30 September 2024
EMA/PRAC/410474/2024
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 30 September-03 October 2024

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

30 September 2024, 10:30 – 19:30, via teleconference

01 October 2024, 08:30 – 19:30, via teleconference

02 October 2024, 08:30 – 19:30, via teleconference

03 October 2024, 08:30 – 16:00, via teleconference

Organisational, regulatory and methodological matters (ORGAM)

17 October 2024, 09:00 – 12:00, via teleconference

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PRAC plenary session to be held 30 September – 03 October 2024. See October month 2024 PRAC minutes (to be published post November 2024 PRAC meeting).

1.2. Agenda of the meeting on 30 September-03 October 2024

Action: For adoption

1.3. Minutes of the previous meeting on 02-05 September 2024

Action: For adoption

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

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

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

3.1. Newly triggered procedures

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

Applicant(s): various

PRAC Rapporteur: To be appointed; PRAC Co-rapporteur: To be appointed

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 questions (LoQ)

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination procedures[1]

None

3.5. Others

None

4. Signals assessment and prioritisation[2]

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

4.1.1. Adagrasib – KRAZATI (CAP)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Signal of thrombocytopenia

Action: For adoption of PRAC recommendation

EPITT 20112 – New signal

Lead Member State(s): FI

4.1.2. Mogamulizumab – POTELIGEO (CAP)

Applicant: Kyowa Kirin Holdings B.V.

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

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Signal of colitis

Action: For adoption of PRAC recommendation

EPITT 20113 – New signal

Lead Member State(s): DK

4.1.3. Oxytetracycline hydrochloride, hydrocortisone acetate, polymyxin B sulfate (ear/eye drops/suspension/ointment) (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of hearing and vestibular disorders

Action: For adoption of PRAC recommendation

EPITT 20120 – New signal

Lead Member State(s): BE

4.2. Signals follow-up and prioritisation

4.2.1. Eptinezumab - VYEPTI (CAP) - EMEA/H/C/005287/SDA/007; Erenumab - AIMOVIG (CAP) - EMEA/H/C/004447/SDA/006; Fremanezumab - AJOVY (CAP) - EMEA/H/C/004833/SDA/009; Galcanezumab - EMGALITY (CAP) - EMEA/H/C/004648/SDA/006

Applicant: Eli Lilly Nederland B.V. (Emgality), H. Lundbeck A/S (Vyepti), Novartis Europharm Limited (Aimovig), TEVA GmbH (Ajovy)

PRAC Rapporteur: Terhi Lehtinen

Scope: Signal of erectile dysfunction

Action: For adoption of PRAC recommendation

EPITT 20074 – Follow-up to May 2024

4.3. Variation procedure(s) resulting from signal evaluation

None

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Acoramidis (CAP MAA) - EMEA/H/C/006333, Orphan

Applicant: BridgeBio Europe B.V.

Scope (pre D-180 phase): For the treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)

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

5.1.2. Beremagene geperpavec (CAP MAA) - EMEA/H/C/006330, PRIME, Orphan

Applicant: Krystal Biotech Netherlands B.V., ATMP

Scope (pre D-180 phase): Treatment of patients from birth with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene

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

5.1.3. Chikungunya virus virus-like particle (CAP MAA) - EMEA/H/C/005470, PRIME, Article 28

Scope (pre D-120 phase, accelerated assessment): Prevention of disease caused by chikungunya (CHIKV) virus

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

5.1.4. Clascoterone (CAP MAA) - EMEA/H/C/006138

Scope (pre D-180 phase): Indicated for the topical treatment of acne vulgaris in adults and adolescents

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

5.1.5. Delandistrogene moxeparvovec (CAP MAA) - EMEA/H/C/005293, Orphan

Applicant: Roche Registration GmbH, ATMP

Scope (pre D-120 phase): Treatment of ambulatory patients aged 3 to 7 years old with Duchenne muscular dystrophy

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

5.1.6. Denosumab (CAP MAA) - EMEA/H/C/006424

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

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

5.1.7. Denosumab (CAP MAA) - EMEA/H/C/006468

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

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

5.1.8. Dorocubicel, Allogeneic umbilical cord-derived CD34- cells, non-expanded CAP MAA) - EMEA/H/C/005772, PRIME, Orphan

Applicant: Cordex Biologics International Limited, ATMP

Scope (pre D-120 phase, accelerated assessment): Treatment of adult patients with haematological malignancies

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

5.1.9. Guanfacine (CAP MAA) - EMEA/H/C/006312

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

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

5.1.10. Imetelstat (CAP MAA) - EMEA/H/C/006105, Orphan

Applicant: Geron Netherlands B.V.

Scope (pre D-180 phase): For the treatment of transfusion-dependent anaemia in adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS), for the treatment of transfusion-dependent anaemia in adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS)

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

5.1.11. Ivermectin, albendazole (Art 58[3] MAA) - EMEA/H/W/005186

Scope (pre D-180 phase): Prevention and treatment of lymphatic filariasis, and soil-transmitted helminths infections

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

[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)

5.1.12. Linvoseltamab (CAP MAA) - EMEA/H/C/006370

Scope (pre D-180 phase): Monotherapy for the treatment of adult patients with relapsed or refractory multiple myeloma

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

5.1.13. Methylphenidate hydrochloride - TUZULBY (CAP MAA) - EMEA/H/C/005975, PUMA[4]

Scope (pre D-180 phase): Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years of age and over

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

5.1.14. Nemolizumab (CAP MAA) - EMEA/H/C/006149

Scope (pre D-180 phase): For the treatment of moderate-to-severe atopic dermatitis and for the treatment of prurigo nodularis

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

5.1.15. Pegfilgrastim (CAP MAA) - EMEA/H/C/006348, PUMA[5]

Scope (pre D-180 phase): Treatment of neutropenia in paediatric patients

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

5.1.16. Seladelpar lysine dihydrate (CAP MAA) - EMEA/H/C/004692, PRIME, Orphan

Applicant: CymaBay Ireland, Ltd

Scope (pre D-180 phase): Treatment of primary biliary cholangitis (PBC) including pruritus in adults without cirrhosis or with compensated cirrhosis (Child-Pugh A) in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA

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

5.1.17. Tiratricol (CAP MAA) - EMEA/H/C/005220, Orphan

Applicant: Rare Thyroid Therapeutics International AB

Scope (pre D-180 phase): Treatment of monocarboxylate transporter 8 (MCT8) deficiency

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

5.1.18. Tisotumab vedotin (CAP MAA) - EMEA/H/C/005363

Scope (pre D-180 phase): Treatment of adult patients with recurrent or metastatic cervical

[4] Paediatric use marketing authorisation(s)
[5] Paediatric use marketing authorisation(s)

cancer with disease progression on or after systemic therapy

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. Burosumab - CRYSVITA (CAP) - EMEA/H/C/004275/II/0040, Orphan

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of an updated RMP version 8.0 in order to remove hyperphosphataemia as an important potential risk and to add a specific adverse drug reaction follow-up form/questionnaire for increased parathyroid hormone levels as a routine pharmacovigilance activity

Action: For adoption of PRAC Assessment Report

5.2.2. Conestat alfa - RUCONEST (CAP) - EMEA/H/C/001223/II/0088/G

Applicant: Pharming Group N.V

PRAC Rapporteur: Jan Neuhauser

Scope: Submission of an updated RMP version 19.3 in order to request the early termination of the EU registry study C1 1412, as well as to update safety information based on cumulative data from clinical trials, the EU registry data, post-marketing data and literature. A request for the extension of the due date for the European survey of educational materials for Ruconest is also included

Action: For adoption of PRAC Assessment Report

5.2.3. Covid-19 Vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - EMEA/H/C/005808/II/0082

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of an updated RMP version 5.1 in order to include the safety and effectiveness data available from the non-clinical studies and post-authorization usage regarding the JN.1 variant strain

Action: For adoption of PRAC Assessment Report

5.2.4. Rotavirus vaccine (live, oral) - ROTARIX (CAP) - EMEA/H/C/000639/II/0135

Applicant: GlaxoSmithKline Biologicals S.A.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Submission of an updated RMP version 24 in order to remove missing information related to long term genetic stability of the vaccine virus strain.

