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SCIENCE MEDICINES HEALTH

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Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 08-11 April 2024

Chair: Sabine Straus – Vice-Chair: Martin Huber

08 April 2024, 13:00 – 19:30, room 1C / via teleconference

09 April 2024, 08:30 – 19:30, room 1C / via teleconference

10 April 2024, 08:30 – 19:30, room 1C / via teleconference

11 April 2024, 08:30 – 16:00, room 1C / via teleconference

Organisational, regulatory and methodological matters (ORGAM)

25 April 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.

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

Note on access to documents

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

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1. Introduction

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

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

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

Action: For adoption

1.3. Minutes of the previous meeting on 04-07 March 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

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination procedures¹

None

3.5. Others

None

4. Signals assessment and prioritisation²

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

4.1.1. Anakinra – KINERET (CAP)

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Karin Erneholm

Scope: Signal of amyloidosis

Action: For adoption of PRAC recommendation

EPITT 20073 – New signal

Lead Member State(s): DK

4.1.2. Apalutamide – ERLEADA (CAP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Signal of lichenoid keratosis

Action: For adoption of PRAC recommendation

EPITT 20060 – New signal

Lead Member State(s): FR

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

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

4.1.3. Eptinezumab - VYEPTI (CAP); erenumab – AIMOVIG (CAP); galcanezumab – EMGALITY (CAP)

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

PRAC Rapporteur: to be appointed

Scope: Signal of erectile dysfunction

Action: For adoption of PRAC recommendation

EPITT 20074 – New signal

Lead Member State(s): FI, NL

4.1.4. Pirfenidone – ESBRIET (CAP), Pirfenidone axunio (CAP); Pirfenidone Viatris (CAP); NAP

Applicant: Roche Registration GmbH, various

PRAC Rapporteur: Rhea Fitzgerald

Scope: Signal of lichenoid drug eruption

Action: For adoption of PRAC recommendation

EPITT 20069 – New signal

Lead Member State(s): IE

4.1.5. Posaconazole - NOXAFIL (CAP), Posaconazole Accord (CAP), Posaconazole AHCL (CAP); NAP

Applicant: Merck Sharp & Dohme B.V. (Noxafil), Accord Healthcare S.L.U. (Posaconazole Accord, Posaconazole AHCL), various

PRAC Rapporteur: Nathalie Gault

Scope: Signal of photosensitivity reaction

Action: For adoption of PRAC recommendation

EPITT 20076 – New signal

Lead Member State(s): FR

4.2. Signals follow-up and prioritisation

4.2.1. Adagrasib – KRAZATI (CAP)

Applicant: Mirati Therapeutics B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Signal of serious cutaneous adverse reactions (SCARs)

Action: For adoption of PRAC recommendation

EPITT 20051 – Follow-up to February 2024

- 4.2.2. [Atezolizumab - TECENTRIQ \(CAP\) - EMEA/H/C/004143/SDA/025.1](#); [Avelumab - BAVENCIO \(CAP\) - EMEA/H/C/004338/SDA/011.1](#); [Cemiplimab - LIBTAYO \(CAP\) - EMEA/H/C/004844/SDA/010.1](#); [Dostarlimab - JEMPERLI \(CAP\) - EMEA/H/C/005204/SDA/005.1](#); [Durvalumab - IMFINZI \(CAP\) - EMEA/H/C/004771/SDA/012.1](#); [Ipilimumab – YERVOY \(CAP\) - EMEA/H/C/002213/SDA/048.1](#); [Nivolumab - OPDIVO \(CAP\) - EMEA/H/C/003985/SDA/056.1](#); [Nivolumab, relatlimab - OPDUALAG \(CAP\) - EMEA/H/C/005481/SDA/006.1](#); [Pembrolizumab - KEYTRUDA \(CAP\) - EMEA/H/C/003820/SDA/040.1](#); [Tislelizumab – TEVIMBRA \(CAP\) - EMEA/H/C/005919/SDA/002.1](#); [Tremelimumab - IMJUDO \(CAP\) - EMEA/H/C/006016/SDA/003.1](#)
-

Applicant: AstraZeneca AB (Imjudo), Bristol-Myers Squibb Pharma EEIG (Imfinzi, Opdivo, Opdualag), GlaxoSmithKline (Ireland) Limited (Jemperli), Merck Europe B.V. (Bavencio), Merck Sharp & Dohme B.V.(Keytruda), Novartis Europharm Limited (Tevimbra), Regeneron Ireland Designated Activity Company (Libtayo), Roche Registration GmbH (Tecentriq)

PRAC Rapporteur: Bianca Mulder

Scope: Signal of coeliac disease

Action: For adoption of PRAC recommendation

EPITT 19958 – Follow-up to February 2024

- 4.2.3. [Atezolizumab - TECENTRIQ \(CAP\) - EMEA/H/C/004143/SDA/024.1](#); [Avelumab - BAVENCIO \(CAP\) - EMEA/H/C/004338/SDA/010.1](#); [Cemiplimab - LIBTAYO \(CAP\) - EMEA/H/C/004844/SDA/009.1](#); [Dostarlimab - JEMPERLI \(CAP\) - EMEA/H/C/005204/SDA/004.1](#); [Durvalumab – IMFINZI \(CAP\) – EMEA/H/C/004771/SDA/011.1](#); [Ipilimumab – YERVOY \(CAP\) – EMEA/H/C/002213/SDA/047.1](#); [Nivolumab - OPDIVO \(CAP\) - EMEA/H/C/003985/SDA/055.1](#); [Nivolumab, relatlimab - OPDUALAG \(CAP\) - EMEA/H/C/005481/SDA/005.1](#); [Pembrolizumab - KEYTRUDA \(CAP\) - EMEA/H/C/003820/SDA/039.1](#); [Tislelizumab - TEVIMBRA \(CAP\) - EMEA/H/C/005919/SDA/001.1](#); [Tremelimumab - IMJUDO \(CAP\) - EMEA/H/C/006016/SDA/002.1](#)
-

Applicant(s): AstraZeneca AB (Imjudo), Bristol-Myers Squibb Pharma EEIG (Imfinzi, Opdivo, Opdualag), GlaxoSmithKline (Ireland) Limited (Jemperli), Merck Europe B.V. (Bavencio), Merck Sharp & Dohme B.V.(Keytruda), Novartis Europharm Limited (Tevimbra), Regeneron Ireland Designated Activity Company (Libtayo), Roche Registration GmbH (Tecentriq)

PRAC Rapporteur: Martin Huber

Scope: Signal of pancreatic failure

Action: For adoption of PRAC recommendation

EPITT 19955 – Follow-up to February 2024

- 4.2.4. [Axicabtagene ciloleucel – YESCARTA \(CAP\) - EMEA/H/C/004480/SDA/015](#); [idecabtagene vicleucel – ABECMA \(CAP\) - EMEA/H/C/004662/SDA/020](#); [lisocabtagene maraleucel – BREYANZI \(CAP\) - EMEA/H/C/004731/SDA/019](#); [ciltabtagene autoleucel – CARVYKTI \(CAP\) - EMEA/H/C/005095/SDA/016](#);

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

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Signal of secondary malignancy of T-cell origin

