00010889/202304

Applicant: Pacira Ireland Limited

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[4] Liposomal formulation(s) only

6.1.8. Canagliflozin; canagliflozin, metformin - INVOKANA (CAP); VOKANAMET (CAP) - PSUSA/00010077/202303 (with RMP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.9. Capmatinib - TABRECTA (CAP) - PSUSA/00011022/202305

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.10. Cholera vaccine (inactivated, oral) - DUKORAL (CAP) - PSUSA/00000730/202304

Applicant: Valneva Sweden AB

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.11. Cobicistat, elvitegravir, emtricitabine, tenofovir alafenamide - GENVOYA (CAP) - PSUSA/00010449/202305

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Valentina Di Giovanni

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.12. Conestat alfa - RUCONEST (CAP) - PSUSA/00000873/202304

Applicant: Pharming Group N.V

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.13. Coronavirus (COVID-19) vaccine (B.1.351 variant, prefusion Spike delta TM protein, recombinant) - VIDPREVTYN BETA (CAP) - PSUSA/00011035/202305

Applicant: Sanofi Pasteur

PRAC Rapporteur: Jana Lukacisinova

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.14. Delamanid - DELTYBA (CAP) - PSUSA/00010213/202304

Applicant: Otsuka Novel Products GmbH

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.15. Dimethyl fumarate, diroximel fumarate[5] - TECFIDERA (CAP); VUMERITY (CAP) - PSUSA/00010143/202303

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.16. Dolutegravir, rilpivirine - JULUCA (CAP) - PSUSA/00010689/202305

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.17. Dostarlimab - JEMPERLI (CAP) - PSUSA/00010931/202304

Applicant: GlaxoSmithKline (Ireland) Limited

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.18. Drospirenone, estetrol - DROVELIS (CAP); LYDISILKA (CAP) - PSUSA/00010938/202305

Applicant: Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.) (Drovelis), Estetra SRL (Lydisilka)

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[5] Multiple sclerosis indication only

6.1.19. Durvalumab - IMFINZI (CAP) - PSUSA/00010723/202304

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. Emtricitabine - EMTRIVA (CAP) - PSUSA/00001209/202304

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.21. Emtricitabine, tenofovir alafenamide - DESCOVY (CAP) - PSUSA/00010515/202304

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.22. Emtricitabine, tenofovir disoproxil - TRUVADA (CAP) - PSUSA/00001210/202304

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.23. Erenumab - AIMOVIG (CAP) - PSUSA/00010699/202305

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Kirsti Villikka

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.24. Febuxostat - ADENURIC (CAP) - PSUSA/00001353/202304

Applicant: Menarini International Operations Luxembourg S.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.25. Fenofibrate, pravastatin - PRAVAFENIX (CAP) - PSUSA/00001363/202304

Applicant: Laboratoires SMB s.a.

PRAC Rapporteur: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.26. Fostamatinib - TAVLESSE (CAP) - PSUSA/00010819/202304

Applicant: Instituto Grifols, S.A.

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.27. Fulvestrant - FASLODEX (CAP) - PSUSA/00001489/202304

Applicant: AstraZeneca AB

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.28. Glycopyrronium bromide, formoterol - BEVESPI AEROSPHERE (CAP) - PSUSA/00010739/202304

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.29. Golimumab - SIMPONI (CAP) - PSUSA/00001560/202304

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.30. Hepatitis B surface antigen, CpG 1018 adjuvant - HEPLISAV B (CAP) - PSUSA/00010919/202305

Applicant: Dynavax GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.31. Insulin glulisine - APIDRA (CAP) - PSUSA/00001752/202304

Applicant: Sanofi-Aventis Deutschland GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.32. Ivacaftor, tezacaftor, elexacaftor - KAFTRIO (CAP) - PSUSA/00010868/202304

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.33. Linzagolix choline - YSELTY (CAP) - PSUSA/00010998/202305

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. Loncastuximab tesirine - ZYNLONTA (CAP) - PSUSA/00011027/202304

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.35. Meningococcal group A, C, W135, Y conjugate vaccine[6] - MENQUADFI (CAP); NIMENRIX (CAP) - PSUSA/00010044/202304

Applicant: Sanofi Pasteur (MenQuadfi), Pfizer Europe MA EEIG (Nimenrix)

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[6] Conjugated to tetanus toxoid carrier protein

6.1.36. Mitotane - LYSODREN (CAP) - PSUSA/00002075/202304

Applicant: HRA Pharma Rare Diseases

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.37. Nintedanib[7] - OFEV (CAP) - PSUSA/00010319/202304

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.38. Nirsevimab - BEYFORTUS (CAP) - PSUSA/00011026/202304

Applicant: AstraZeneca AB

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. Parathyroid hormone - NATPAR (CAP) - PSUSA/00010591/202304

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.40. Parecoxib - DYNASTAT (CAP) - PSUSA/00002314/202303

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. Pegcetacoplan - ASPAVELI (CAP) - PSUSA/00010974/202305

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

[7] Respiratory indication only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.42. Pemigatinib - PEMAZYRE (CAP) - PSUSA/00010923/202304

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.43. Potassium citrate, potassium hydrogen carbonate - SIBNAYAL (CAP) - PSUSA/00010932/202304

Applicant: Advicenne

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - ERVEBO (CAP) - PSUSA/00010834/202305

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Remdesivir (Veklury) - VEKLURY (CAP) - PSUSA/00010840/202305

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Ripretinib - QINLOCK (CAP) - PSUSA/00010962/202305

Applicant: Deciphera Pharmaceuticals (Netherlands) B.V.