Action: For adoption of PRAC Assessment Report

5.2.5. Saxagliptin, metformin hydrochloride - KOMBOGLYZE (CAP) - EMEA/H/C/002059/WS2743/0060; Saxagliptin - ONGLYZA (CAP) - EMEA/H/C/001039/WS2743/0061

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Submission of an updated RMP version 18.1 in order to remove the previously classified important potential risk serious cutaneous adverse reactions (SCAR)

Action: For adoption of PRAC Assessment Report

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

5.3.1. Adalimumab - HUKYNDRA (CAP) - EMEA/H/C/005548/X/0026

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Mari Thorn

Scope: Extension application to add a new strength of 20 mg for adalimumab solution for injection in the pre-filled syringe administered by subcutaneous use

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

5.3.2. Amivantamab - RYBREVANT (CAP) - EMEA/H/C/005454/X/0014

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Extension application to introduce a new pharmaceutical form (solution for injection), two new strengths of 1600 mg and 2240 mg (160 mg/ml concentration) and a new route of administration (subcutaneous use)

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

5.3.3. Axicabtagene ciloleucel - YESCARTA (CAP) - EMEA/H/C/004480/II/0075/G, Orphan

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Grouped application comprising two type II variations as follows:
C.I.13 - Submission of the final report from study KTE-C19-101 (ZUMA-1) listed as a category 3 study in the RMP. This is a Phase 1/2 Multicenter Study Evaluating The Safety And Efficacy Of Kte-C19 In Subjects With Refractory Aggressive Non-Hodgkin Lymphoma.
C.I.13 - Submission of the final report from study KTE-C19-106 (ZUMA-6) listed as a category 3 study in the RMP. This is a Phase 1-2 Multi-Center Study Evaluating The Safety And Efficacy Of Kte-C19 In Combination With Atezolizumab In Subjects With Refractory Diffuse Large B-Cell Lymphoma (Dlbcl).

The RMP version 9.2 has also been submitted

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

5.3.4. Baloxavir marboxil - XOFLUZA (CAP) - EMEA/H/C/004974/II/0021

Applicant: Roche Registration GmbH

PRAC Rapporteur: Sonja Hrabcik

Scope: Extension of indication to include treatment of patients aged 3 weeks and above for Xofluza, based on final results from study CP40559 (MiniSTONE-1); this was a global Phase 3, multicenter, single-arm, open-label study to assess the safety, PK, and efficacy of baloxavir marboxil in OwH pediatric patients from birth to < 1 year with influenza-like symptoms. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4

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

5.3.5. Belimumab - BENLYSTA (CAP) - EMEA/H/C/002015/II/0133

Applicant: GlaxoSmithKline (Ireland) Limited

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of paediatric patients from 5 years of age with active, autoantibody-positive systemic lupus erythematosus (SLE) for BENLYSTA, based on final results from study 200908; this is a worldwide population pharmacokinetic analysis of subcutaneous administered belimumab plus standard therapy to paediatric patients aged 5-17 years with systematic lupus erythematous (SLE), which was aimed to describe the pharmacokinetic (PK) analysis of belimumab to support an appropriate weight-based dosing regimen for subcutaneous administration in paediatric patients aged 5-17 years with SLE. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 46.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4

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

5.3.6. Blinatumomab - BLINCYTO (CAP) - EMEA/H/C/003731/II/0056, Orphan

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Jana Lukacisinova

Scope: Extension of indication to include treatment as part of consolidation therapy for the treatment of patients with Philadelphia chromosome negative CD19 positive B-cell precursor ALL for BLINCYTO. The proposed indication is supported by efficacy data from Studies

E1910, 20120215, and AALL1331, safety data for Studies E1910, 20120215, AALL1331, MT103-202, and MT103-203, and Pharmacokinetic data for Studies 20120215, AALL1331, MT103-202, MT103-203, and 20190360. 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 18.0 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. Brexpiprazole - RXULTI (CAP) - EMEA/H/C/003841/II/0015

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Miroslava Gocova

Scope: Extension of indication to include treatment of schizophrenia in adolescent patients aged from 13 years to 17 years for RXULTI, based on results from the following clinical studies: one phase 1 dose-escalation trial (Trial 331-10-233) and two phase 3 clinical trials (Trial 331-10-234 and Trial 331-10-236). In addition, a paediatric extrapolation study was completed (Study 331-201-00185). These studies investigated the efficacy and safety of brexpiprazole in paediatric patients (13-17 years old) with schizophrenia. 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 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, and to bring the PI in line with the latest QRD template version 10.4

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

5.3.8. Brolucizumab - BEOVU (CAP) - EMEA/H/C/004913/II/0029

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Update of sections 4.2 and 5.1 of the SmPC in order to include information on maintenance treatment and to update efficacy and safety information based on final results from studies CRTH258A2303 (TALON) and CRTH258A2303E1 (TALON Extension). TALON is a 64-week, two-arm, randomized, double-masked, phase IIIb study assessing the efficacy and safety of brolucizumab 6 mg compared to aflibercept 2 mg in a treat-to-control regimen in patients with neovascular age-related macular degeneration. TALON Extension is a 56-week phase IIIb/IV, open-label, one-arm extension study to assess the efficacy and safety of brolucizumab 6 mg in a Treat-to-Control regimen with maximum treatment intervals up to 20 weeks for the treatment of subjects with neovascular age-related macular degeneration who have completed the CRTH258A2303 (TALON) study.
The Package Leaflet is updated accordingly. The RMP version 12.0 has also been submitted

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

5.3.9. Bulevirtide - HEPCLUDEX (CAP) - EMEA/H/C/004854/II/0031, Orphan

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of chronic hepatitis delta virus (HDV) infection in paediatric patients 3 years of age and older weighing at least 10 kg with compensated liver disease for Hepcludex, based on a modelling and simulation study and an extrapolation study to evaluate the use of Bulevirtide for the treatment of chronic hepatitis D infection in children from 3 to less than 18 years of age. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet has been updated accordingly. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI

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

5.3.10. Darunavir, Cobicistat - REZOLSTA (CAP) - EMEA/H/C/002819/X/0054/G

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new strength (675 mg/150 mg film-coated tablets) grouped with an extension of indication (C.I.6.a) to include, treatment of HIV-1 infected paediatric patients (aged 6 years and older with body weight at least 25 kg) for REZOLSTA, based on the 48-week ad hoc interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicenter, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of cobicistat-boosted darunavir in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1,4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.3, 6.5 and 8 of the SmPC and Annex II are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4

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

5.3.11. Decitabine, cedazuridine - INAQOVI (CAP) - EMEA/H/C/005823/II/0002

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Grouped application consisting of:
C.I.6: Extension of indication to include treatment of adult patients with myelodysplastic syndromes (MDS) for INAQOVI.

C.I.6: Extension of indication to include treatment of adult patients with chronic myelomonocytic leukaemia (CMML) for INAQOVI.

Based on final results from studies ASTX727-01, ASTX727-02, ASTX727-04, E7727-01, and E7727-02. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.
Furthermore, the PI is brought in line with the latest QRD template version 10.3. As part of the application the MAH is requesting a 1-year extension of the market protection

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

5.3.12. Durvalumab - IMFINZI (CAP) - EMEA/H/C/004771/II/0069

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Extension of indication to include treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy for IMFINZI, based on final results from study D933QC00001 (ADRIATIC); this is a phase III, randomized, double-blind, placebo-controlled, multi-centre, global study to assess the efficacy and safety of durvalumab monotherapy and durvalumab in combination with tremelimumab compared to placebo as consolidation treatment in patients with LS-SCLC whose disease had not progressed following definitive platinum-based chemoradiation therapy (ADRIATIC). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 12,s1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to Annex II. Furthermore, the PI is brought in line with the latest QRD template version 10.4

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

5.3.13. Eliglustat - CERDELGA (CAP) - EMEA/H/C/003724/X/0036/G, Orphan

Applicant: Sanofi B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension application to introduce a new strength (21 mg capsule, hard) grouped with an extension of indication (C.I.6.a) to include treatment of paediatric patients with GD1 who are 6 years and older with a minimum body weight of 15 kg, who have been previously treated with enzyme replacement therapy (ERT), and who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs) or extensive metabolisers (EMs) for Cerdelga, based on interim results from study EFC13738 (Open label, two cohort (with and without imiglucerase), multicenter study to evaluate pharmacokinetics, safety, and efficacy of eliglustat in paediatric patients with Gaucher disease type 1 and type 3). 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. The RMP version 8.0 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI

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

5.3.14. Fedratinib - INREBIC (CAP) - EMEA/H/C/005026/II/0020, Orphan

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Sonja Hrabcik

Scope: Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update information regarding thiamine levels based on a review of the primary results of the study FEDR-MF-002. This is a Phase 3, multicenter, open-label, randomized study to evaluate the efficacy and safety of fedratinib compared with BAT in subjects with DIPSS intermediate-2 or high-risk primary MF, post-PV MF, or post-ET MF and previously treated with ruxolitinib. The RMP

version 3 has also been submitted

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

5.3.15. Nivolumab - OPDIVO (CAP) - EMEA/H/C/003985/WS2717/0146; Ipilimumab - YERVOY (CAP) - EMEA/H/C/002213/WS2717/0115

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Bianca Mulder

Scope: A Worksharing application for OPDIVO and YERVOY, as follows:

Extension of indication to include a new indication for OPDIVO in combination with ipilimumab as first line treatment of adult patients with unresectable or advanced hepatocellular carcinoma (HCC) based on study CA2099DW. This is a phase 3 randomised, multi-centre, open label study of Nivolumab in combination with Ipilimumab compared to Sorafenib or Lenvatinib as first-line treatment in participants with advanced HCC. 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 41.0 of the RMP has also been submitted.