Action: For adoption of PRAC recommendation

EPITT 20040 – follow up to January 2024

4.2.5. Chlorhexidine (NAP)³ and other relevant fixed-dose combinations⁴

Applicant: various

PRAC Rapporteur: Lina Seibokiene

Scope: Signal of persistent corneal injury and significant visual impairment

Action: For adoption of PRAC recommendation

EPITT 19970 – Follow-up to February 2024

4.2.6. Doxycycline (NAP)

Applicant: various

PRAC Rapporteur: Liana Martirosyan

Scope: Signal of suicidality

Action: For adoption of PRAC recommendation

EPITT 19997 – follow up to December 2023⁵

4.2.7. Ethambutol (NAP)

Applicant: various

PRAC Rapporteur: Sonja Hrabcik

³ For cutaneous use only

⁴ Chlorhexidine, chlorocresol, hexamidine; chlorhexidine gluconate, chlorocresol, hexamidine; chlorocresol, hexamidine, chlorhexidine digluconate; benzalkonium chloride, chlorhexidine gluconate; chlorhexidine gluconate, benzoxonium chloride, retinol; benzalkonium chloride, chlorhexidine gluconate, benzyl alcohol; chlorhexidine gluconate; chlorhexidine gluconate, cetrimonium; chlorhexidine gluconate, chlorocresol, hexamidine; chlorhexidine gluconate, dexpanthenol; chlorhexidine gluconate, hydrocortisone; chlorhexidine gluconate, hydrogen peroxide, isopropyl alcohol; chlorhexidine gluconate, isopropyl alcohol; chlorhexidine gluconate, ethanol; chlorhexidine gluconate, phenol; benzalkonium chloride, chlorhexidine gluconate; benzalkonium chloride, chlorhexidine digluconate; chlorhexidine digluconate, ethanol; chlorhexidine digluconate, isopropyl alcohol; chlorhexidine dihydrochloride; benzalkonium chloride, chlorhexidine dihydrochloride, isopropyl myristate, liquid paraffin; chlorhexidine dihydrochloride, dexpanthenol; chlorhexidine dihydrochloride, nystatin; chlorhexidine dihydrochloride, nystatin, dexamethasone; chlorhexidine dihydrochloride, nystatin, hydrocortisone; chlorhexidine dihydrochloride, zinc oxide, pramocaine hydrochloride; triamcinolone acetonide; chlorhexidine dihydrochloride, dexpanthenol, alphatocopherol acetate, vitamin A; chlorhexidine gluconate; cetrimide, chlorhexidine digluconate; chlorhexidine acetate; cetrimide, chlorhexidine acetate; retinol palmitate, chlorhexidine acetate; retinol palmitate, benzocaine, retinol, chlorhexidine acetate; bacitracin zinc, chlorhexidine acetate; nystatin, hydrocortisone, chlorhexidine acetate.

⁵ Held on 27-30 November 2023

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

Action: For adoption of PRAC recommendation

EPITT 20018 – follow up to December 2023⁶

- 4.2.8. Exenatide - BYDUREON (CAP) - EMEA/H/C/002020/SDA/030.1, BYETTA (CAP) - EMEA/H/C/000698/SDA/050.1; Dulaglutide - TRULICITY (CAP) - EMEA/H/C/002825/SDA/010.1; Insulin glargine, lixisenatide - SULIQUA (CAP) - EMEA/H/C/004243/SDA/009.1; Lixisenatide - LYXUMIA (CAP) - EMEA/H/C/002445/SDA/017.1; liraglutide - SAXENDA (CAP) - EMEA/H/C/003780/SDA/020.1, VICTOZA (CAP) - EMEA/H/C/001026/SDA/040.1, XULTOPHY (CAP) - EMEA/H/C/002647/SDA/006.1; Semaglutide - OZEMPIC (CAP) - EMEA/H/C/004174/SDA/008.1, RYBELSUS (CAP) - EMEA/H/C/004953/SDA/013.1, WEGOVY (CAP) - EMEA/H/C/005422/SDA/007.1
-

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

PRAC Rapporteur: Bianca Mulder

Scope: Signal of suicidal ideation and self-injurious ideation

Action: For adoption of PRAC recommendation

EPITT 19946 – follow up to December 2023⁷

- 4.2.9. Teriparatide – FORSTEO (CAP) – EMEA/H/C/000425/SDA/053, MOVYmia (CAP) - EMEA/H/C/004368/SDA/003, TERROSA (CAP) - EMEA/H/C/003916/SDA/003, LIVOGIVA (CAP) - EMEA/H/C/005087/SDA/002, SONDELbay (CAP) - EMEA/H/C/005827/SDA/002, KAULIV (CAP) - EMEA/H/C/004932/SDA/002, TERIPARATIDE SUN (CAP); NAP - EMEA/H/C/005793/SDA/002
-

Applicant: Accord Healthcare S.L.U. (Sondelbay), Eli Lilly Nederland B.V. (Forsteo), Gedeon Richter Plc. (Terrosa), STADA Arzneimittel AG (Movymia), Strides Pharma (Cyprus) Limited (Kauliv), Sun Pharmaceutical Industries Europe B.V. (Teriparatide SUN), Theramex Ireland Limited (Livogiva)

PRAC Rapporteur: Tiphaine Vaillant

Scope: Signal of alopecias

Action: For adoption of PRAC recommendation

EPITT 19972 – Follow-up to October 2023⁸

⁶ Held on 27-30 November 2023

⁷ Held on 27-30 November 2023

⁸ Held on 25-28 September 2023

4.3. Variation procedure(s) resulting from signal evaluation

4.3.1. Dabrafenib - FINLEE (CAP) - EMEA/H/C/005885/WS2670/0004; Trametinib - SPEXOTRAS (CAP) - EMEA/H/C/005886/WS2670/0003

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Ulla Wändel Liminga

Scope: To include into the product information for dabrafenib and trametinib the signal 'peripheral neuropathy' in line with the PRAC recommended wording from EMA/PRAC/289010/2023, EPITT No. 19947

Action: For adoption of PRAC assessment report

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Autologous cartilage-derived articular chondrocytes, in-vitro expanded - (CAP MAA) - EMEA/H/C/004594

Scope (pre D-120 phase): repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV

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

5.1.2. Axitinib - (CAP MAA) - EMEA/H/C/006206

Scope (pre D-180 phase): treatment of adult patients with advanced renal cell carcinoma (RCC)

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

5.1.3. Crovalimab - (CAP MAA) - EMEA/H/C/006061

Scope (pre D-180 phase): treatment of paroxysmal nocturnal haemoglobinuria

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

5.1.4. Donanemab - (CAP MAA) - EMEA/H/C/006024

Scope (pre D-180 phase): to slow disease progression in adult patients with Alzheimer's disease (AD)

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

5.1.5. Enzalutamide - (CAP MAA) - EMEA/H/C/006299

Scope (pre D-180 phase): treatment of prostate cancer

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

5.1.6. Erdafitinib - (CAP MAA) - EMEA/H/C/006050

Scope (pre D-180 phase): treatment of adult patients with locally advanced unresectable or metastatic urothelial carcinoma (UC)

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

5.1.7. Macitentan, tadalafil - (CAP MAA) - EMEA/H/C/005001

Scope (pre D-180 phase): treatment of pulmonary arterial hypertension (PAH) in adults patients

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

5.1.8. Nilotinib - (CAP MAA) - EMEA/H/C/006315

Scope (pre D-180 phase): treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (CML)

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

5.1.9. Odronextamab - (CAP MAA) - EMEA/H/C/006215, Orphan

Applicant: Regeneron Ireland Designated Activity Company

Scope (pre D-180 phase): treatment of blood cancers (follicular lymphoma (FL) or diffuse large B cell lymphoma (DLBCL) and large B cell lymphoma)

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

5.1.10. Pomalidomide - (CAP MAA) - EMEA/H/C/006273

Scope (pre D-180 phase): treatment of adult patients with multiple myeloma

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

5.1.11. Pomalidomide - (CAP MAA) - EMEA/H/C/006314

Scope (pre D-180 phase): treatment of multiple myeloma

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

5.1.12. Pomalidomide - (CAP MAA) - EMEA/H/C/006294

Scope (pre D-180 phase): treatment of adults with multiple myeloma

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

5.1.13. [Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation – \(CAP MAA\) - EMEA/H/C/006278](#)

Scope (pre D-180 phase): prevention of lower respiratory tract disease (LRTD) and acute respiratory disease (ARD) caused by respiratory syncytial virus (RSV)

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

5.1.14. [Sotatercept - \(CAP MAA\) - EMEA/H/C/005647, PRIME, Orphan](#)

Applicant: Merck Sharp & Dohme B.V.