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Sacituzumab govitecan - TRODELVY (CAP) - PSUSA/00010959/202304

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. Selpercatinib - RETSEVMO (CAP) - PSUSA/00010917/202305

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.49. Somatrogon - NGENLA (CAP) - PSUSA/00010982/202304

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.50. Tafamidis - VYNDAQEL (CAP) - PSUSA/00002842/202305

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.51. Tenofovir disoproxil - VIREAD (CAP) - PSUSA/00002892/202303 (with RMP)

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.52. Tirzepatide - MOUNJARO (CAP) - PSUSA/00011019/202305

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.53. Tixagevimab, cilgavimab - EVUSHELD (CAP) - PSUSA/00010992/202305

Applicant: AstraZeneca AB

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.54. Tremelimumab - IMJUDO (CAP); TREMELIMUMAB ASTRAZENECA (CAP) - PSUSA/00011038/202304

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.55. Tucatinib - TUKYSA (CAP) - PSUSA/00010918/202304

Applicant: Seagen B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.56. Volanesorsen - WAYLIVRA (CAP) - PSUSA/00010762/202305

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.57. Zanubrutinib - BRUKINSA (CAP) - PSUSA/00010960/202305

Applicant: BeiGene Ireland Ltd

PRAC Rapporteur: Menno van der Elst

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. Bortezomib - BORTEZOMIB ACCORD (CAP); BORTEZOMIB FRESENIUS KABI (CAP); BORTEZOMIB HOSPIRA (CAP); BORTEZOMIB SUN (CAP); VELCADE (CAP); NAP - PSUSA/00000424/202304

Applicant: Accord Healthcare S.L.U. (Bortezomib Accord), Fresenius Kabi Deutschland GmbH (Bortezomib Fresenius Kabi), Pfizer Europe MA EEIG (Bortezomib Hospira), Sun Pharmaceutical Industries Europe B.V. (Bortezomib SUN), Janssen-Cilag International N.V. (VELCADE), various

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.2. Ivabradine - CORLENTOR (CAP); IVABRADINE ANPHARM (CAP); PROCORALAN (CAP); NAP - PSUSA/00001799/202304

Applicant: ANPHARM Przedsiebiorstwo Farmaceutyczne S.A. (Ivabradine Anpharm), Les Laboratoires Servier (Corlentor, Procoralan), various

PRAC Rapporteur: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.3. Somatropin - NUTROPINAQ (CAP); OMNITROPE (CAP); NAP - PSUSA/00002772/202303

Applicant: Ipsen Pharma (NutropinAq), Sandoz GmbH (Omnitrope), various

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.4. Tacrolimus[8] - PROTOPIC (CAP); NAP - PSUSA/00002840/202303

Applicant: LEO Pharma A/S (Protopic), various

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[8] Topical formulation(s) only

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

6.3.1. Acarbose (NAP) - PSUSA/00000017/202303

Applicant(s): various

PRAC Lead: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.2. Aceclofenac (NAP) - PSUSA/00000022/202303

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Benzyl nicotinate, camphor, dimethyl sulfoxide, nonivamide, turpentine oil; nicoboxil, nonivamide (NAP) - PSUSA/00010584/202303

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.4. Ciprofloxacin[9] (NAP) - PSUSA/00000775/202304

Applicant(s): various

PRAC Lead: Karen Pernille Harg

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. Clarithromycin (NAP) - PSUSA/00000788/202304

Applicant(s): various

PRAC Lead: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

[9] Systemic use only

6.3.6. Cytarabine (NAP) - PSUSA/00000911/202303

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.7. Deproteinised hemoderivative of calf blood; deproteinised hemoderivative of calf blood, macrogol 400 (NAP) - PSUSA/00010600/202303

Applicant(s): various

PRAC Lead: Jana Lukačišinová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. Doxylamine (NAP) - PSUSA/00001174/202304

Applicant(s): various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.9. Dronabinol, cannabidiol (NAP) - PSUSA/00010844/202304

Applicant(s): various

PRAC Lead: Liana Gross-Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. Enalapril (NAP) - PSUSA/00001211/202303

Applicant(s): various

PRAC Lead: Mari Thörn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. Epinephrine, mepivacaine hydrochloride; mepivacaine, norepinephrine; mepivacaine (NAP) - PSUSA/00001979/202303

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. Estradiol; estradiol, prednisolone[10] (NAP) - PSUSA/00010441/202304

Applicant(s): various

PRAC Lead: Rugilė Pilvinienė

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. Fentanyl[11] (NAP) - PSUSA/00001370/202304

Applicant(s): various

PRAC Lead: Liana Gross-Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.14. Foscarnet (NAP) - PSUSA/00001472/202303

Applicant(s): various

PRAC Lead: Liana Gross-Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.15. Gentamicin[12] (NAP) - PSUSA/00009159/202303