Extension of indication to include a new indication for YERVOY in combination with ipilimumab as first line treatment of adult patients with unresectable or advanced hepatocellular carcinoma (HCC) based on study CA2099DW. This is a phase 3 randomised, multi-centre, open label study of Nivolumab in combination with Ipilimumab compared to Sorafenib or Lenvatinib as first-line treatment in participants with advanced HCC. 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 44.0 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. Iptacopan - FABHALTA (CAP) - EMEA/H/C/005764/II/0001, Orphan

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Lina Seibokiene

Scope: Extension of indication to include, in combination with a renin-angiotensin system (RAS) inhibitor, the treatment of adult patients with complement 3 glomerulopathy (C3G) for FABHALTA, based on interim analysis results from study CLNP023B12301 (APPEAR-C3G) and supported by additional evidence of efficacy and safety data from Phase II study CLNP023X2202 (X2202) and Phase IIIb study CLNP023B12001B (C3G-REP). APPEAR-C3G is a Phase 3, multicenter, randomized, double-blind, parallel arm, placebo-controlled study to evaluate the efficacy and safety of iptacopan in patients with C3G. The study included a 6-month blinded, placebo-controlled period, followed by a 6-month period in which all patients receive open-label iptacopan (total study duration of 12 months). As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8 and 5.1 of the SmPC are being updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI

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

5.3.17. Isatuximab - SARCLISA (CAP) - EMEA/H/C/004977/II/0030

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Monica Martinez Redondo

Scope: Extension of indication to include in combination with bortezomib, lenalidomide, and dexamethasone for the treatment of adult patients with newly diagnosed active multiple myeloma who are not eligible for autologous stem cell transplant (ASCT) or with no intent for ASCT as initial therapy for Sarclisa, based on results from EFC12522 (IMROZ) pivotal phase III study and the supportive TCD13983 phase 1b/2 study. EFC12522 is an ongoing prospective, multicenter, international, randomized, open-label, 2-arm parallel group study to assess the clinical benefit of VRd (control group) versus IVRd (active group) for the treatment of participants with NDMM who are not eligible for ASCT. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.7, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted

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

5.3.18. Levetiracetam - KEPPRA (CAP); NAP - EMEA/H/C/000277/WS2529/0200

Applicant(s): UCB Pharma S.A.

PRAC Rapporteur: Jo Robays

Scope: Type II - B.IV.1.a.3 - To replace the CE marked oral dosing syringes and press-in bottle adaptor used in the Keppra 100 mg/ml oral solution (EU/1/00/146/027, 031, 032) with dosing syringes and press-in bottle adaptor from a new manufacturer. The 3 ml oral dosing syringe used in the Keppra 100 mg/ml oral solution (EU/1/00/146/031) is replaced with a 5 ml oral dosing syringe. An updated RMP version 10.0 and a DHPC are proposed. In addition, the Applicant has taken the opportunity to include the change in the local representatives of the Marketing Authorisation Holder in Estonia, Latvia, and Lithuania

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

5.3.19. Mycophenolate mofetil - CELLCEPT (CAP) - EMEA/H/C/000082/II/0170/G

Applicant: Roche Registration GmbH

PRAC Rapporteur: Karin Erneholm

Scope: C.I.6.a: Extension of indication to include paediatric patients (3 months to 18 years of age) for hepatic and cardiac transplants and to extend the indication for renal transplants for paediatric patients starting from 3 months, based on pharmacokinetic data, published literature and the Roche Global Safety Database. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly.

Type IB (C.I.z): To update section 4.2 of the SmPC for the CellCept 500 mg tablets formulation in order to be in line with the other three CellCept formulations. And for alignment with the current QRD guidance, the Package Leaflet was updated to cross reference section 2 in section 6 for sodium content.

In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and

bring the PI in line with the latest QRD template version 10.3

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

5.3.20. Nivolumab - OPDIVO (CAP) - EMEA/H/C/003985/X/0144

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Martin Huber

Scope: Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (600 mg) and a new route of administration (subcutaneous use). Version 40.0 of the RMP has also been submitted

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

5.3.21. Pembrolizumab - KEYTRUDA (CAP) - EMEA/H/C/003820/II/0154

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include in combination with pemetrexed and platinum chemotherapy the first-line treatment of adults and adolescents aged 12 years and older with unresectable advanced or metastatic malignant pleural mesothelioma for Keytruda, based on final results from study KEYNOTE-483; this is a multicenter, open-label, Phase 2/3 randomized study to evaluate the efficacy and safety of pembrolizumab in combination with pemetrexed/platinum chemotherapy in participants with unresectable advanced or metastatic malignant pleural mesothelioma (MPM). As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 47.1 of the RMP has also been submitted

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

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

Applicant: Bayer AG

PRAC Rapporteur: Kimmo Jaakkola

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

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

5.3.23. Ruxolitinib - JAKAVI (CAP) - EMEA/H/C/002464/X/0070/G

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: Extension application to introduce a new pharmaceutical form associated with a new

strength (5 mg/ml oral solution) and a new route of administration (gastric use), indicated for the treatment of Graft versus host disease (GvHD) in patients aged 28 days or older.

The above line extension is grouped with a type II variation:
- C.I.6.a - To include treatment of paediatric patients aged 28 days to less than 18 years old in acute and chronic Graft versus Host Disease for JAKAVI, based on final results from studies REACH4 (CINC424F12201) and REACH5 (Study CINC424G12201). REACH4 is a Phase I/II open-label, single-arm, multi-center study of ruxolitinib added to corticosteroids in pediatric patients with grade II-IV acute graft vs. host disease after allogeneic hematopoietic stem cell transplantation; while REACH5 is a Phase II open-label, single-arm, multi-center study of ruxolitinib added to corticosteroids in pediatric subjects with moderate and severe chronic graft vs. host disease after allogeneic stem cell transplantation (both for oral solution and already approved tablets presentations). As a consequence, sections 4.1,4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.

The RMP (version 16) is updated in accordance. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to implement editorial changes to Annex II

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

5.3.24. Sacubitril, valsartan - ENTRESTO (CAP) - EMEA/H/C/004062/WS2738/0065; Sacubitril, valsartan - NEPARVIS (CAP) - EMEA/H/C/004343/WS2738/0062

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Karin Erneholm

Scope: Update of sections 4.8 and 5.3 of the SmPC in order to update information on long-term data in paediatric patients, based on final results from study CLCZ696B2319E1(PANAROMA-HF OLE) listed as a category 3 study in the RMP (MEA/009); this is a phase 3, multicenter, uncontrolled study to evaluate long-term safety and tolerability of open label sacubitril/valsartan in pediatric patients with heart failure due to systemic left ventricle systolic dysfunction who have completed study CLCZ696B2319 (PANORAMA-HF); the RMP version 8 has also been submitted

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

5.3.25. Semaglutide - RYBELSUS (CAP) - EMEA/H/C/004953/II/0041

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Update of section 4.6 of the SmPC in order to update information on breast-feeding based on final results from study NN9924-4669. This was an open-label, single-armed, multiple-dose, multi-centre study evaluating the semaglutide and SNAC concentrations in breastmilk from healthy lactating women dosed once daily with oral semaglutide for 10 days (3 mg for 5 days followed by 7 mg for 5 days). The primary endpoints were evaluated during a 24 hours pharmacokinetic (PK) sampling period after the 10th dose. The package leaflet is updated accordingly. The RMP version 9.0 has also been submitted

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

5.3.26. Sparsentan - FILSPARI (CAP) - EMEA/H/C/005783/II/0002, Orphan

Applicant: Vifor France

PRAC Rapporteur: Martin Huber

Scope: Update of sections 4.8, and 5.1 of the SmPC in order to amend the frequency of the adverse drug reactions (ADRs) based on final results from study 021IGAN17001 (PROTECT) listed as a specific obligation in the Annex II; this is a randomized, multicenter, double-blind parallel-group, active control study of the efficacy and safety of sparsentan for the treatment of immunoglobulin A nephropathy. The Package Leaflet is updated accordingly. The RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II and to bring the PI in line with the latest QRD template version 10.4. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation

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

5.3.27. Sugammadex - BRIDION (CAP) - EMEA/H/C/000885/II/0047

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: Extension of indication to include treatment of paediatric patients from birth to less than 2 years of age for Bridion based on final results from paediatric study PN169 (MK-8616-P169); this is a Phase 4 double-blinded, randomized, active comparator-controlled clinical trial to study the efficacy, safety, and pharmacokinetics of sugammadex (MK-8616) for reversal of neuromuscular blockade in pediatric participants aged birth to <2 years. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, to implement minor editorial corrections and to update the information intended for healthcare professionals (HCPs) at the end of the Package Leaflet

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

5.3.28. Tedizolid phosphate - SIVEXTRO (CAP) - EMEA/H/C/002846/II/0054

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include treatment of paediatric patients aged from birth to less than 12 years for SIVEXTRO, based on final results from studies MK-1986-013, MK-1986-014 and MK-1986-018. MK-1986-013 is a single-dose trial to evaluate pharmacokinetics (PK) and safety of oral and intravenous (IV) administration of tedizolid phosphate in patients from 2 years to <12 years of age; MK-1986-014 is an open-label, multicentre, 2-part, single and multiple dose study to assess the PK of tedizolid phosphate and its active metabolite, tedizolid, and the safety of tedizolid phosphate following single and multiple dose IV and single oral dose. MK-1986-018 is a randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in patients from birth to

less than 12 years of age; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement minor editorial corrections

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

5.3.29. Tirzepatide - MOUNJARO (CAP) - EMEA/H/C/005620/II/0027

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include, as an adjunct to diet and exercise, the treatment of moderate to severe obstructive sleep apnoea (OSA) in adults with obesity for MOUNJARO based on final results from studies I8F-MC-GPI1 and I8F-MC-GPI2; these are multicenter, randomized, parallel-arm, double-blind, placebo-controlled studies investigating the effects of tirzepatide compared with placebo in adult participants with moderate-to-severe OSA and obesity. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted

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

5.3.30. Upadacitinib - RINVOQ (CAP) - EMEA/H/C/004760/II/0056

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include treatment of giant cell arteritis (GCA) in adult patients for RINVOQ based on final results from study M16-852. This is a phase 3, global, multicenter, randomized, double-blind, PBO-controlled study evaluating the efficacy and safety of upadacitinib in subjects with GCA. 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 15.0 of the RMP has also been submitted

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

5.3.31. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/II/0108

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy or have medical contraindications to such therapies for STELARA, based on final results from study CNTO1275CRD3004. This is a Phase 3 Study of the Efficacy, Safety, and Pharmacokinetics of Ustekinumab as Open label Intravenous Induction Treatment Followed by Randomized Double blind Subcutaneous Ustekinumab Maintenance in Pediatric Participants with Moderately to Severely Active Crohn’s Disease. 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 29.1 of the RMP has also been submitted

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

5.3.32. Ustekinumab - UZPRUVO (CAP) - EMEA/H/C/006101/X/0001

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength (130 mg concentrate for solution for infusion) and a new route of administration (intravenous use). The RMP version 1.1 is updated in accordance

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. Abrocitinib - CIBINQO (CAP) - PSUSA/00010976/202403

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.2. Agomelatine - VALDOXAN (CAP) - PSUSA/00000071/202402

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Pernille Harg

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.3. Atazanavir, cobicistat - EVOTAZ (CAP) - PSUSA/00010404/202401

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.4. Baloxavir marboxil - XOFLUZA (CAP) - PSUSA/00010895/202402

Applicant: Roche Registration GmbH

PRAC Rapporteur: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.5. Bedaquiline - SIRTURO (CAP) - PSUSA/00010074/202403

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.6. Bempedoic acid - NILEMDO (CAP); bempedoic acid, ezetimibe - NUSTENDI (CAP) - PSUSA/00010841/202402

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.7. Bimekizumab - BIMZELX (CAP) - PSUSA/00010953/202402

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.8. Brimonidine[6] - MIRVASO (CAP) - PSUSA/00010093/202402

Applicant: Galderma International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.9. Burosumab - CRYSVITA (CAP) - PSUSA/00010669/202402

Applicant: Kyowa Kirin Holdings B.V.

[6] Centrally authorised product only

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.10. Cabotegravir[7] - APRETUDE (CAP) - PSUSA/00000116/202403

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.11. Cabotegravir[8]- VOCABRIA (CAP) - PSUSA/00010900/202403

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.12. Ciclosporin[9] - IKERVIS (CAP); VERKAZIA (CAP) - PSUSA/00010362/202403

Applicant: Santen Oy

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.13. Ciltacabtagene autoleucel - CARVYKTI (CAP) - PSUSA/00011000/202402

Applicant: Janssen-Cilag International NV, ATMP

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.14. Cipaglucosidase alfa - POMBILITI (CAP) - PSUSA/00011047/202403

Applicant: Amicus Therapeutics Europe Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

[7] Indicated for pre-exposure prophylaxis of HIV-1 infection
[8] Indicated for treatment of human immunodeficiency virus type 1 (HIV-1))
[9] Topical use only

Action: For adoption of recommendation to CHMP

6.1.15. COVID-19 vaccine (Ad26.COV2-S [recombinant]) - JCOVDEN (CAP)[10] - PSUSA/00010916/202402

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For discussion

6.1.16. Dengue tetravalent vaccine (live, attenuated) - DENGUE TETRAVALENT VACCINE (LIVE, ATTENUATED) TAKEDA (Art 58[11]) - EMEA/H/W/005362/PSUV/0014

Applicant: Takeda GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUR procedure

Action: For adoption of recommendation to CHMP

6.1.17. Dengue tetravalent vaccine[12] (live, attenuated) - QDENGA (CAP) - PSUSA/00011034/202402

Applicant: Takeda GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.18. Deucravacitinib - SOTYKTU (CAP) - PSUSA/00011046/202403

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[10] European Commission decision for withdrawal of marketing authorisation for Jcovden (COVID-19 Vaccine Janssen (Ad26.COV2.S)) in the European Union (EU) is dated 26 July 2024. The withdrawal was at the request of the marketing authorisation holder, Janssen-Cilag International N.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.
[11] 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)
[12] Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated, Dengue virus, serotype 2, live, attenuated

6.1.19. Difelikefalin - KAPRUVIA (CAP) - PSUSA/00010995/202402

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. Elosulfase alfa - VIMIZIM (CAP) - PSUSA/00010218/202402

Applicant: BioMarin International Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.21. Epcoritamab - TEPKINLY (CAP) - PSUSA/00000107/202403

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.22. Eptinezumab - VYEPTI (CAP) - PSUSA/00010966/202402

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.23. Esketamine[13] - SPRAVATO (CAP) - PSUSA/00010825/202403

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.24. Ex vivo expanded autologous human corneal epithelial cells containing stem cells - HOLOCLAR (CAP) - PSUSA/00010352/202402

Applicant: Holostem S.r.l., ATMP

[13] For centrally authorised product only

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.25. Ferric maltol - FERACCRU (CAP) - PSUSA/00010476/202402

Applicant: Norgine B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.26. Fosdenopterin - NULIBRY (CAP) - PSUSA/00011017/202402

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.27. Gadopiclenol - ELUCIREM (CAP); VUEWAY (CAP) - PSUSA/00000232/202403

Applicant: Guerbet (Elucirem), Bracco Imaging S.p.A. (Vueway)

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.28. Ganaxolone - ZTALMY (CAP) - PSUSA/00000093/202403

Applicant: Marinus Pharmaceuticals Emerald Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.29. Glycerol phenylbutyrate - RAVICTI (CAP) - PSUSA/00010454/202401

Applicant: Immedica Pharma AB

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.30. Hepatitis B (rDNA[14]) vaccine (adjuvanted, adsorbed) - FENDRIX (CAP) - PSUSA/00001598/202402

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.31. Imlifidase - IDEFIRIX (CAP) - PSUSA/00010870/202402

Applicant: Hansa Biopharma AB

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.32. Influenza vaccine (surface antigen, inactivated, adjuvanted) - FLUAD TETRA (CAP); - PSUSA/00010300/202403

Applicant(s): Seqirus Netherlands B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.33. Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - FLUCELVAX TETRA (CAP) - PSUSA/00010737/202403

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. Lenacapavir - SUNLENCA (CAP) - PSUSA/00011012/202402

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[14] Recombinant deoxyribonucleic acid