Scope (pre D-180 phase): treatment of pulmonary arterial hypertension in adults

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

5.1.15. [Vorasicidenib - \(CAP MAA\) - EMEA/H/C/006284, Orphan](#)

Applicant: Les Laboratoires Servier

Scope (pre D-120 phase, accelerated assessment): treatment of predominantly non-enhancing astrocytoma or oligodendroglioma with a IDH1 R132 mutation or IDH2 R172 mutation

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. [Afamelanotide - SCENESSE \(CAP\) - EMEA/H/C/002548/II/0049, Orphan](#)

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

Scope: Termination of study CUV-RCR-001 (Scenesse (Afamelanotide 16mg) Retrospective Chart Review) listed as an obligation in the Annex II of the product information. This is a retrospective study comparing long term safety data and outcome endpoints in patients receiving and not receiving Scenesse, or having discontinued Scenesse use. The Annex II and the RMP (version 9.6) are updated accordingly

Action: For adoption of PRAC Assessment Report

5.2.2. [Avelumab - BAVENCIO \(CAP\) - EMEA/H/C/004338/II/0044/G](#)

Applicant: Merck Europe B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Grouped application comprising four variations as follows:

Type II (C.I.11.b): To update Annex II and the RMP version 7.1 for Bavencio to change the classification of 'safety in patients with autoimmune disease' to the important identified risk 'other immune mediated adverse reactions' along with removal of the patient information brochure from the educational material, following the PRAC assessment report

PSUSA/00010635/202303.

Type IA (A.6): To change ATC level name from 'Other antineoplastic agents, monoclonal antibodies' to 'Antineoplastic agents, monoclonal antibodies, PD-1/PDL-1 (Programmed cell death protein 1/death ligand 1) inhibitors' in Section 5.1 of the Summary of Product Characteristics (SmPC). The ATC code remains unchanged.

Type IA (C.I.z): To update the statement for 'infusion-related reactions' in section 4.4 of the SmPC and to align terminology with the RMP for the term 'immune-related' versus 'immune-mediated'.

Type IAIN (C.I.12): To remove from the product information the black symbol and explanatory statements for medicinal products subject to additional monitoring.

In addition, the MAH took this opportunity to introduce editorial changes and to bring the PI in line with the latest QRD template version 10.3

Action: For adoption of PRAC Assessment Report

5.2.3. [Coronavirus \(COVID-19\) vaccine \(recombinant, adjuvanted\) - NUVAXOVID \(CAP\) - EMEA/H/C/005808/II/0060](#)

Applicant: Novavax CZ, a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of an updated RMP version 4.2 after approval of adapted COVID-19 vaccine by new strain, Omicron XBB.1.5

5.2.4. [Dasatinib - SPRYCEL \(CAP\) - EMEA/H/C/000709/II/0090](#)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

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

Action: For adoption of PRAC Assessment Report

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

5.3.1. [Afamelanotide - SCENESSE \(CAP\) - EMEA/H/C/002548/II/0044, Orphan](#)

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

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

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

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

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Gabriele Maurer

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

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

5.3.3. Brexucabtagene autoleucel - TECARTUS (CAP) - EMEA/H/C/005102/WS2632/0041; Axicabtagene ciloleucel - YESCARTA (CAP) - EMEA/H/C/004480/WS2632/0072

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Update of sections 4.2 and 5.1 of the SmPC in order to update the safety monitoring timelines based on data from clinical studies, postmarketing studies, and literature. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to sections 2.2, 6.3 and 6.6 and to update sections 4.4 and 4.5 of the SmPC to align the language across both products

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

5.3.4. Bedaquiline - SIRTURO (CAP) - EMEA/H/C/002614/II/0056, Orphan

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Extension of indications by removal of the restriction for use of SIRTURO (bedaquiline [BDQ]), based on final results from study STREAM Stage 2; this is a multicentre, open-label, parallel-group, randomised, active-controlled study in participants aged 15 years or older with RR/MDR-TB to evaluate an investigational BDQ-containing, all-oral, 40-week regimen of anti-TB drugs (Regimen C) compared to an injectable-containing 40-week control regimen (Regimen B). As a consequence of the data emerging from the submitted study, sections 2, 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. In addition, section E of Annex II has also been updated. The Labelling and

package leaflet are updated in accordance. Version 10.1 of the RMP has also been submitted. Furthermore, the product information is brought in line with the latest QRD template version 10.3. As part of the application, the MAH is requesting the switch from a conditional MA to standard MA

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

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

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

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

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

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

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to slow kidney function decline in adults with primary immunoglobulin A (IgA) nephropathy (IgAN) for KINPEYGO, based on Part B of study NefIgArd (NEF-301), listed as the final specific obligation in the Annex II; this is a Phase 3, randomised, double-blind, placebo-controlled, multicentre study to evaluate the efficacy, safety, and tolerability of oral Nefecon compared to matching placebo in patients with primary IgAN on a background of optimised renin-angiotensin system (RAS) inhibitor therapy. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted

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

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

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Martin Huber

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

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

5.3.8. Cariprazine - REAGILA (CAP) - EMEA/H/C/002770/II/0034

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Update of sections 4.3 and 4.5 of the SmPC in order to update an existing contraindication and update drug-drug interaction information with CYP3A4 inhibitors, based on final results from study RGH-188-301 (CYPRESS) listed as a category 3 study in the RMP; this is an open-label, single-arm, fixed-sequence study to investigate the effect of erythromycin, a moderate CYP3A4 inhibitor on the pharmacokinetics of cariprazine in male patients with schizophrenia. The package leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the product information

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

5.3.9. Ceftazidime, avibactam - ZAVICEFTA (CAP) - EMEA/H/C/004027/II/0035

Applicant: Pfizer Ireland Pharmaceuticals

PRAC Rapporteur: Rugile Pilviniene

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

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

5.3.10. Coronavirus (COVID-19) vaccine (Ad26.COVID-S, recombinant) - JCOVDEN (CAP) - EMEA/H/C/005737/II/0076

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Update of sections 4.5, 4.8 and 5.1 of the SmPC in order to update information regarding the co-administration of JCOVDEN with influenza vaccine based on the final report from study VAC31518COV3005 listed as a category 3 study in the RMP; this is a randomised, double-blind, phase 3 study to evaluate safety, reactogenicity, and immunogenicity of co-administration of Ad26.COVID.S and influenza vaccines in healthy adults 18 years of age and older. The package leaflet is updated accordingly. Version 8.1 of the RMP has also been submitted

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

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

Applicant: Hipra Human Health S.L.

PRAC Rapporteur: Zane Neikena

Scope: Submission of the final report from study HIPRA-HH-5, a phase III, open label, single arm, multi-centre, trial to assess the safety and immunogenicity of a booster vaccination with a recombinant protein RBD fusion heterodimer candidate (PHH-1V) against SARS-COV-2, in adults vaccinated against COVID-19. The RMP version 1.3 has also been submitted

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

5.3.12. [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 based on final results from studies ASTX727-01, ASTX727-02, ASTX727-04, E7727-01, and E7727-02: C.I.6: Extension of indication to include treatment of adult patients with myelodysplastic syndromes (MDS) for INAQOVI and C.I.6: Extension of indication to include treatment of adult patients with chronic myelomonocytic leukaemia (CMML) for INAQOVI. 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 product information 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

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

Applicant: AstraZeneca AB

PRAC Rapporteur: Amelia Cupelli

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

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

5.3.14. [Elasomeran - SPIKEVAX \(CAP\) - EMEA/H/C/005791/II/0120](#)

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Submission of the final report from study mRNA-1273-P301 (phase 3, randomised, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine in adults aged 18 years and older) listed as a category 3 study in the RMP. The RMP version 8.2 has also been submitted

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

5.3.15. [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), multicentre study to evaluate pharmacokinetics, safety, and efficacy of eliglustat in pediatric 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 product information

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

5.3.16. [Enfortumab vedotin - PADCEV \(CAP\) - EMEA/H/C/005392/II/0013](#)

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include in combination with pembrolizumab, the first-line treatment of adult patients with locally advanced or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy for PADCEV, based on the final results from study KEYNOTE-A39/EV-302: 'An open label, randomised, controlled phase 3 study of enfortumab vedotin in combination with pembrolizumab versus chemotherapy alone in previously untreated locally advanced (LA) or metastatic urothelial cancer (mUC)'; As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The package leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection

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

5.3.17. Entrectinib - ROZLYTREK (CAP) - EMEA/H/C/004936/X/0017/G

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Grouped application consisting of: 1) Extension application to: a) Introduce a new pharmaceutical form (coated granules) associated with a new strength (50 mg); b) Introduce a new route of administration (gastroenteral use) for the already authorised 100 mg and 200 mg hard capsules presentations based on final results from studies CO40778 (STARTRK-NG), GO40782 (STARTRK-2) and BO41932 (TAPISTRY). Study CO40778 is a Phase I/II open-label, dose-escalation and expansion study of entrectinib in pediatrics with locally advanced or metastatic solid or primary CNS tumors and/or who have no satisfactory treatment options; Study GO40782 is an open-label, multicenter, global Phase II basket study of entrectinib for the treatment of patients with solid tumors that harbor an NTRK1/2/3, ROS1, or ALK gene rearrangement (fusion), and Study BO41932 is a Phase II, global, multicenter, open-label, multi-cohort study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in rational, specified combinations in participants with unresectable, locally advanced or metastatic solid tumors determined to harbor specific oncogenic genomic alterations or who are tumor mutational burden (TMB)-high as identified by a validated next-generation sequencing (NGS) assay; 2) grouped with the following type II variations:

a) to extend the currently approved indication in solid tumours with NTRK gene fusion to patients from birth to 12 years of age (both for the coated granules and already approved hard capsules presentations);

b) to add a new paediatric indication from birth to 18 years of age for patients with solid tumours with a ROS1 gene fusion (both for the coated granules and already approved hard capsules presentations).