Applicant(s): various

PRAC Lead: Valentina Di Giovanni

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.16. Isotretinoin (NAP) - PSUSA/00010488/202305

Applicant(s): various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

[10] Only cream/balm/emulsion for application in the female genital area
[11] Transdermal patches, solution for injection
[12] Systemic use only

6.3.17. Ivabradine, metoprolol (NAP) - PSUSA/00010381/202304

Applicant(s): various

PRAC Lead: Menno van der Elst

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.18. Lavender oil (NAP) - PSUSA/00010810/202304

Applicant(s): various

PRAC Lead: Gudrun Thengilsdottir

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.19. Methylphenobarbital (NAP) - PSUSA/00002025/202303

Applicant(s): various

PRAC Lead: Benjamin Micallef

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.20. Mometasone furoate, olopatadine (NAP) - PSUSA/00010957/202304

Applicant(s): various

PRAC Lead: Mari Thörn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.21. Nortriptyline (NAP) - PSUSA/00002192/202303

Applicant(s): various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.22. Ofloxacin[13] (NAP) - PSUSA/00002203/202304

Applicant(s): various

PRAC Lead: Petar Mas

[13] Systemic use only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.23. Pimecrolimus (NAP) - PSUSA/00002411/202303

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.24. Piribedil (NAP) - PSUSA/00002436/202303

Applicant(s): various

PRAC Lead: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.25. Piroxicam (NAP) - PSUSA/00002438/202304

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.26. Porfimer (NAP) - PSUSA/00010332/202304

Applicant(s): various

PRAC Lead: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.27. Pravastatin (NAP) - PSUSA/00002500/202303

Applicant(s): various

PRAC Lead: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.28. Racecadotril (NAP) - PSUSA/00002602/202303

Applicant(s): various

PRAC Lead: Mónica Martínez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.29. Rifamycin (NAP) - PSUSA/00002641/202304

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.30. Sodium tetradecyl sulphate (NAP) - PSUSA/00002767/202304

Applicant(s): various

PRAC Lead: Jana Lukačišinová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.31. Triamcinolone[14] (NAP) - PSUSA/00010292/202303

Applicant(s): various

PRAC Lead: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.32. Venlafaxine (NAP) - PSUSA/00003104/202305

Applicant(s): various

PRAC Lead: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/LEG 057

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Submission of a cumulative review of cases of hepatotoxicity and drug-induced liver

[14] Intraocular formulations only

injury (DILI) associated with ustekinumab use following the assessment of the PSUSA procedure PSUSA/00003085/202212 concluded in September 2023[15]

Action: For adoption of advice to CHMP

6.5. Variation procedure(s) resulting from PSUSA evaluation

None

6.6. Expedited summary safety reviews[16]

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[17]

7.1.1. Ketoconazole - Ketoconazole HRA (CAP) - EMEA/H/C/PSA/S/0109

Applicant: HRA Pharma Rare Diseases

PRAC Rapporteur: Petar Mas

Scope: Substantial amendment to a protocol for 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

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

7.1.2. Selumetinib - KOSELUGO (CAP) - EMEA/H/C/PSA/S/0108

Applicant: AstraZeneca AB

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Substantial amendment to a PASS of paediatric patients initiating selumetinib in order to confirm the long-term safety of selumetinib in the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric patients with NF1 aged 3 years and above

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

[15] Meeting held on 28-31 August 2023
[16] Submission of expedited summary safety reports for review in addition to the requirements for submission of PSUR(s) falling within the pandemic period and requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC
[17] In accordance with Article 107n of Directive 2001/83/EC

7.1.3. Valproate[18] (NAP) - EMEA/H/N/PSP/J/0074.8

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

PRAC Rapporteur: Jean-Michel Dogné

Scope: Responses to the 2nd RSI of the 2nd Interim report: Observational study to evaluate and identify the best practices for switching of valproate in clinical practice [MAH's response to PSP/J/0074.7]

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

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

7.2.1. Anifrolumab - SAPHNELO (CAP) - EMEA/H/C/004975/MEA 001.2

Applicant: AstraZeneca AB

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: Revised protocol for a non-imposed PASS Study D3461R00028: A multiple database study of the use (and safety) of anifrolumab in women with SLE during pregnancy.

Action: For adoption of advice to CHMP

7.2.2. Ataluren - TRANSLARNA (CAP) - EMEA/H/C/002720/MEA 002.10

Applicant: PTC Therapeutics International Limited

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: MAH’s response to MEA 002.9 [post-approval registry Protocol PTC124-GD-0250-DMD: Long-Term Observational Study of Translarna Safety and Effectiveness in Usual Care] as per request for supplementary information (RSI) adopted in July 2023

Action: For adoption of advice to CHMP

7.2.3. Baricitinib - OLUMIANT (CAP) - EMEA/H/C/004085/MEA 015.1

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: MAH’s response to MEA 015 [submission of a protocol for study I4V-MC-B025: Rheumatologist and Dermatologist Survey to Assess the Effectiveness of the Risk Minimisation Measures (RMM) for Olumiant (baricitinib), a JAK1/2 Inhibitor] as per request for supplementary information (RSI) adopted in July 2023