6.1.35. Lenvatinib - KISPLYX (CAP); LENVIMA (CAP) - PSUSA/00010380/202402

Applicant: Eisai GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.36. Lonapegsomatropin - SKYTROFA (CAP) - PSUSA/00010969/202402

Applicant: Ascendis Pharma Endocrinology Division A/S

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.37. Lorlatinib - LORVIQUA (CAP) - PSUSA/00010760/202403

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.38. Miglustat[15] - OPFOLDA (CAP) - PSUSA/00000077/202403

Applicant: Amicus Therapeutics Europe Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. Mitapivat - PYRUKYND (CAP) - PSUSA/00011025/202402

Applicant: Agios Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.40. Momelotinib - OMJJARA (CAP) - PSUSA/00000263/202403

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Mari Thorn

[15] For treatment of Pompe disease only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. Nalmefene - SELINCRO (CAP) - PSUSA/00010120/202402

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.42. Nilotinib - TASIGNA (CAP) - PSUSA/00002162/202401

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.43. Nivolumab, relatlimab - OPDUALAG (CAP) - PSUSA/00011018/202403

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Omaveloxolone - SKYCLARYS (CAP) - PSUSA/00000245/202402

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Oritavancin - TENKASI (CAP) - PSUSA/00010368/202403

Applicant: Menarini International Operations Luxembourg S.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Ospemifene - SENSHIO (CAP) - PSUSA/00010340/202402

Applicant: Shionogi B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Phenylephrine, ketorolac - OMIDRIA (CAP) - PSUSA/00010419/202401

Applicant: Rayner Surgical (Ireland) Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. Pirfenidone - ESBRIET (CAP) - PSUSA/00002435/202402

Applicant: Roche Registration GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.49. Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - MOSQUIRIX (Art 58[16]) - EMEA/H/W/002300/PSUV/0083

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUR procedure

Action: For adoption of recommendation to CHMP

6.1.50. Pomalidomide - IMNOVID (CAP) - PSUSA/00010127/202402

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

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

6.1.51. Ponesimod - PONVORY (CAP) - PSUSA/00010940/202403

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.52. Pralsetinib - GAVRETO (CAP) - PSUSA/00010961/202403

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.53. Prasugrel - EFIENT (CAP) - PSUSA/00002499/202402

Applicant: Substipharm

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.54. Reslizumab - CINQAERO (CAP) - PSUSA/00010523/202402

Applicant: Teva B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.55. Rezafungin - REZZAYO (CAP) - PSUSA/00000221/202403

Applicant: Mundipharma GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.56. Ribociclib - KISQALI (CAP) - PSUSA/00010633/202403

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.57. Rilpivirine[17] - REKAMBYS (CAP) - PSUSA/00010901/202403

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.58. Rimegepant - VYDURA (CAP) - PSUSA/00010997/202402

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.59. Ruxolitinib - JAKAVI (CAP) - PSUSA/00010015/202402

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.60. Ruxolitinib[18] - OPZELURA (CAP) - PSUSA/00011052/202403

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.61. Samarium (^{153}Sm) lexidronam - QUADRAMET (CAP) - PSUSA/00002682/202402

Applicant: CIS BIO International

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[17] For intramuscular use only
[18] For non-segmental vitiligo only

6.1.62. Sodium thiosulfate - PEDMARQSI (CAP) - PSUSA/00000066/202403

Applicant: Norgine B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.63. Solriamfetol - SUNOSI (CAP) - PSUSA/00010831/202403

Applicant: Atnahs Pharma Netherlands B.V.

PRAC Rapporteur: Julia Pallos

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.64. Spesolimab - SPEVIGO (CAP) - PSUSA/00011033/202403

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.65. Teclistamab - TECVAYLI (CAP) - PSUSA/00011010/202402

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jana Lukacisinova

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.66. Telotristat - XERMELO (CAP) - PSUSA/00010639/202402

Applicant: SERB S.A.S.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.67. Tildrakizumab - ILUMETRI (CAP) - PSUSA/00010720/202403

Applicant: Almirall S.A

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.68. Tolcapone - TASMAR (CAP) - PSUSA/00002985/202403

Applicant: Viatris Healthcare Limited

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.69. Trastuzumab emtansine - KADCYLA (CAP) - PSUSA/00010136/202402

Applicant: Roche Registration GmbH

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.70. Valoctocogene roxaparvovec - ROCTAVIAN (CAP) - PSUSA/00011009/202402

Applicant: BioMarin International Limited, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.71. Velaglucerase alfa - VPRIV (CAP) - PSUSA/00003103/202402

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.72. Vildagliptin - GALVUS (CAP); JALRA (CAP); XILIARX (CAP); metformin, vildagliptin - EUCREAS (CAP); ICANDRA (CAP); ZOMARIST (CAP) - PSUSA/00003113/202402

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.73. Vismodegib - ERIVEDGE (CAP) - PSUSA/00010140/202401

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.74. Vosoritide - VOXZOGO (CAP) - PSUSA/00010952/202402

Applicant: BioMarin International Limited

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.75. Zanamivir[19] - DECTOVA (CAP) - PSUSA/00010763/202401

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Mari Thorn

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. Atosiban - TRACTOCILE (CAP); NAP - PSUSA/00000264/202401

Applicant(s): Ferring Pharmaceuticals A/S (Tractocile), various

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.2. Cladribine[20] - LITAK (CAP); NAP - PSUSA/00000787/202402

Applicant(s): Lipomed GmbH (Litak), various

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[19] Centrally authorised products only
[20] Apart from product(s) with multiple sclerosis indication

6.2.3. Dexrazoxane - SAVENE (CAP); NAP - PSUSA/00001001/202402

Applicant(s): Cnx Therapeutics Ireland Limited (Savene), various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.4. Pemetrexed - ALIMTA (CAP); ARMISARTE (CAP); PEMETREXED ACCORD (CAP); PEMETREXED FRESENIUS KABI (CAP); NAP - PSUSA/00002330/202402

Applicants: Accord Healthcare S.L.U. (Pemetrexed Accord), Actavis Group PTC ehf. (Armisarte), Eli Lilly Nederland B.V. (Alimta), Fresenius Kabi Deutschland GmbH (Pemetrexed Fresenius Kabi), various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.5. Rivastigmine - PROMETAX (CAP); RIVASTIGMINE 1A PHARMA (CAP); RIVASTIGMINE HEXAL (CAP); RIVASTIGMINE SANDOZ (CAP); NAP - PSUSA/00002654/202401

Applicants: 1 A Pharma GmbH (Rivastigmine 1A Pharma), Almirall S.A. (Prometax), Hexal AG (Rivastigmine HEXAL), Sandoz GmbH (Rivastigmine Sandoz), various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.6. Sugammadex - BRIDION (CAP); NAP - PSUSA/00002799/202401

Applicant(s): Merck Sharp & Dohme B.V. (Bridion), various

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.7. Voriconazole - VFEND (CAP); NAP - PSUSA/00003127/202402

Applicant(s): Pfizer Europe MA EEIG (Vfend), various

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

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

6.3.1. Ampicillin, sulbactam (NAP) - PSUSA/00000197/202402

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.2. Aprotinin (NAP) - PSUSA/00000230/202402

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Argatroban (NAP) - PSUSA/00009057/202401

Applicant(s): various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.4. Calcium chloride, histidine, magnesium chloride, mannitol, potassium chloride, sodium chloride, tryptophan, oxogluric acid (NAP) - PSUSA/00000002/202401

Applicant(s): various

PRAC Lead: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. Chlormadinone (NAP) - PSUSA/00000677/202401

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.6. Chlormadinone acetate, ethinylestradiol (NAP) - PSUSA/00000679/202401

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.7. Cilazapril (NAP); cilazapril, hydrochlorothiazide (NAP) - PSUSA/00000749/202402

Applicant(s): various

PRAC Lead: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. Dobutamine (NAP) - PSUSA/00001151/202403

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.9. Dorzolamide, timolol (NAP) - PSUSA/00001166/202402

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. Flubendazole (NAP) - PSUSA/00001400/202402

Applicant(s): various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. Galantamine (NAP) - PSUSA/00001512/202403

Applicant(s): various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. Human coagulation factor VIII (inhibitor bypassing fraction) (NAP) - PSUSA/00009174/202402

Applicant(s): various

PRAC Lead: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. Hydroxyethyl starch (NAP) - PSUSA/00001694/202403

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.14. Iloprost[21] (NAP) - PSUSA/00009190/202401

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.15. Influenza vaccine[22] (split virion, inactivated) (NAP) - PSUSA/00010298/202403

Applicant(s): various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.16. Influenza vaccine (surface antigen, inactivated) (NAP) - PSUSA/00001744/202403

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

[21] Intravenous (IV)use only
[22] Non centrally authorised products

6.3.17. Lisdexamfetamine (NAP) - PSUSA/00010289/202402

Applicant(s): various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.18. Mesalazine (NAP) - PSUSA/00001990/202402

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.19. Nafarelin (NAP) - PSUSA/00002105/202402

Applicant(s): various

PRAC Lead: Karen Pernille Harg

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.20. Nomegestrol (NAP) - PSUSA/00002181/202401

Applicant(s): various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.21. Octenidine dihydrochloride, 1-propanol, 2-propanol (NAP) - PSUSA/00010417/202401

Applicant(s): various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.22. Ondansetron (NAP) - PSUSA/00002217/202402

Applicant(s): various

PRAC Lead: Polona Golmajer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.23. Sterculia (NAP); Frangula, Sterculia (NAP) - PSUSA/00010428/202402

Applicant(s): various

PRAC Lead: Gudrun Stefansdottir

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Delafloxacin - QUOFENIX (CAP) - EMEA/H/C/004860/LEG 004.1

Applicant: A. Menarini Industrie Farmaceutiche Riunite s.r.l.