As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated accordingly. The package leaflet and Labelling are updated in accordance.

c) to add wording regarding the option of suspension in water of the content of the capsules to be used orally or via the e.g. gastric or nasogastric tube (in sections 4.2 and 5.2 of the SmPC).

The RMP (version 5) is updated in accordance. The MAH took the opportunity to introduce minor editorial changes to the product information and to update Annex II of the SmPC

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

5.3.18. Efgartigimod alfa - VYVGART (CAP) - EMEA/H/C/005849/II/0014, Orphan

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

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

weakness. The RMP version 2.2 has also been submitted

5.3.19. 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, multicentre, open-label, randomised 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

5.3.20. Filgotinib - JYSELECA (CAP) - EMEA/H/C/005113/II/0031/G

Applicant: Galapagos N.V.

PRAC Rapporteur: Petar Mas

Scope: Grouped application comprising two variations as follows:

Type II (C.I.4): Update of sections 4.8 and 5.1 of the SmPC to update the safety mean duration exposure and efficacy information based on final results (up to Week 432) from study GLPG0634-CL-205 (DARWIN 3) listed as a category 3 study in the RMP (MEA/009); this is a phase II, open-label, long-term follow-up safety and efficacy study to evaluate the long-term safety and tolerability of filgotinib for the treatment of rheumatoid arthritis in patients who received treatment in their parent studies. The RMP version 6.1 has also been submitted.

Type IA (A.6): To change the ATC code for Janus-associated kinase (JAK) inhibitor from L04AA45 filgotinib to L04AF04 filgotinib

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

5.3.21. Ganaxolone - ZTALMY (CAP) - EMEA/H/C/005825/II/0004/G, Orphan

Applicant: Marinus Pharmaceuticals Emerald Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application comprised of 8 Type II variations as follows:

1 Type II (C.I.4): Update of section 5.2 of the SmPC in order to update ganaxolone metabolite pattern at steady state based on re-analysis of 1042-TQT-1001 listed as a category 3 study in the RMP to evaluate the ganaxolone steady-state metabolite.

7 Type II (C.I.13): Submission of the final non-clinical study reports for the in vitro drug-drug interaction (DDI) potential and in vivo pharmacokinetics (PK) of the metabolite M17 listed as category 3 studies in the RMP.

The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to introduce updates to the product information that reflect clarifications and typographical corrections, including to sections 4.2 and 4.4 of the SmPC

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

5.3.22. [Ganaxolone - ZTALMY \(CAP\) - EMEA/H/C/005825/II/0006, Orphan](#)

Applicant: Marinus Pharmaceuticals Emerald Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Update of section 5.1 of the SmPC in order to update open-label data based on the final report from study 1042-CDD-3001 OLE listed as a category 3 study in the RMP. This was the open-label portion of the pivotal study 1042-CDD-3001; a double-blind, randomised, placebo-controlled trial of adjunctive ganaxolone treatment in children and young adults with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) followed by long-term open-label treatment. The RMP version 1.4 has also been submitted

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

5.3.23. [Inclisiran - LEQVIO \(CAP\) - EMEA/H/C/005333/II/0021](#)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Kimmo Jaakkola

Scope: Submission of the final report from study ORION-8 - a long-term extension trial of the phase III lipid-lowering trials to assess the effect of long-term dosing of inclisiran given as subcutaneous injections in subjects with high cardiovascular risk and elevated LDL-C, listed as a category 3 study in the RMP. The RMP version 3.0 has also been submitted

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

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

Applicant: Basilea Pharmaceutica Deutschland GmbH

PRAC Rapporteur: Adam Przybylkowski

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

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

5.3.25. Lanadelumab - TAKHZYRO (CAP) - EMEA/H/C/004806/II/0040, Orphan

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Kirsti Villikka

Scope: Update of section 4.4 of the SmPC in order to remove the information related to non-availability of clinical data on the use of lanadelumab in hereditary angioedema (HAE) patients with normal C1 Inhibitor (C1-INH) activity, based on results from studies CASPIAN (SHP643-303) and CASPIAN OLE (TAK-743-3001). CASPIAN (SHP643-303) is a phase 3, multicentre, randomised, placebo-controlled, double-blind study to evaluate the efficacy and safety of lanadelumab for prevention against acute attacks of nonhistaminergic angioedema with C1-INH; and CASPIAN OLE (TAK-743-3001) is an open-label study to evaluate the long-term safety and efficacy of lanadelumab for prevention against acute attacks of nonhistaminergic Angioedema with C1-INH. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and the package leaflet

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

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

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Grouped variation consisting of: 1) Extension of indication to include treatment of Progressive Familial Intrahepatic Cholestasis (PFIC) in patients 2 months of age and older for LIVMARLI, based on results from studies MRX-502, LUM001-501, MRX-503, MRX-800 and MRX-801; MRX-502 is an international, multicenter, randomised, double-blind, placebo-controlled, parallel group Phase 3 study that evaluated the efficacy and safety of maralixibat in PFIC participants aged >12 months to <18 years on a proposed dosage of up to 600 µg/kg BID over 6 months. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet and Annex II are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes; 2) B.I.b.1.b In addition, further editorial changes are made in module 3 which are consequential to the extension of indication and the higher maximum daily dose

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

5.3.27. Meningococcal Group A, C, W and Y conjugate vaccine - MENQUADFI (CAP) - EMEA/H/C/005084/II/0027

Applicant: Sanofi Pasteur

PRAC Rapporteur: Jean-Michel Dogné

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

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

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

Applicant: Neuraxpharm Pharmaceuticals S.L.

PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include treatment of adults to Buccolam 10 mg, based on the results from study 2023-504903-10-00; this is an interventional study, relative bioavailability to investigate the pharmacokinetics of a single dose of midazolam oromucosal solution (Buccolam) compared to midazolam solution for intramuscular injection (Hypnovel) in healthy volunteers under fasting conditions. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 6.5 and 6.6 of the SmPC are updated. The package leaflet and labelling are updated in accordance. Version 8.1 of the RMP has also been submitted

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

5.3.29. Nivolumab - OPDIVO (CAP) - EMEA/H/C/003985/II/0140

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include Opdivo for the treatment of patients with resectable stage II-IIIB non-small cell lung cancer, based on results from study CA209977T; a phase 3, randomised, double-blind study of neoadjuvant chemotherapy plus nivolumab versus neoadjuvant chemotherapy plus placebo, followed by surgical resection and adjuvant treatment with nivolumab or placebo for participants with resectable stage II-IIIB non-small cell lung cancer. 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 36.0 of the RMP has also been submitted

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

5.3.30. Ocrelizumab - OCREVUS (CAP) - EMEA/H/C/004043/X/0039

Applicant: Roche Registration GmbH

PRAC Rapporteur: Gabriele Maurer

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

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

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

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include TAGRISSO in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally

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

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

5.3.32. Pembrolizumab - KEYTRUDA (CAP) - EMEA/H/C/003820/II/0150

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include in combination with enfortumab vedotin, the first-line treatment of locally advanced or metastatic urothelial carcinoma in adults, based on the final results from KEYNOTE-A39/EV-302: 'an open label, randomised, controlled phase 3 study of enfortumab vedotin in combination with pembrolizumab versus chemotherapy alone in previously untreated locally advanced (LA) or metastatic urothelial cancer (mUC)'; As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. Version 45.1 of the RMP has also been submitted