Action: For adoption of advice to CHMP

[18] Valproic acid, sodium valproate, valproate pivoxil, valproate semisodium, valpromide, valproate bismuth, calcium valproate, valproate magnesium
[19] In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

7.2.4. Baricitinib - OLUMIANT (CAP) - EMEA/H/C/004085/MEA 016.1

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: MAH's response to MEA 016 [Submission of a protocol for study I4V-MC-B038: Baricitinib Drug Utilisation Study: Assessment of Effectiveness of New Recommendations for Use Based on Secondary Data Sources in France, Germany, The Netherlands, and Sweden. This study aims to assess the utilisation of baricitinib in patients with RA, AA, or AD with respect to the new recommendations further to the completion of the Pharmacovigilance article 20 in the aRMMs (DHPC, Healthcare Professional educational materials, and Patient Alert Card)] as per request for supplementary information (RSI) adopted in July 2023

Action: For adoption of advice to CHMP

7.2.5. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/MEA 002.3

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: From Initial MAA: Bimekizumab real-world outcomes study: The goal of this study is to evaluate any potential increase in the risk of safety outcomes of interest in bimekizumab exposed PSO patients compared to PSO patients exposed to other biologics (e.g., anti TNF, anti-IL-23, but not anti IL 17)

Action: For adoption of advice to CHMP

7.2.6. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/MEA 004.2

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: From Initial MAA: An observational cohort study to evaluate bimekizumab exposure during pregnancy. To monitor the safety of bimekizumab use in pregnancy

Action: For adoption of advice to CHMP

7.2.7. Coronavirus (COVID-19) vaccine (ChAdOx1-S [recombinant]) - VAXZEVRIA (CAP) - EMEA/H/C/005675/MEA 006.10

Applicant: AstraZeneca AB

PRAC Rapporteur: Jean-Michel Dogné

Scope: From Initial MAA: COVID-19 Vaccines International Pregnancy Registry of Women Exposed to AZD1222 Immediately Before or During Pregnancy

Action: For adoption of advice to CHMP

7.2.8. Coronavirus (COVID-19) vaccine (Ad26.COV2-S, recombinant) - JCOVDEN (CAP) - EMEA/H/C/005737/MEA 007.1

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: From Initial MAA: COVID-19 Vaccines International Pregnancy Exposure Registry (C VIPER) (VAC31518COV4005), to assess the occurrence of obstetric, neonatal, and infant outcomes among women administered with Ad26.COV2.S during pregnancy. (Cat.3)

Action: For adoption of advice to CHMP

7.2.9. Coronavirus (COVID-19) vaccine (Ad26.COV2-S, recombinant) - JCOVDEN (CAP) - EMEA/H/C/005737/MEA 077

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Results of the test made on samples from suspected TTS cases from study COV3001 in a platelet activation assay, namely PF4-induced platelet activation assay (PIPAA); the assay also tests in heparin independent conditions.
Platelet Factor 4-Induced Platelet Activation Assessment of Selected Samples from the VAC31518COV3001 Study. Title: A Randomised, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older

Action: For adoption of advice to CHMP

7.2.10. Daridorexant - QUVIVIQ (CAP) - EMEA/H/C/005634/MEA 003.1

Applicant: Idorsia Pharmaceuticals Deutschland GmbH

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: To compare the maternal, foetal, and infant outcomes of women exposed to daridorexant during pregnancy to an unexposed control population

Action: For adoption of advice to CHMP

7.2.11. Dupilumab - DUPIXENT (CAP) - EMEA/H/C/004390/MEA 011

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: From II/0060: Title: Registry-based study to evaluate the long-term safety of dupilumab in children aged ≥ 6 months to <6 years with moderate-to-severe Atopic Dermatitis using the PEDISTAD registry

Action: For adoption of advice to CHMP

7.2.12. Efgartigimod alfa - VYVGART (CAP) - EMEA/H/C/005849/MEA 002.2

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: From Initial MAA: PASS to characterize the risks and missing information outlined in this risk management plan and evaluate whether there are specific and/or unexpected

patterns of adverse events

Action: For adoption of advice to CHMP

7.2.13. Efgartigimod alfa - VYVGART (CAP) - EMEA/H/C/005849/MEA 004.2

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: MAH's response to MEA 004.1 [Submission of a protocol for a PASS to characterise the missing information use in pregnant woman outlined in the risk management plan] as per request for supplementary information (RSI) adopted in July 2023

Action: For adoption of advice to CHMP

7.2.14. Ozanimod - ZEPOSIA (CAP) - EMEA/H/C/004835/MEA 005.2

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: MAH's response to MEA 005.1 [protocol for study IM0471037: a PASS titled 'Long-term real-world safety of ozanimod – A PASS in patients diagnosed with ulcerative colitis'. This study is a category 3 study (required additional pharmacovigilance activity - UC indication) listed in the RMP version 3.0] as per the request for supplementary information (RSI) adopted in June 2023