PRAC Rapporteur: Petar Mas

Scope: MAH's responses to LEG 004 [Cumulative review on spontaneously reported cases of prolonged, potentially irreversible, serious suspected adverse drug reactions to fluoroquinolones] as adopted in June 2024.

The MAH should comment on the proposed PI amendments updating the existing information in section 4.8, to reflect the new aspects of prolonged, disabling and potentially irreversible adverse drug reactions

Action: For adoption of advice to CHMP

6.4.2. Eculizumab - SOLIRIS (CAP) - EMEA/H/C/000791/LEG 064

Applicant: Alexion Europe SAS

PRAC Rapporteur: Monica Martinez Redondo

Scope: MAH response to PSUR#19 (EMEA/H/C/PSUSA/00001198/202310) as adopted in 16 May 2024.
The MAH for Soliris is requested to provide cumulative data from all the available sources in a tabulated format for all the hepatotoxicity cases (irrespective of whether, according to the MAH, they have alternative aetiologies) with transaminases elevation and clinical consequences, reported with eculizumab until de DLP of this PSUR

Action: For adoption of advice to CHMP

6.4.3. Levofloxacin - QUINSAIR (CAP) - EMEA/H/C/002789/LEG 006.1

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: MAH's responses to LEG 006 [***5-year Cumulative Safety Review***(from 1

January 2017 - 31 December 2022)
Regarding long-lasting, disabling and potentially irreversible side effect.]RSI as adopted in June 2024.

The MAH should comment on the proposed PI amendments updating the existing information in section 4.8, to reflect the new aspects of prolonged, disabling and potentially irreversible adverse drug reactions

Action: For adoption of advice to CHMP

6.5. Variation procedure(s) resulting from PSUSA evaluation

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

Applicant: Orexigen Therapeutics Ireland Limited

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

Action: For adoption of LoQ for AHEG meeting

6.6. Expedited summary safety reviews[23]

None

7. Post-authorisation safety studies (PASS)

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

None

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[25]

7.2.1. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/MEA 002.4

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: From Initial MAA:
Amendment 2 of protocol v.3.0 for PASS No. PS0038
Bimekizumab real-world outcomes study:

[23] Submission of expedited summary safety reports for review in addition to the requirements for submission of PSUR(s) falling within the pandemic period and requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC
[24] In accordance with Article 107n of Directive 2001/83/EC
[25] In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

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 (eg, anti TNF, anti-IL-23, but not anti IL 17)

Action: For adoption of advice to CHMP

7.2.2. Danicopan - VOYDEYA (CAP) - EMEA/H/C/005517/MEA 002

Applicant: Alexion Europe

PRAC Rapporteur: Martin Huber

Scope: ***Draft Study Protocol / ALX-PNH-502***
Title: An observational cohort study to assess long-term safety of danicopan add-on therapy in patients with paroxysmal nocturnal hemoglobinuria: analysis of IPIG-registry data

Action: For adoption of advice to CHMP

7.2.3. Fenfluramine - FINTEPLA (CAP) - EMEA/H/C/003933/MEA 005.5

Applicant: UCB Pharma SA

PRAC Rapporteur: Martin Huber

Scope: ***Protocol amendment (version 5.1) / Study (EP0219 [former ZX008-2102])***
Post Authorisation Safety Study (PASS): A Drug Utilisation Study of Fenfluramine In Europe (DUS)

Action: For adoption of advice to CHMP

7.2.4. Glofitamab - COLUMVI (CAP) - EMEA/H/C/005751/MEA 004.1

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jana Lukacisinova

Scope: MAH's response to MEA 004 [***PASS No BO43309***] RSI as adopted in May 2024.
Evaluation of the Effectiveness of the Additional Risk Minimisation Measures for Glofitamab - A Survey Among Healthcare Professionals in 10 Countries in the European Economic Area

Action: For adoption of advice to CHMP

7.2.5. Omaveloxolone - SKYCLARYS (CAP) - EMEA/H/C/006084/MEA 002.1

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: MAH's answers to questions regarding MEA/002 [Protocol 296FA401 (408-C-2301)] as adopted in June 2024.
An observational, multinational, post-marketing registry of omaveloxolone-treated patients with Friedreich's ataxia

Action: For adoption of advice to CHMP

7.2.6. Respiratory syncytial virus vaccine (bivalent, recombinant) - ABRYSVO (CAP) - EMEA/H/C/006027/MEA 003.1

Applicant: Pfizer Europe Ma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Updated protocol for Study C3671026 and MAH's responses to MEA 003 [**PROTOCOL FOR PASS NO. C3671026**] RSI as adopted in June 2024

Action: For adoption of advice to CHMP

7.2.7. Respiratory syncytial virus vaccine (bivalent, recombinant) - ABRYSVO (CAP) - EMEA/H/C/006027/MEA 004.1

Applicant: Pfizer Europe Ma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: MAH's response to MEA 004 [*PROTOCOL PASS NO. C3671038*] RSI as adopted in June 2024.

- Section 9.5 protocol/section 2.4.5. of this AR shall be addressed
- It is assumed that the background rates used for the study size calculation (Willame C et al. Vaccine. 2023) is also applicable for the population at issue (i.e. immunocompromised, renally impaired, hepatically impaired). The MAH is asked to confirm.
- The MAH is expected to provide regular updates regarding enrollment (e.g. in the PSURs) and timely notify the Rapporteur in case of delays

Action: For adoption of advice to CHMP

7.2.8. Ritlecitinib - LITFULO (CAP) - EMEA/H/C/006025/MEA 002.1

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Adam Przybylkowski

Scope: MAH's response to MEA 002 [Study B7981092] RSI as adopted in June 2024.
Title: A Prospective Active Surveillance Study to Monitor the Real-World Safety of Ritlecitinib Among Adolescents with Alopecia areata

Action: For adoption of advice to CHMP

7.2.9. Romosozumab - EVENITY (CAP) - EMEA/H/C/004465/MEA 003.9

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: MAH's response to MEA 003.8 [***Protocol Amendment for study OP0006***] RSI as adopted in May 2024

Action: For adoption of advice to CHMP

7.2.10. Rozanolixizumab - RYSTIGGO (CAP) - EMEA/H/C/005824/MEA 001

Applicant: UCB Pharma

PRAC Rapporteur: Maria del Pilar Rayon

Scope: ***Draft PASS Protocol***/ Real-world observational secondary data study (MG0027).(Non-Imposed)
A Multi-National Cohort Study to evaluate the safety of rozanolixizumab in generalized myasthenia gravis patients

Action: For adoption of advice to CHMP

7.2.11. Ruxolitinib - OPZELURA (CAP) - EMEA/H/C/005843/MEA 001.2

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: MAH's response to MEA 001.1 [REVISED PROTOCOL for PASS INCB 88888-037] RSI as adopted in May 2024.
Title: To evaluate the safety of long-term ruxolitinib cream use with respect to incidence of non-melanoma skin cancers

Action: For adoption of advice to CHMP

7.2.12. Somapacitan - SOGROYA (CAP) - EMEA/H/C/005030/MEA 005.2

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Martin Huber

Scope: ***Revised protocol (v. 3.0) / Study No. NN8640-4787***
Title: 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.