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

5.3.33. Pemigatinib - PEMAZYRE (CAP) - EMEA/H/C/005266/II/0015, Orphan

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of adults with myeloid/lymphoid neoplasms (MLNs) with Fibroblast Growth Factor Receptor1 (FGFR1) rearrangement for Pemazyre, based on final results from study INCB 54828-203 (FIGHT-203); this is a phase 2, open-label, monotherapy, multicentre study to evaluate the efficacy and safety of INCB054828 in subjects with myeloid/lymphoid neoplasms with FGFR1 rearrangement. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the product information. As part of the application, the MAH is requesting a 1-year extension of the market protection

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

5.3.34. Pertuzumab, trastuzumab - PHESGO (CAP) - EMEA/H/C/005386/II/0023/G

Applicant: Roche Registration GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: A grouped application comprised of 2 Type II variations and 1 Type IA variation, as follows:

Type II variation (C.I.4): Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information, based on the final report from study WO40324 (FeDeriCa) listed as a category 3 study in the RMP. This is a phase 3, randomised, multicentre, open-label, two-arm study to evaluate the pharmacokinetics, efficacy, and safety of subcutaneous administration of the fixed-dose combination of pertuzumab and trastuzumab in combination with chemotherapy in patients with HER2-positive early breast cancer.

Type II variation (C.I.4): Update of section 4.8 of the SmPC in order to only present specific Phesgo safety data by updating the summary of safety profile and the tabulated list of adverse reactions to reflect this information. The package leaflet is updated accordingly.

Type IA variation (A.6): To change the ATC code of pertuzumab and trastuzumab from L01XY02 to L01FY01. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the product information and to update the list of local representatives in the package leaflet

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

5.3.35. [Pneumococcal polysaccharide conjugate vaccine \(20-valent, adsorbed\) - PREVENAR 20 \(CAP\) - EMEA/H/C/005451/II/0023](#)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Submission of the final current B7471015 study protocol, the Statistical Analysis Plan (SAP) and the final country feasibility assessment report for Apexxnar. The RMP (version 5.0) is updated accordingly

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

5.3.36. [Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - AREXVY \(CAP\) - EMEA/H/C/006054/II/0008](#)

Applicant: GlaxoSmithkline Biologicals S.A.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include treatment of adults 50-59 years of age who are at increased risk for respiratory syncytial virus (RSV) disease for Arexvy, based on results from study 219238 (RSV OA=ADJ-018); this is a phase 3, observer-blind, placebo-controlled, randomised, multi-country, multi-centre, non-inferiority study with 2 cohorts to evaluate immunogenicity, reactogenicity and safety of a single dose of RSVPreF3 OA in adults 50-59 years of age. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the product information, to bring it in line with the latest QRD template version 10.3, and to update the list of local representatives in the package leaflet. As part of the application, the MAH is requesting a 1-year extension of the market protection

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

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

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

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

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

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

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Ulla Wändel Liminga

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-centre study of ruxolitinib added to corticosteroids in paediatric 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-centre study of ruxolitinib added to corticosteroids in paediatric 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 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

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

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Monica Martinez Redondo

Scope: Extension application to add a new strength of 175 mg/ml solution for injection in vial, grouped with an extension of indication to include treatment of active polyarticular-course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older for KEVZARA,

based on results from study DRI13925; this is a multinational, multi-centre, open-label, 2 phase, 3 portions study to describe the pharmacokinetics (PK) profile as well as safety and efficacy of sarilumab. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the product information

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

5.3.40. Teclistamab - TECVAYLI (CAP) - EMEA/H/C/005865/II/0009

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jana Lukacisinova

Scope: Update of section 4.4 of the SmPC in order to update the warning on progressive multifocal leukoencephalopathy (PML) based on a cumulative safety review. The package leaflet is updated accordingly. The RMP version 4.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor updates to the PI and to update the list of local representatives in the package leaflet

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

5.3.41. Tildrakizumab - ILUMETRI (CAP) - EMEA/H/C/004514/II/0055

Applicant: Almirall S.A

PRAC Rapporteur: Adam Przybylkowski

Scope: Type II (B.IV.1.c) - to add the 200 mg solution for injection in pre-filled pen which is an integrated part of the primary packaging of the medicinal product

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

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

Applicant: Beigene Ireland Limited

PRAC Rapporteur: Bianca Mulder

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

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

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

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Martin Huber

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

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

5.3.44. Voclosporin - LUPKYNIS (CAP) - EMEA/H/C/005256/II/0013

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Update of section 4.6 of the SmPC in order to update breast-feeding information based on final results from study AUR-VCS-2021-04. This study is a single-centre, open-label, phase 1, lactation study to investigate the amount of voclosporin excreted in breast milk following a single oral dose of 23.7 mg voclosporin in healthy, lactating, female volunteers. The package leaflet is updated accordingly. The updated RMP version 5.0 has also been submitted

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

6. Periodic safety update reports (PSURs)

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

6.1.1. Abemaciclib - VERZENIOS (CAP) - PSUSA/00010724/202309

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.2. Abrocitinib - CIBINQO (CAP) - PSUSA/00010976/202309

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.3. Amikacin⁹ - ARIKAYCE LIPOSOMAL (CAP) - PSUSA/00010882/202309

Applicant: Insmmed Netherlands B.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.4. Avacopan - TAVNEOS (CAP) - PSUSA/00010967/202309

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.5. Bedaquiline - SIRTURO (CAP) - PSUSA/00010074/202309

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.6. Caplacizumab - CABLIVI (CAP) - PSUSA/00010713/202308

Applicant: Ablynx NV

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.7. Cenobamate - ONTOZRY (CAP) - PSUSA/00010921/202309

Applicant: Angelini S.p.A.

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.8. Cholic acid¹⁰ - ORPHACOL (CAP) - PSUSA/00010208/202309

Applicant: Theravia

PRAC Rapporteur: Sofia Trantza

⁹ For centrally authorised product(s) only

¹⁰ For oxosteroid-reductase or hydroxy-steroid dehydrogenase deficiency indication only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.9. Ciltacabtagene autoleucl - CARVYKTI (CAP) - PSUSA/00011000/202308

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

6.1.10. Cipaglucoosidase alfa - POMBILITI (CAP) - PSUSA/00011047/202309

Applicant: Amicus Therapeutics Europe Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.11. Cobicistat - TYBOST (CAP) - PSUSA/00010081/202308

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.12. Cobicistat, elvitegravir, emtricitabine, tenofovir disoproxil - STRIBILD (CAP) - PSUSA/00010082/202308

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.13. Cobimetinib - COTELLIC (CAP) - PSUSA/00010450/202308

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.14. Crizotinib - XALKORI (CAP) - PSUSA/00010042/202308

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.15. Damoctocog alfa pegol - JIVI (CAP) - PSUSA/00010732/202308

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.16. Darvadstrocel - ALOFISEL (CAP) - PSUSA/00010676/202309

Applicant: Takeda Pharma A/S, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.17. Deucravacitinib - SOTYKTU (CAP) - PSUSA/00011046/202309

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.18. Duvelisib - COPIKTRA (CAP) - PSUSA/00010939/202309

Applicant: Secura Bio Limited

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.19. Ebola vaccine (rDNA, replication-incompetent) - MVABEA (CAP); ZABDENO (CAP) - PSUSA/00010857/202309

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. [Emtricitabine, rilpivirine, tenofovir disoproxil - EVIPLERA \(CAP\) - PSUSA/00009142/202308](#)

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.21. [Enzalutamide - XTANDI \(CAP\) - PSUSA/00010095/202308](#)

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.22. [Eravacycline - XERAVA \(CAP\) - PSUSA/00010718/202308](#)

Applicant: Paion Deutschland GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.23. [Filgotinib - JYSELECA \(CAP\) - PSUSA/00010879/202309](#)

Applicant: Galapagos N.V.