Action: For adoption of advice to CHMP

7.2.15. Respiratory syncytial virus vaccine (bivalent, recombinant) - ABRYSVO (CAP) - EMEA/H/C/006027/MEA 002

Applicant: Pfizer Europe Ma EEIG

PRAC Rapporteur: Menno van der Elst

Scope: Title: A PASS of Guillain-Barré Syndrome (GBS) Following ABRYSVOTM Among Older Adults in the United States

Action: For adoption of advice to CHMP

7.2.16. Risankizumab - SKYRIZI (CAP) - EMEA/H/C/004759/MEA 009.1

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Gross-Martirosyan

Scope: MAH's response to MEA 009 [Protocol for study P23-653 (non-imposed/non-interventional): Pregnancy Exposure and Outcomes for Women with Crohn's Disease Treated with Risankizumab. A comparative cohort study to describe risankizumab exposure in pregnant patients with Crohn's disease, and compare pregnancy and infant outcomes to pregnant patients with Crohn's disease who were treated with alternative therapies (e.g., biologics). In addition, descriptive analyses of pregnancy outcomes in patients with Crohn's disease without exposure to any treatments under investigation will also be conducted] as

per request for supplementary information (RSI) adopted in June 2023.

Action: For adoption of advice to CHMP

7.2.17. Somapacitan - SOGROYA (CAP) - EMEA/H/C/005030/MEA 005

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Martin Huber

Scope: From X/0006/G: Paediatric GHD register-based study: A non-interventional, observational, register-based study to investigate long-term safety and clinical parameters of somapacitan treatment in paediatric patients with GHD in the setting of routine clinical practice

Action: For adoption of advice to CHMP

7.2.18. Tezepelumab - TEZSPIRE (CAP) - EMEA/H/C/005588/MEA 005

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: From initial MAA An observational multi-country PASS to evaluate the risk of serious adverse cardiovascular events in adolescent and adult patients with severe asthma taking Tezepelumab

Action: For adoption of advice to CHMP

7.2.19. Upadacitinib - RINVOQ (CAP) - EMEA/H/C/004760/MEA 004.5

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: MAH's response to MEA 004.4 [amendment to a previously agreed protocol for study P19-141: a long-term PASS of upadacitinib use in rheumatoid arthritis (RA) patients in the US in order to: 1) compare the incidence of malignancy, non-melanoma skin cancer (NMSC), major adverse cardiovascular events (MACE), venous thromboembolism (VTE) and serious infection events in adults with RA who receive upadacitinib in the course of routine clinical care relative to those who receive biologic therapy for the treatment of RA; 2) describe the incidence rates of herpes zoster, opportunistic infections and evidence of druginduced liver injury (DILI); 3) describe the incidence of the above outcomes in very elderly patients (aged ≥ 75 years); 4) characterise VTE clinical risk factors and baseline biomarkers in a sub-study of new initiators of upadacitinib and comparator biologic therapies] as per request for supplementary information (RSI) adopted in June 2023

Action: For adoption of advice to CHMP

7.2.20. Upadacitinib - RINVOQ (CAP) - EMEA/H/C/004760/MEA 005.3

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Upadacitinib Drug Utilisation Study (DUS) for aRMM Effectiveness Evaluation to describe the baseline characteristics of new users of upadacitinib (e.g., demographics, medical history, medical condition associated with upadacitinib use, and concomitant medication use), and in a similar manner, to describe new users of a bDMARD for comparison

Action: For adoption of advice to CHMP

7.2.21. Upadacitinib - RINVOQ (CAP) - EMEA/H/C/004760/MEA 012.4

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Evaluation of the Effectiveness of Additional Risk Minimisation Measures for Upadacitinib in the Treatment of Atopic Dermatitis

Action: For adoption of advice to CHMP

7.2.22. Upadacitinib - RINVOQ (CAP) - EMEA/H/C/004760/MEA 016.2

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: Title: Drug Utilization Study for Evaluation of the Effectiveness of Additional Risk Minimisation Measures for Upadacitinib in the Treatment of Ulcerative Colitis in Sweden and Denmark

Action: For adoption of advice to CHMP

7.2.23. Velaglucerase alfa - VPRIV (CAP) - EMEA/H/C/001249/MEA 030

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Martin Huber

Scope: A Survey among Patients, Caregivers and Home Infusion Nurses based in the European Union to Assess their Awareness and Understanding of Educational Materials (EM) Supporting VPRIV Infusion at Home. Objectives: To determine whether patients/caregivers and home infusion nurses appropriately understand and implement the EM associated with VPRIV home infusion. Specifically, to assess the proportion of patients/caregivers and home infusion nurses who are aware of the EM; who understand the EM; and who use the EM. Safety concerns addressed: Infusion-related reactions, including allergic-type hypersensitivity reactions

Action: For adoption of advice to CHMP

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

7.3.1. Levofloxacin – QUINSAIR (CAP) - EMEA/H/C/PSR/S/0046

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Final study report for a post-marketing, observational safety study of Quinsair (levofloxacin hemihydrate) in patients with cystic fibrosis (CF) to evaluate the long-term safety compared to other inhaled approved antibiotic therapies in CF patients