As a follow-up of MEA 005.1, the MAH needs to provide the answers to a second Request for supplementary information. A revised study protocol is expected

Action: For adoption of advice to CHMP

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

None

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

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

7.4.1. COVID-19 Vaccine Janssen (Ad26.COV2.S) - JCOVDEN (CAP)[28] - EMEA/H/C/005737/II/0078/G

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Mari Thorn

Scope: A grouped application consisting of three Type II variations, as follows:
C.I.13: Submission of the final report from study COV3003 listed as a category 3 study in the RMP. This is a randomized, double-blind, phase 3 study to evaluate 6 dose levels of Ad26.COV2.S administered as a two-dose schedule in healthy adults. The RMP version 8.3 has also been submitted.

C.I.13: Submission of the final report from study COV3009 listed as a category 3 study in the RMP. This is a randomized, double-blind, placebo controlled phase 3 study to assess the efficacy and safety ofAd26.COV2.S for the prevention of SARS-CoV-2-mediated COVID-19 in adults aged 18 years and older.

C.I.13: Submission of the final report from study RSV2008 listed as a category 3 study in the RMP. This is a randomized, observer-blind, phase 1 study to evaluate innate and pro-inflammatory responses of an Ad26.RSV.preF-based vaccine, Ad26.COV2.S vaccine and Ad26.ZEBOV vaccine in adults aged 18 to 59 years

Action: For adoption of PRAC Assessment Report

7.4.2. Denosumab - PROLIA (CAP) - EMEA/H/C/001120/II/0100

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Mari Thorn

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

Action: For adoption of PRAC Assessment Report

7.4.3. Dolutegravir - TIVICAY (CAP) - EMEA/H/C/002753/WS2620/0092; Dolutegravir, lamivudine - DOVATO (CAP) - EMEA/H/C/004909/WS2620/0047; Dolutegravir, rilpivirine - JULUCA (CAP) - EMEA/H/C/004427/WS2620/0056;

[27] In accordance with Article 61a (6) of Regulation (EC) No 726/2004, in line with the revised variations regulation for any submission as of 4 August 2013
[28] European Commission decision for withdrawal of marketing authorisation for Jcovden (COVID-19 Vaccine Janssen (Ad26.COV2.S)) in the European Union (EU) is dated 26 July 2024. The withdrawal was at the request of the marketing authorisation holder, Janssen-Cilag International N.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Dolutegravir, Abacavir, Lamivudine - TRIUMEQ (CAP) - EMEA/H/C/002754/WS2620/0118

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Update of section 4.6 of the SmPC in order to update information about the use of DTG-containing regimens in pregnancy and at conception based on final results from non-interventional Tsepamo study and the Eswatini Birth Outcomes Surveillance study. In addition, data from other cohort studies and pregnancy registries, including the APR, DOLOMITE-EPPICC (Study 208613) and DOLOMITE-NEAT-ID Network study (Study 208759) both listed as category 3 studies in the RMP; and the US Chart Review (Study 212976) as well as data from literature are included. DOLOMITE-EPPICC (Study 208613) is a non-interventional study to Assess "real-world" maternal and foetal outcomes following DTG use during pregnancy and to describe patterns of DTG utilization; DOLOMITE NEAT ID Network Study (208759) is a non-interventional, multi-site observational study to define the safety and effectiveness of Dolutegravir use in HIV positive pregnant women. The Package Leaflet is updated accordingly. The RMP version 19 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to sections 4.4 and 4.5 of the SmPC

Action: For adoption of PRAC Assessment Report

7.4.4. Lasmiditan - RAYVOW (CAP) - EMEA/H/C/005332/II/0007

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Anna Mareková

Scope: Submission of the final report from study H8H-MC-B005, listed as a category 3 study in the RMP (MEA/003). This is a Real-World Observational Study to Assess Drug Utilisation Patterns in the US Among Migraine Patients Treated with Lasmiditan. The RMP version 2.1 is submitted alongside the final study report

Action: For adoption of PRAC Assessment Report

7.4.5. Lenvatinib - LENVIMA (CAP) - EMEA/H/C/003727/II/0056

Applicant: Eisai GmbH

PRAC Rapporteur: Mari Thorn

Scope: Update of section 5.1 of the SmPC in order to update the safety and efficacy information for the current HCC indication based on final results from study E7080-M000-508 (STELLAR), listed as a category 3 PASS in the RMP; this is a multicentre non-interventional, observational Phase 4 study to evaluate the safety and tolerability of lenvatinib in patients with advanced or unresectable HCC. The RMP version 17.0 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.6. Naloxegol - MOVENTIG (CAP) - EMEA/H/C/002810/II/0043

Applicant: Gruenenthal GmbH

PRAC Rapporteur: Eamon O'Murchu

Scope: Submission of the final report from the PASS study D3820R0008 listed as a category 3 study in the RMP. This is a US post-marketing, comparative, observational study to evaluate the cardiovascular safety of Naloxegol in patients with non-cancer pain in comparison to other treatments for opioid induced constipation. The RMP version 9.0 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.7. Selexipag - UPTRAVI (CAP) - EMEA/H/C/003774/II/0045

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of the final report from study 67896049PAH0002 (EXTRACT) and interim report for study AC-065A401 (EXPOSURE), listed as a category 3 study in the RMP. EXTRACT is a Retrospective Medical Chart Review of Patients with PAH newly treated with either Uptravi (selexipag) or any other PAH-specific therapy. EXPOSURE is an observational cohort study of PAH patients newly treated with either Uptravi (selexipag) or any other PAH-specific therapy, in clinical practice

Action: For adoption of PRAC Assessment Report

7.4.8. Tafamidis - VYNDAQEL (CAP) - EMEA/H/C/002294/II/0091/G, Orphan

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Tiphaine Vaillant

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

C.I.4: Update of the Annex II based on final results from study B3461001 (THAOS) listed as a category 3 study in the RMP. This is a global, multi-center, longitudinal, observational survey of patients with documented transthyretin gene mutations or wild-type transthyretin amyloidosis.

C.I.13: Submission of the final report from study B3461042 listed as a category 3 study in the RMP. This is a post-marketing safety surveillance study in Japanese patients with AATR-PN.

The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to provide B3461028 Clinical Study Report (CSR) Errata

Action: For adoption of PRAC Assessment Report

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

7.5.1. Abatacept - ORENCIA (CAP) - EMEA/H/C/000701/MEA 043

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: From R/55:
An Observational Registry of Abatacept in Patients with Juvenile Idiopathic Arthritis is ongoing. The primary objective is to describe the long-term safety of abatacept treatment for JIA in routine clinical practice by quantifying the incidence rates of serious infections, autoimmune disorders, and malignancies. Recruitment updates are provided each February, and interim reports will be submitted in 2014, 2019, and 2024. The planned date for submission of final data is 2029.
The data in these studies do not change the safety profile of abatacept. The MAH will supply interim reports from the above mentioned studies according to the set schedules.
Third Interim Report / Study IM101240

Action: For adoption of advice to CHMP

7.5.2. Botulinum toxin type A - NUCEIVA (CAP) - EMEA/H/C/004587/MEA 002.5

Applicant: Evolus Pharma B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: ***Second Interim Report / Study EV-010***
Title: Non-Interventional Post-Authorisation Safety Study of NUCEIVA for the Treatment of Moderate-to-Severe Glabellar Lines

Action: For adoption of advice to CHMP

7.5.3. COVID-19 mRNA vaccine - SPIKEVAX (CAP) - EMEA/H/C/005791/MEA 065.5

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: From II/0028:
Study mRNA-1273-P910
Clinical course, outcomes and risk factors of myocarditis and pericarditis following administration of Moderna vaccines targeting SARS-CoV-2.
5th Interim Report & revised protocol & Responses to MEA 065.3

Action: For adoption of advice to CHMP

7.5.4. Ganaxolone - ZTALMY (CAP) - EMEA/H/C/005825/MEA 002

Applicant: Marinus Pharmaceuticals Emerald Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: From initial MAA (RMP)
Safety Review Study LLF001 (CANDID observational study):
Endpoint Enabling Study in Cyclin-dependent kinase-like 5 Deficiency Disorder.
ANNUAL UPDATE (Milestone reports after 50 and 100 participants have completed the 1st year visti)

Action: For adoption of advice to CHMP

7.5.5. Ganaxolone - ZTALMY (CAP) - EMEA/H/C/005825/MEA 003

Applicant: Marinus Pharmaceuticals Emerald Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: From RMP:
Safety review CDD-IPR-CDD-01 CDKL5 Deficiency Disorder International Patient Registry.
Six monthly updates (data lock points [DLPs] in line with those of the ganaxolone Periodic Safety Update Report [PSUR; 17 Mar & 17 Sept]
SIX MONTHS UPDATES / CDD-IPR-CDD-01 CDKL5 Patient Registry

Action: For adoption of advice to CHMP

7.5.6. Imiglucerase - CEREZYME (CAP) - EMEA/H/C/000157/MEA 040.12

Applicant: Sanofi B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: ***Tenth Interim report from the Gaucher Pregnancy and Lactation Sub-Registry***
Covering the period: 08 May 2021 to 03 May 2024

Action: For adoption of advice to CHMP

7.5.7. Siponimod - MAYZENT (CAP) - EMEA/H/C/004712/MEA 002.5

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: ***Third Annual Interim Report for PRIM / study no CBAF312A2411 + MAH's responses to MEA 002.4 [Second Annual Interim Report for PRIM]***
Study title: Evaluation of pregnancy and infant outcomes in Mayzent patients using PRegnancy outcomes Intensive Monitoring (PRIM) data – The Mayzent PRIM study

Action: For adoption of advice to CHMP

7.5.8. Tofacitinib - XELJANZ (CAP) - EMEA/H/C/004214/MEA 024.1

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: ***Second Interim Report / A3921347 study*** (RMP category 3 study)
Study A3921347 - An Active Surveillance, Post-Authorization Study to Characterize the

Safety of Tofacitinib in Patients with Moderately to Severely Active Ulcerative Colitis in the Real-World Setting Using Data from a US Administrative Healthcare Claims Database.