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.24. [Fosdenopterin - NULIBRY \(CAP\) - PSUSA/00011017/202308](#)

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.25. [Fremanezumab - AJOVY \(CAP\) - PSUSA/00010758/202309](#)

Applicant: TEVA GmbH

PRAC Rapporteur: Kirsti Villikka
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.26. [Galcanezumab - EMGALITY \(CAP\) - PSUSA/00010733/202309](#)

Applicant: Eli Lilly Nederland B.V.
PRAC Rapporteur: Kirsti Villikka
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.27. [Ganaxolone - ZTALMY \(CAP\) - PSUSA/00000093/202309](#)

Applicant: Marinus Pharmaceuticals Emerald Limited
PRAC Rapporteur: Adam Przybylkowski
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.28. [Gilteritinib - XOSPATA \(CAP\) - PSUSA/00010832/202309](#)

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

6.1.29. [Glofitamab - COLUMVI \(CAP\) - PSUSA/00000067/202309](#)

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

6.1.30. [Gozetotide - LOCAMETZ \(CAP\) - PSUSA/00011030/202309](#)

Applicant: Novartis Europharm Limited
PRAC Rapporteur: John Joseph Borg
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.31. Idebenone¹¹ - RAXONE (CAP) - PSUSA/00010412/202309

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.32. Idecabtagene vicleucel - ABECMA (CAP) - PSUSA/00010954/202309

Applicant: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.33. Imlifidase - IDEFIRIX (CAP) - PSUSA/00010870/202308

Applicant: Hansa Biopharma AB

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. Influenza vaccine (intranasal, live attenuated) - FLUENZ TETRA (CAP) - PSUSA/00001742/202308

Applicant: AstraZeneca AB

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.35. Linaclotide - CONSTELLA (CAP) - PSUSA/00010025/202308

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.36. Lonapegsomatropin - SKYTROFA (CAP) - PSUSA/00010969/202308

Applicant: Ascendis Pharma Endocrinology Division A/S

PRAC Rapporteur: Martin Huber

¹¹ For centrally authorised product(s) only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.37. [Lorlatinib - LORVIQUA \(CAP\) - PSUSA/00010760/202309](#)

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. [Lusutrombopag - MULPLEO \(CAP\) - PSUSA/00010755/202309](#)

Applicant: Shionogi B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. [Lutetium \(¹⁷⁷LU\) vipivotide tetraxetan - PLUVICTO \(CAP\) - PSUSA/00011031/202309](#)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: John Joseph Borg

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.40. [Maralixibat - LIVMARLI \(CAP\) - PSUSA/00011032/202309](#)

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. [Mecasermin - INCRELEX \(CAP\) - PSUSA/00001942/202308](#)

Applicant: Ipsen Pharma

PRAC Rapporteur: Kirsti Villikka

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.42. Mepolizumab - NUCALA (CAP) - PSUSA/00010456/202309

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.43. Meropenem, vaborbactam - VABOREM (CAP) - PSUSA/00010727/202308

Applicant: Menarini International Operations Luxembourg S.A.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Miglustat¹² - OPFOLDA (CAP) - PSUSA/00000077/202309

Applicant: Amicus Therapeutics Europe Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Mirikizumab - OMVOH (CAP) - PSUSA/00000049/202309

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Naloxegol - MOVENTIG (CAP) - PSUSA/00010317/202309

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Naltrexone, bupropion - MYSIMBA (CAP) - PSUSA/00010366/202309

Applicant: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

¹² For treatment of Pompe disease only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. [Nivolumab, relatlimab - OPDUALAG \(CAP\) - PSUSA/00011018/202309](#)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.49. [Nonacog alfa - BENEFIX \(CAP\) - PSUSA/00002183/202308](#)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.50. [Ofatumumab - KESIMPTA \(CAP\) - PSUSA/00010927/202309](#)

Applicant: Novartis Ireland Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.51. [Olipudase alfa - XENPOZYME \(CAP\) - PSUSA/00011003/202309](#)

Applicant: Sanofi B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.52. [Pembrolizumab - KEYTRUDA \(CAP\) - PSUSA/00010403/202309](#)

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.53. [Pralsetinib - GAVRETO \(CAP\) - PSUSA/00010961/202309](#)

Applicant: Roche Registration GmbH

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

6.1.54. Pyronaridine. artesunate - PYRAMAX (Art 58¹³) - EMEA/H/W/002319/PSUV/0035

Applicant: Shin Poong Pharmaceutical Co., Ltd.
PRAC Rapporteur: Nathalie Gault
Scope: Evaluation of a PSUR procedure
Action: For adoption of recommendation to CHMP

6.1.55. Raltegravir - ISENTRESS (CAP) - PSUSA/00010373/202309

Applicant: Merck Sharp & Dohme B.V.
PRAC Rapporteur: Nathalie Gault
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.56. Rimegepant - VYDURA (CAP) - PSUSA/00010997/202308

Applicant: Pfizer Europe MA EEIG
PRAC Rapporteur: Karin Erneholm
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.57. Ruxolitinib¹⁴ - OPZELURA (CAP) - PSUSA/00011052/202309

Applicant: Incyte Biosciences Distribution B.V.
PRAC Rapporteur: Adam Przybylkowski
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.1.58. Sodium thiosulfate - PEDMARQSI (CAP) - PSUSA/00000066/202309

Applicant: Fennec Pharmaceuticals (EU) Limited
PRAC Rapporteur: Karin Erneholm
Scope: Evaluation of a PSUSA procedure

¹³ 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)

¹⁴ For non-segmental vitiligo indication only

Action: For adoption of recommendation to CHMP

6.1.59. Somapacitan - SOGROYA (CAP) - PSUSA/00010920/202308

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.60. Spesolimab - SPEVIGO (CAP) - PSUSA/00011033/202309

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Nathalie Gault

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.61. Teduglutide - REVESTIVE (CAP) - PSUSA/00009305/202308

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.62. Tepotinib - TEPMETKO (CAP) - PSUSA/00010979/202309

Applicant: Merck Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.63. Valoctocogene roxaparvovec - ROCTAVIAN (CAP) - PSUSA/00011009/202308

Applicant: BioMarin International Limited, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.64. Vosoritide - VOXZOGO (CAP) - PSUSA/00010952/202308

Applicant: BioMarin International Limited

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.65. Zoledronic acid¹⁵ - ACLASTA (CAP) - PSUSA/00009334/202308

Applicant: Sandoz Pharmaceuticals d.d.

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. Azilsartan medoxomil, chlortalidone - EDARBI (CAP); NAP - PSUSA/00000280/202308

Applicant: Takeda Pharma A/S (Edarbi), various

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.2. Duloxetine - CYMBALTA (CAP); DULOXETINE LILLY (CAP); YENTREVE (CAP); NAP - PSUSA/00001187/202308

Applicant: Eli Lilly Nederland B.V. (Cymbalta, Duloxetine Lilly, Yentreve), various

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.3. Glycopyrronium¹⁶ - SIALANAR (CAP); NAP - PSUSA/00010529/202309

Applicant: Proveca Pharma Limited (Sialanar), various

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.4. Mercaptopurine - XALUPRINE (CAP); NAP - PSUSA/00001988/202309

Applicant: Nova Laboratories Ireland Limited (Xaluprine), various

¹⁵ For osteoporosis indication only

¹⁶ For severe sialorrhoea indication only

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

6.2.5. [Sitagliptin - JANUVIA \(CAP\); RISTABEN \(CAP\); TESAVEL \(CAP\); XELEVIA \(CAP\); NAP; metformin hydrochloride, sitagliptin - EFFICIB \(CAP\); JANUMET \(CAP\); RISTFOR \(CAP\); VELMETIA \(CAP\); NAP - PSUSA/00010673/202308](#)

Applicant: Merck Sharp & Dohme B.V., various
PRAC Rapporteur: Bianca Mulder
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.2.6. [Trientine - CUFENCE \(CAP\); CUPRIOR \(CAP\); NAP - PSUSA/00010637/202309](#)

Applicant: Univar Solutions BV (Cufence), Orphalan (Cuprior), various
PRAC Rapporteur: Ana Sofia Diniz Martins
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CHMP

6.2.7. [Zoledronic acid¹⁷ - ZOLEDRONIC ACID HOSPIRA \(SRD\) \(CAP\); ZOLEDRONIC ACID MEDAC \(CAP\); ZOMETA \(CAP\); NAP - PSUSA/00003149/202308](#)