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

7.3.2. Valproate[21] (NAP) - EMEA/H/N/PSR/J/0043

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

PRAC Rapporteur: Liana Gross-Martirosyan

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

Action: Feedback from the stakeholder's and SAG meetings

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

7.4.1. Dolutegravir, rilpivirine - JULUCA (CAP) - EMEA/H/C/004427/II/0054

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Nathalie Gault

Scope: Submission of the final report from non-interventional PASS study COMBINE-2 listed as a category 3 study in the RMP. This is a real-world evidence study to evaluate effectiveness of two drug regimen, antiretroviral therapy with integrase inhibitors plus a reverse transcriptase inhibitor. The RMP version 6.0 has also been submitted in order to remove the important identified risk of ''drug resistance"

Action: For adoption of PRAC Assessment Report

7.4.2. Empagliflozin, linagliptin - GLYXAMBI (CAP) - EMEA/H/C/003833/WS2571/0055; Empagliflozin - JARDIANCE (CAP) - EMEA/H/C/002677/WS2571/0082; Empagliflozin, metformin - SYNJARDY (CAP) - EMEA/H/C/003770/WS2571/0076

Applicant: Boehringer Ingelheim International GmbH

[20] In accordance with Article 107p-q of Directive 2001/83/EC
[21] Valproic acid, sodium valproate, valproate pivoxil, valproate semisodium, valpromide, valproate bismuth, calcium valproate, valproate magnesium
[22] 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

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the final report from study 1245-0201. This is an observational PASS to assess the risk of acute pancreatitis in type 2 diabetes mellitus (T2DM) patients newly initiating empagliflozin compared to other oral non-incretin/non-sodium glucose co-transporter-2 inhibitors (SGLT2i)-containing glucose lowering drugs. The RMP versions 22.0, 15.0 and 10.0 have also been submitted for Jardiance, Synjardy and Glyxambi, respectively

Action: For adoption of PRAC Assessment Report

7.4.3. Filgrastim - NIVESTIM (CAP) - EMEA/H/C/001142/II/0074/G

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Kirsti Villikka

Scope: Grouped application consisting of:
C.I.13: Submission of the final report from non-interventional PASS study ZOB-NIV-1513/C1121008 listed as a category 3 study in the RMP. This is a multinational, multi-centre, prospective, non-interventional, PASS in Healthy Donors (HDs) exposed to nivestim (biosimilar filgrastim) for Haematopoietic Stem Cell (HSC) Mobilisation (NEST). The RMP version 12 has also been submitted.
C.I.11 for RMP: Submission of an updated RMP version 12.0 in order to align it with the reference product, Neupogen, RMP v. 6.3 dated June 2022

Action: For adoption of PRAC Assessment Report

7.4.4. Golimumab - SIMPONI (CAP) - EMEA/H/C/000992/II/0117/G

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Mari Thorn

Scope: Grouped application consisting of:
C.I.13: Submission of the final report from study UC Nordic (MK-8259-013) listed as a category 3 study in the RMP. This is a Non-interventional Observational Longitudinal Post Authorisation Safety Study (PASS) of SIMPONI in Treatment of Ulcerative Colitis using Nordic National Health Registries.
C.I.13: Submission of the final report from study ENEIDA (MK-8259-042) listed as a category 3 study in the RMP. This is a PASS of Golimumab in ulcerative colitis (UC) Using the Spanish ENEIDA Registry. The RMP version 27.1 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.5. Hepatitis B surface antigen (rDNA) - HEPLISAV B (CAP) - EMEA/H/C/005063/II/0031

Applicant: Dynavax GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from study DV2-HBV-28 - Post-marketing observational surveillance study to evaluate pregnancy outcomes among women who receive HEPLISAV-B or Engerix-

B; HBV-28 was conducted using the same patient population as two observational post-marketing surveillance studies designed to evaluate the incidence of AMI (HBV-25) or new-onset immune-mediated diseases, herpes zoster, and anaphylaxis (HBV-26) in recipients of HEPLISAV-B compared with recipients of Engerix-B. The primary objective of this study was to describe and compare pregnancy outcomes in recipients of HEPLISAV-B and recipients of Engerix-B. The package leaflet is updated accordingly. The RMP version 1.4 has also been submitted. In addition, the MAH took the opportunity to bring the product information in line with the latest QRD template version 10.3

Action: For adoption of PRAC Assessment Report

7.4.6. Infliximab - REMICADE (CAP) - EMEA/H/C/000240/II/0241

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Mari Thorn

Scope: Submission of the final report for the PSOLAR (C0168Z03) registry "A Multicenter, Open Registry of Patients with Psoriasis Who Are Candidates for Systemic Therapy Including Biologics: PSOLAR", listed as a category 3 study in the RMP (MEA114). This is an international, multicenter, prospective observational registry for monitoring the long-term safety experience and clinical status of patients ≥18 years of age who are eligible to receive or are actively receiving any systemic therapies for psoriasis, including those currently receiving or planning to receive infliximab. The RMP version 21.1 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.7. Lenvatinib - LENVIMA (CAP) - EMEA/H/C/003727/II/0053

Applicant: Eisai GmbH

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of section 5.1 of the SmPC in order to update safety and efficacy information for the hepatocellular carcinoma (HCC) indication, based on interim results from study E7080-M000-508 (STELLAR), listed as a category 3 PASS in the RMP. This is a non-interventional multicentre, observational, phase 4 study to evaluate the safety and tolerability of lenvatinib in patients with advanced or unresectable HCC. RMP version 15.2 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.8. Rituximab - MABTHERA (CAP) - EMEA/H/C/000165/II/0199