Action: For adoption of advice to CHMP

7.5.9. Tozinameran - COMIRNATY (CAP) - EMEA/H/C/005735/MEA 041.6

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: ***Fourth Interim Report / Study C4591036***
Clinical study to characterize the clinical course, risk factors, long-term sequelae, and quality oflife in children and young adults <21 years with acute post-vaccine myocarditis.

Action: For adoption of advice to CHMP

7.6. Others

7.6.1. Capivasertib - TRUQAP (CAP) - EMEA/H/C/006017/MEA 001

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Hrabcik

Scope: ***Feasibility Assessment***
A database study of the safety and effectiveness of TRUQAP (capivasertib) + fulvestrant in patients with advanced breast cancer and type 1 or type 2 diabetes. (NINI; RMP)

Action: For adoption of advice to CHMP

7.6.2. SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer, Selvacovatein - BIMERVAX (CAP) - EMEA/H/C/006058/MEA 010.2

Applicant: Hipra Human Health S.L.

PRAC Rapporteur: Zane Neikena

Scope: ***Study Progress Report (Version 1.0) / VAC4EU***
Post-authorisation Safety Study of BIMERVAX Vaccine in Europe.

Action: For adoption of advice to CHMP

7.7. New Scientific Advice

7.8. Ongoing Scientific Advice

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

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Dinutuximab beta - QARZIBA (CAP) - EMEA/H/C/003918/S/0063 (without RMP)

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.2. Ebola vaccine (rDNA[29], replication-incompetent) - MVABEA (CAP) - EMEA/H/C/005343/S/0022 (without RMP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.3. Ebola vaccine (rDNA[30], replication-incompetent) - ZABDENO (CAP) - EMEA/H/C/005337/S/0020 (without RMP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

[29] Recombinant deoxyribonucleic acid
[30] Recombinant deoxyribonucleic acid

8.2. Conditional renewals of the marketing authorisation

8.2.1. Etranacogene dezaparvovec - HEMGENIX (CAP) - EMEA/H/C/004827/R/0020 (without RMP)

Applicant: CSL Behring GmbH, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CAT and CHMP

8.2.2. Exagamglogene autotemcel - CASGEVY (CAP) - EMEA/H/C/005763/R/0006 (without RMP)

Applicant: Vertex Pharmaceuticals (Ireland) Limited, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CAT and CHMP

8.2.3. Selpercatinib - RETSEVMO (CAP) - EMEA/H/C/005375/R/0035 (without RMP)

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Arsenic trioxide - ARSENIC TRIOXIDE MYLAN (CAP) - EMEA/H/C/005235/R/0012 (without RMP)

Applicant: Mylan Ireland Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.2. Azacitidine - AZACITIDINE BETAPHARM (CAP) - EMEA/H/C/005075/R/0020 (without RMP)

Applicant: betapharm Arzneimittel GmbH

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Budesonide, Formoterol fumarate dihydrate - GORESP DIGIHALER (CAP) - EMEA/H/C/004882/R/0016 (without RMP)

Applicant: Teva Pharma B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Cefiderocol - FETCROJA (CAP) - EMEA/H/C/004829/R/0022 (with RMP)

Applicant: Shionogi B.V.

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.5. Cholera vaccine, oral, live - VAXCHORA (CAP) - EMEA/H/C/003876/R/0024 (without RMP)

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Jean-Michel Dogné

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.6. Cinacalcet - CINACALCET ACCORDPHARMA (CAP) - EMEA/H/C/005236/R/0013 (without RMP)

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.7. Influenza vaccine (surface antigen, inactivated, adjuvanted) - FLUAD TETRA (CAP) - EMEA/H/C/004993/R/0055 (without RMP)

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.8. Tigecycline - TIGECYCLINE ACCORD (CAP) - EMEA/H/C/005114/R/0007 (without RMP)

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

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

Applicant: SciPharm Sarl

PRAC Rapporteur: Zane Neikena

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspections

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

9.3. Others

None

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

10.1. Safety related variations of the marketing authorisation

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

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jana Lukacisinova

Scope: PRAC consultation on a direct healthcare professional communication (DHCP) in the

context of a type II variation to update sections 4.4 and 4.6 of the SmPC and the package leaflet to amend the duration of the period for which female patients of child-bearing potential must use highly effective contraceptive methods following the last dose of Alecensa, and must be informed of potential harm to the foetus in the event of pregnancy, from 3 months to 5 weeks based on the latest guidelines on contraception requirements for drugs with aneugenic potential, on request of CHMP

Action: For adoption of advice to CHMP

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

None

10.3. Other requests

None

10.4. Scientific Advice

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

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

11.1. Safety related variations of the marketing authorisation

11.1.1. Fluoroquinolones for systemic and inhalation use: ciprofloxacin (NAP); levofloxacin (NAP); lomefloxacin (NAP); moxifloxacin (NAP); norfloxacin (NAP); ofloxacin (NAP); pefloxacin (NAP); prulifloxacin (NAP); rufloxacin (NAP) - CZ/H/PSUFU/A31/1452/202210

Applicant: various

PRAC Lead: Eva Jirsová

Scope: PRAC consultation on a PSUR follow-up procedure regarding risk minimisation measures following submission of cumulative reviews of spontaneously reported cases of prolonged, potentially irreversible, serious suspected adverse drug reactions, in accordance to the outcome of the referral procedure under Article 31 of Directive 2001/83/EC (EMEA/H/A-31/1452) concluded in 2019, on request of Czech Republic (follow up to the advice adopted by PRAC in June 2024)

Action: For adoption of advice to Member States

11.1.2. Human plasma protein - OCTAPLASLG - SE/H/1866/01-02/II/99

Applicant: Octapharma AB

PRAC Lead: Mari Thorn

Scope: PRAC consultation on a type II variation procedure to amend the product information section 4.8 in order to add TRALI (transfusion-related acute lung injury) as an adverse reaction (as a follow up of the request made by PRAC in the PSUSA/00001635/202302 concluded in November 2023), on request of Sweden

Action: For adoption of advice to Member States

11.2. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC membership

Action: For information

12.1.2. Vote by proxy

None

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

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

None

12.4. Cooperation within the EU regulatory network

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

Action: For discussion

12.5. Cooperation with International Regulators

None

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

None

12.7. PRAC work plan

None

12.8. Planning and reporting

12.8.1. Marketing authorisation applications (MAA) forecast for 2024 – planning update dated Q3 2024

Action: For discussion

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

PRAC lead: Jana Lukacisinova

Action: For discussion

12.10.3. PSURs repository

None

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

Action: For adoption

12.11. Signal management

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

None

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Specific adverse drug reaction (ADR) follow-up questionnaire (FUQ) drafting group – update on the activities

PRAC lead: Tiphaine Vaillant

Action: For adoption

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

None

12.21. Others

12.21.1. ADEPT study (Antiepileptic Drugs Exposure and Pregnancy and neonaTal outcomes research) – protocol and study deliverables)

Action: For discussion

12.21.2. Committees' timetables and deadlines around the end of year holiday period

PRAC Lead(s): Liana Martirosyan, Bianca Mulder

Action: For discussion

12.21.3. CHMP AR template – Revamp Project

PRAC Lead(s): Ulla Wändel Liminga

Action: For discussion

13. Any other business

None

14. Explanatory notes

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

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

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

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

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

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

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

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

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

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

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

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

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

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