Applicant: Pfizer Europe MA EEIG (Zoledronic acid Hospira (SRD)), medac Gesellschaft für klinische Spezialpräparate mbH (Zoledronic acid medac), Phoenix Labs Unlimited Company (Zometa), various
PRAC Rapporteur: Karin Erneholm
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. [Aztreonam¹⁸ \(NAP\) - PSUSA/00010178/202308](#)

Applicant(s): various
PRAC Lead: Marie Louise Schougaard Christiansen
Scope: Evaluation of a PSUSA procedure
Action: For adoption of recommendation to CMDh

¹⁷ For cancer and fractures indications only

¹⁸ For parenteral use only

6.3.2. Bromazepam (NAP) - PSUSA/00000435/202308

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Dexamfetamine (NAP) – PSUSA/00000986/202309

Applicant(s): various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.4. Dexibuprofen (NAP) - PSUSA/00000996/202308

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. Dienogest, estradiol¹⁹ (NAP) - PSUSA/00010444/202309

Applicant(s): various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.6. Finasteride (NAP) - PSUSA/00001392/202308

Applicant(s): various

PRAC Lead: Ulla Wändel Liminga

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.7. Fluocinolone acetonide²⁰ (NAP) - PSUSA/00010224/202308

Applicant(s): various

PRAC Lead: Carla Torre

¹⁹ For contraception indication only

²⁰ Intravitreal implant in applicator

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. [Human plasma protease C1 inhibitor \(NAP\) - PSUSA/00010163/202308](#)

Applicant(s): various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.9. [Ipratropium, xylometazoline \(NAP\) - PSUSA/00009201/202308](#)

Applicant(s): various

PRAC Lead: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. [Lithium \(NAP\) - PSUSA/00001897/202308](#)

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. [Mirtazapine \(NAP\) - PSUSA/00002068/202308](#)

Applicant(s): various

PRAC Lead: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. [Modafinil \(NAP\) - PSUSA/00010242/202308](#)

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. [Naloxone, oxycodone \(NAP\) - PSUSA/00002114/202308](#)

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.14. Naproxen (NAP) - PSUSA/00002125/202308

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.15. Pefloxacin (NAP) - PSUSA/00002322/202308

Applicant(s): various

PRAC Lead: Polona Golmajer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.16. Permethrin (NAP) - PSUSA/00002355/202308

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.17. Phenytoin (NAP) - PSUSA/00002392/202308

Applicant(s): various

PRAC Lead: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.18. Prednisolone (NAP) - PSUSA/00002506/202308

Applicant(s): various

PRAC Lead: Polona Golmajer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.19. Ramipril (NAP) - PSUSA/00002607/202308

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.20. Rosuvastatin, perindopril, indapamide (NAP) - PSUSA/00010752/202308

Applicant(s): various

PRAC Lead: Polona Golmajer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.21. Suxamethonium (NAP) - PSUSA/00002834/202308

Applicant(s): various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.22. Trazodone (NAP) - PSUSA/00003012/202308

Applicant(s): various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.23. Trimetazidine (NAP) - PSUSA/00003043/202308

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.24. Typhoid polysaccharide vaccine (NAP) - PSUSA/00003065/202308

Applicant(s): various

PRAC Lead: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.25. Vincristine (NAP) - PSUSA/00003121/202308

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.26. Zolpidem (NAP) - PSUSA/00003151/202308

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Dolutegravir - TIVICAY (CAP) - EMEA/H/C/002753/LEG 015.4

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Second annual report for the submission of the available data from the RESPOND study – LEG requested after the procedure EMEA/H/C/PSUSA/00010075/202101 which concerns dolutegravir (Tivicay), dolutegravir/abacavir/lamivudine (Triumeq) and dolutegravir/lamivudine (Dovato)

Action: For adoption of advice to CHMP

6.4.2. Dolutegravir, abacavir, lamivudine - TRIUMEQ (CAP) - EMEA/H/C/002754/LEG 010.4

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Second annual report for the submission of the available data from the RESPOND study – LEG requested after the procedure EMEA/H/C/PSUSA/00010075/202101 which concerns dolutegravir (Tivicay), dolutegravir/abacavir/lamivudine (Triumeq) and dolutegravir/lamivudine (Dovato)

Action: For adoption of advice to CHMP

6.4.3. Dolutegravir, lamivudine - DOVATO (CAP) - EMEA/H/C/004909/LEG 005.4

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: David Olsen

Scope: Second annual report for the submission of the available data from the RESPOND study – LEG requested after the procedure EMEA/H/C/PSUSA/00010075/202101 which concerns dolutegravir (Tivicay), dolutegravir/abacavir/lamivudine (Triumeq) and dolutegravir/lamivudine (Dovato)

Action: For adoption of advice to CHMP

6.4.4. [Meningococcal group A, C, W135 and Y conjugate vaccine - NIMENRIX \(CAP\) - EMEA/H/C/002226/LEG 058](#)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: David Olsen

Scope: From PSUSA/20044/202304: cumulative review of cases of hypersensitivity/allergic reaction (including anaphylaxis)

Action: For adoption of advice to CHMP

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. [Etanercept - ENBREL \(CAP\) - EMEA/H/C/000262/II/0254](#)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Monica Martinez Redondo

Scope: Update of section 4.8 of the SmPC in order to update the frequency of Adverse Drug Reaction (ADR) 'glomerulonephritis' from 'not known' to 'rare' following PSUSA/00010795/202302 procedure, based on available evidence from clinical trials, literature, and post-marketing data. The package leaflet is updated accordingly

Action: For adoption of PRAC Assessment Report

6.5.2. [Ioflupane \(¹²³I\) - DATSCAN \(CAP\) - EMEA/H/C/000266/II/0067](#)

Applicant: GE Healthcare B.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: To update sections 4.4 and 4.5 of the SmPC and section 2 of the package leaflet to implement the recommendation of the PRAC following the PSUSA procedure (EMEA/H/C/PSUSA/00001767/202207). In addition, the MAH took the opportunity to update the list of local representatives in the package leaflet

Action: For adoption of PRAC Assessment Report

6.5.3. [Isatuximab - SARCLISA \(CAP\) - EMEA/H/C/004977/II/0027](#)

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Monica Martinez Redondo

Scope: Update of section 4.8 of the SmPC in order to add 'thrombocytopenia' and 'anaemia'

to the list of adverse drug reactions (ADRs) and to amend the frequency of all remaining ADRs with their appropriate frequencies, following PRAC request in the outcome of the PSUSA procedure PSUSA/00010851/202303

Action: For adoption of PRAC Assessment Report

6.5.4. Meningococcal Group A, C, W and Y conjugate vaccine - MENQUADFI (CAP) - EMEA/H/C/005084/II/0031

Applicant: Sanofi Pasteur

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of section 4.8 of the SmPC in order to add 'hypersensitivity including anaphylaxis' to the list of adverse drug reactions (ADRs) with frequency not known, based on a cumulative review of cases of hypersensitivity/allergic reaction (including anaphylaxis) following the request by PRAC in the Assessment Report for PSUSA/00010044/202304. The package leaflet is updated accordingly

Action: For adoption of PRAC Assessment Report

6.6. Expedited summary safety reviews²¹

None

7. Post-authorisation safety studies (PASS)

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

7.1.1. Alemtuzumab - LEMTRADA (CAP) - EMEA/H/C/PSA/S/0107.1

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: Substantial amendment to a non-interventional PASS to investigate drug utilisation and safety monitoring patterns for Lemtrada (alemtuzumab) [MAH's response to PSA/S/0107]

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

7.1.2. Ketoconazole - KETOCONAZOLE HRA (CAP) - EMEA/H/C/PSA/S/0109.1

Applicant: HRA Pharma Rare Diseases

PRAC Rapporteur: Petar Mas

Scope: Substantial amendment to a prospective, multi-country, observational registry to

²¹ Submission of expedited summary safety reports for review in addition to the requirements for submission of PSUR(s) falling within the pandemic period and requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC

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

collect clinical information on patients with endogenous Cushing's syndrome exposed to Ketoconazole (using the existing European Registry on Cushing's Syndrome (ERCUSYN)), to assess drug utilisation pattern and to document the safety (e.g. hepatotoxicity, QT prolongation) and effectiveness of Ketoconazole [MAH's response to PSA/S/0109]