Applicant: Roche Registration GmbH

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the final report for study BE29950 (RIVAS), listed as a category 3 study in the RMP. This is a prospective, single center, secondary data use, long-term surveillance, non-interventional PASS with the objective to better characterise the risk profile of MabThera by collecting long term safety data in patients with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have been treated with rituximab (MabThera) or other available non-rituximab therapies. The RMP version 24.0 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. Adalimumab - HUMIRA (CAP) - EMEA/H/C/000481/MEA 080.9

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Mari Thorn

Scope: Seventh annual interim report for P11-292 registry: a long-term non-interventional registry to assess safety and effectiveness of Humira (adalimumab) in paediatric patients with moderately to severely active Crohn's disease (CD) – CAPE

Action: For adoption of advice to CHMP

7.5.2. Elasomeran - SPIKEVAX (CAP) - EMEA/H/C/005791/MEA 118

Applicant: Moderna Biotech Spain, S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Interim report for PASS mRNA-1273-P920 (non-imposed/RMP); Post-marketing safety of Moderna Omicron-containing bivalent SARS-CoV-2 mRNA 1273 booster vaccines in the United States

Action: For adoption of advice to CHMP

7.5.3. Niraparib - ZEJULA (CAP) - EMEA/H/C/004249/MEA 002.4

Applicant: GlaxoSmithKline (Ireland) Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Interim report for study EUPAS 29407 (category 3 study listed in the RMP): PASS to evaluate the risks of MDS/AML and SPM in adult patients with platinum-sensitive, relapsed, high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer receiving maintenance treatment with Zejula (Niraparib)

Action: For adoption of advice to CHMP

7.5.4. Nivolumab - OPDIVO (CAP) - EMEA/H/C/003985/MEA 008.11

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Martin Huber

Scope: Seventh annual interim report for study CA209234 (listed as a category 3 study in the RMP): a PASS exploring the pattern of use, safety, and effectiveness of nivolumab in routine oncology practice

Action: For adoption of advice to CHMP

7.5.5. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 001.8

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Fifth interim report for PASS Study No. OP0005 (NINI); European non-interventional 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

7.5.6. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 002.8

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Fifth interim report for PASS Study No. OP0004 (NINI); European non-interventional 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

7.5.7. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 003.6

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: From Initial MAA: PASS Study No. OP0006 (NINI); European non-interventional 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

7.5.8. Selumetinib - KOSELUGO (CAP) - EMEA/H/C/005244/SOB 004

Applicant: AstraZeneca AB

PRAC Rapporteur: Ulla Wändel Liminga

Scope: First annual progress report for a non-interventional PASS in order to confirm the long-term safety of selumetinib in the treatment of symptomatic, inoperable PN in paediatric patients with NF1 aged 3 years and above listed as specific obligation in Annex II-D: 'The applicant will conduct and submit the results of a non-interventional PASS in patients with NF1 who have been prescribed at least one dose of selumetinib and who are aged 3 to ≤18 years at the start of selumetinib treatment. A nested cohort of patients aged ≥8 years old (and prior to attainment of Tanner Stage V [sexual maturity rating]) will be followed prospectively'

Action: For adoption of advice to CHMP

7.5.9. Upadacitinib - RINVOQ (CAP) - EMEA/H/C/004760/MEA 013.4

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: First annual progress report for non-imposed non-interventional category 3 PASS study P20-390-825: Cohort Study of Long-term Safety of Upadacitinib in the Treatment of Atopic Dermatitis in Denmark and Sweden

Action: For adoption of advice to CHMP

7.6. Others

None

7.7. New Scientific Advice

7.8. Ongoing Scientific Advice

None

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

None

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Asfotase alfa - STRENSIQ (CAP) - EMEA/H/C/003794/S/0066 (without RMP)

Applicant: Alexion Europe SAS

PRAC Rapporteur: Eamon O'Murchu

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.2. Cerliponase alfa - BRINEURA (CAP) - EMEA/H/C/004065/S/0042 (without RMP)

Applicant: BioMarin International Limited

PRAC Rapporteur: Mari Thorn

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.3. Eladocagene exuparvovec - UPSTAZA (CAP) - EMEA/H/C/005352/S/0017 (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

8.1.4. Lomitapide - LOJUXTA (CAP) - EMEA/H/C/002578/S/0057 (without RMP)

Applicant: Amryt Pharmaceuticals DAC

PRAC Rapporteur: Menno van der Elst

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.5. Mecasermin - INCRELEX (CAP) - EMEA/H/C/000704/S/0081 (without RMP)

Applicant: Ipsen Pharma

PRAC Rapporteur: Kirsti Villikka

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.6. Smallpox vaccine (live modified vaccinia virus Ankara) - IMVANEX (CAP) - EMEA/H/C/002596/S/0095 (without RMP)

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Gabriele Maurer

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.7. Tafamidis - VYNDAQEL (CAP) - EMEA/H/C/002294/S/0090 (without RMP)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Tiphaine Vaillant

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. Delamanid - DELTYBA (CAP) - EMEA/H/C/002552/R/0070 (with RMP)

Applicant: Otsuka Novel Products GmbH

PRAC Rapporteur: Jo Robays

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.2. Ex vivo expanded autologous human corneal epithelial cells containing stem cells - HOLOCLAR (CAP) - EMEA/H/C/002450/R/0058 (with RMP)

Applicant: Holostem, ATMP

PRAC Rapporteur: Eamon O'Murchu

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CAT and CHMP

8.2.3. Parathyroid hormone - NATPAR (CAP) - EMEA/H/C/003861/R/0054 (without RMP)

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Rhea Fitzgerald

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.4. Pemigatinib - PEMAZYRE (CAP) - EMEA/H/C/005266/R/0013 (without RMP)

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Menno van der Elst

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/0026 (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. Ambrisentan - AMBRISENTAN MYLAN (CAP) - EMEA/H/C/004985/R/0009 (without RMP)

Applicant: Mylan Pharmaceuticals Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.2. Avatrombopag - DOPTELET (CAP) - EMEA/H/C/004722/R/0018 (without RMP)

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Monica Martinez Redondo

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Pegfilgrastim - GRASUSTEK (CAP) - EMEA/H/C/004556/R/0014 (with RMP)

Applicant: Juta Pharma GmbH

PRAC Rapporteur: Menno van der Elst

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Turoctocog alfa pegol - ESPEROCT (CAP) - EMEA/H/C/004883/R/0022 (without RMP)

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Gabriele Maurer

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.

None

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

11.1. Safety related variations of the marketing authorisation

None

11.2. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC membership

Action: For information

12.1.2. Vote by proxy

Action: For information

12.1.3. PRAC working group - Best practice guide on using PRAC plenary time efficiently and effectively – update on the implementation of quantitative goals – Q3 2023

Action: For information

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

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

None

12.4. Cooperation within the EU regulatory network

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

Action: For discussion

12.5. Cooperation with International Regulators

None

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

None

12.7. PRAC work plan

12.7.1. PRAC work plan 2024

PRAC lead: Sabine Straus, Martin Huber

Action: For discussion

12.8. Planning and reporting

12.8.1. EU Pharmacovigilance system - quarterly workload measures and performance indicators – Q3 2023 and predictions

Action: For discussion

12.8.2. PRAC workload statistics – Q3 2023

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: Menno van der Elst, Maia Uusküla

Action: For discussion

12.10.3. PSURs repository

None

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

Action: For adoption

12.11. Signal management

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

PRAC lead: Menno van der Elst

Action: For discussion

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.16.2. Referral procedures - minor revision to the (Co-)Rapporteur assessment report templates

Action: For discussion

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. Implementation of EU risk minimisation measures for medicinal products in clinical guidelines (SC01/EMA/2020/46/TDA/L4.02) - PRAC Sponsor's critical appraisal

PRAC lead: Martin Huber

Action: For discussion

12.21. Others

12.21.1. EMA-HMA catalogues of real-world data sources and non-interventional studies

Action: For discussion

12.21.2. Q&A on 'What is the day zero for ICSRs described in physical/hard copy local journals?'published in January 2023 - proposal for update

Action: For discussion

12.21.3. Real World Evidence and Data analysis and real-world interrogation network (DARWIN EU®) – quarterly update

PRAC lead: Sabine Straus, Nathalie Gault, Maria Martinez Gonzalez, Liana Gross-Martirosyan

Action: For discussion

12.21.4. Real World Evidence and Data analysis and real-world interrogation network (DARWIN EU®) - results of a drug utilization study of prescription opioids

PRAC lead(s): Sabine Straus, Nathalie Gault, Liana Gross-Martirosyan

Action: For discussion

12.21.5. Stakeholder engagement for risk minimisation - PRAC Risk Minimisation Alliance (PRISMA) - pilot report for 20233-2023 and planning for 2024

PRAC lead(s): Liana Gross-Martirosyan

Action: For discussion

13. Any other business

Next meeting on: 08-11 January 2024

14. Explanatory notes

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

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

(Items 2 and 3 of the PRAC agenda)

A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the European Union (EU). For further detailed information on safety related referrals please see:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000150.jsp&mid=WC0b01ac05800240d0

Signals assessment and prioritisation

(Item 4 of the PRAC agenda)

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have a comprehensive knowledge of a medicine's benefits and risks.
The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.
The evaluation of safety signals may not necessarily conclude that the medicine caused the adverse event in question. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary and this usually takes the form of an update of the summary of product characteristics and the package leaflet.

Risk Management Plans (RMPs)

(Item 5 of the PRAC agenda)

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

Assessment of Periodic Safety Update Reports (PSURs)

(Item 6 of the PRAC agenda)

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

Post-authorisation Safety Studies (PASS)

(Item 7 of the PRAC agenda)

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

Product related pharmacovigilance inspections

(Item 9 of the PRAC agenda)

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

For a list of acronyms and abbreviations, see:
List of abbreviations used in EMA human medicines scientific committees and CMDh documents, and in

Pharmacovigilance Risk Assessment Committee (PRAC)

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