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

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

7.2.1. Avatrombopag - DOPTLET (CAP) - EMEA/H/C/004722/MEA 003.5

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Monica Martinez Redondo

Scope: MAH's response to MEA 003.4 and revised protocol for a study to further characterise the long-term safety profile of avatrombopag in patients with primary chronic immune thrombocytopenia in European patient registers and electronic healthcare databases as requested in the conclusions of variation II/0004/G finalised in December 2020 as per the request for supplementary information (RSI) adopted November 2023

Action: For adoption of advice to CHMP

7.2.2. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/MEA 003.3

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of a revised protocol for study PS0036: bimekizumab pregnancy exposure and outcome registry - an OTIS autoimmune diseases in pregnancy study

Action: For adoption of advice to CHMP

7.2.3. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/MEA 004.3

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: MAH's response to MEA 004.2 [Protocol amendment v 2.0 for Study No. PS0037: an observational cohort study to evaluate bimekizumab exposure during pregnancy, to monitor the safety of bimekizumab use in pregnancy] as per the request for supplementary information (RSI) adopted in December 2023

Action: For adoption of advice to CHMP

7.2.4. Coronavirus (COVID-19) vaccine (recombinant protein receptor binding domain fusion heterodimer) - BIMERVAX (CAP) - EMEA/H/C/006058/MEA 008.1

Applicant: Hipra Human Health S.L.

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

PRAC Rapporteur: Zane Neikena

Scope: Amended Protocol and MAH's responses to MEA 008 [PASS VAC4EU: non-imposed, non-interventional, category 3 post authorisation observational study to assess the safety of Bimervax using electronic health record (EHR) databases in Europe] as per the request for supplementary information (RSI) adopted in October 2023

Action: For adoption of advice to CHMP

7.2.5. Deucravacitinib - SOTYKTU (CAP) - EMEA/H/C/005755/MEA 001.1

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Revised Protocol / MAH's responses to MEA 001 [PASS IM011194 (non-imposed/non-interventional/RMP)] as adopted in September 2023. Long-term, observational cohort study of adults with plaque psoriasis, who are new users of deucravacitinib, non-TNFi (tumor necrosis factor inhibitor) biologics, TNFi biologics, or non-biologic systemic therapy in the real-world clinical setting (IM011194). To evaluate the long-term safety of deucravacitinib in patients with psoriasis in the real-world setting

Action: For adoption of advice to CHMP

7.2.6. Diroximel fumarate - VUMERITY (CAP) - EMEA/H/C/005437/MEA 001.2

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Interim report for PASS 272MS401 (non-imposed/non-interventional/Cat. 3): a prospective observational pregnancy exposure registry to characterise how DRF may affect pregnancy and infant outcomes. An updated protocol was also submitted

Action: For adoption of advice to CHMP

7.2.7. Elasmomeran - SPIKEVAX (CAP) - EMEA/H/C/005791/MEA 065.4

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Third interim report and revised protocol for study mRNA-1273-P910: clinical course, outcomes and risk factors of myocarditis and pericarditis following administration of Moderna vaccines targeting SARS-CoV-2

Action: For adoption of advice to CHMP

7.2.8. Ivosidenib - TIBSOVO (CAP) - EMEA/H/C/005936/MEA 003.1

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Revised protocol for a non-imposed/non-interventional, category 3 study in the RMP to evaluate the effectiveness of the Ivosidenib Patient Alert Card (additional Risk

Minimisation Measure) for awareness of differentiation syndrome in acute myeloid leukaemia (AML) patients, using process indicators for awareness, receipt of the material, utility and knowledge, as per the request for supplementary information as adopted in November 2023

Action: For adoption of advice to CHMP

7.2.9. Mavacamten - CAMZYOS (CAP) - EMEA/H/C/005457/MEA 002.1

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Revised Protocol for a non-imposed, non-interventional (CV027-1148) meta-analysis of phase 3, placebo-controlled, double-blind, randomised studies of mavacamten in patients with symptomatic hypertrophic cardiomyopathy (HCM), to evaluate the cardiovascular safety profile based on a composite endpoint of time to first occurrence of major cardiovascular event (MACE) meta-analysis event, including three clinical trials in symptomatic obstructive hypertrophic cardiomyopathy (HCM) population (EXPLORER-HCM, VALOR-HCM, China oHCM Phase 3 trial) and one clinical trial in symptomatic non-obstructive HCM population (ODYSSEY-HCM)

Action: For adoption of advice to CHMP

7.2.10. Risankizumab - SKYRIZI (CAP) - EMEA/H/C/004759/MEA 001.8

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: MAH's responses to MEA001.7 [Revised Protocol, Study No. P19-633 a post-marketing registry-based prospective cohort study of long-term safety of risankizumab in real world setting in Denmark and Sweden] as per the request for supplementary information (RSI) adopted in January 2024

Action: For adoption of advice to CHMP

7.2.11. Tezepelumab - TEZSPIRE (CAP) - EMEA/H/C/005588/MEA 005.1

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Revised protocol for PASS D5180R00024 (TRESPASS) (non-imposed/non-interventional): an observational multi-country PASS to evaluate the risk of serious adverse cardiovascular events in adolescent and adult patients with severe asthma taking tezepelumab

Action: For adoption of advice to CHMP

7.2.12. Tozinameran - COMIRNATY (CAP) - EMEA/H/C/005735/MEA 064.2

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Protocol Amendment for Study C4591051: a non-interventional post-approval safety study of Pfizer-BioNTech Bivalent COVID-19 vaccine in the United States to ensure comprehensive understanding of real-world safety of the Pfizer-BioNTech COVID-19 bivalent Omicron-modified vaccine in large samples of general US populations

Action: For adoption of advice to CHMP

7.2.13. Upadacitinib - RINVOQ (CAP) - EMEA/H/C/004760/MEA 012.5

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: MAH's responses to MEA 12.4 and revised protocol for Study P21-825 (drug utilization study evaluating the additional risk minimisation measures for upadacitinib in the treatment of atopic dermatitis in Europe) as per the request for supplementary information (RSI) adopted in December 2023

Action: For adoption of advice to CHMP

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

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

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Final study report for a post-authorisation safety observational cohort study to quantify the incidence and comparative safety of selected cardiovascular and cerebrovascular events in chronic obstructive pulmonary disease (COPD) patients using inhaled umeclidinium/vilanterol (UMEC/VI) combination, or inhaled UMEC versus tiotropium

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

7.4. Results of PASS non-imposed in the marketing authorisation(s)²⁵

7.4.1. Adalimumab - HUMIRA (CAP) - EMEA/H/C/000481/II/0218

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Mari Thorn

Scope: Submission of the final report for study P10-023 listed as a category 3 study in the RMP. This is a 10-year, post marketing, observational registry to assess long term safety of Humira (adalimumab) in adult patients with chronic plaque psoriasis (Ps)

Action: For adoption of PRAC Assessment Report

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

²⁵ In accordance with Article 61a (6) of Regulation (EC) No 726/2004, in line with the revised variations regulation for any submission as of 4 August 2013

7.4.2. Belimumab - BENLYSTA (CAP) - EMEA/H/C/002015/II/0116

Applicant: GlaxoSmithKline (Ireland) Limited

PRAC Rapporteur: Mari Thorn

Scope: Submission of the final report for the Belimumab Pregnancy registry (BEL114256) listed as a category 3 study in the RMP. This is a non-interventional study to evaluate pregnancy and infant outcomes for pregnancies in women with systemic lupus erythematosus (SLE) exposed to commercially supplied belimumab within the 4 months preconception and/or during pregnancy. In addition, the BPR protocol planned to collect pregnancy and infant outcomes for pregnancies in women with systemic lupus erythematosus (SLE) and safety and effectiveness of belimumab in systemic lupus erythematosus (SABLE) protocol who were not exposed to belimumab and enrolled in BPR. The RMP version 45.0 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.3. 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

7.4.4. Etanercept - BENEPALI (CAP) - EMEA/H/C/004007/MEA 003.5

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Monica Martinez Redondo

Scope: Final study results of a prospective, observational cohort study whose objectives are to evaluate the long-term effectiveness, safety, and costs associated with tumour necrosis factor-inhibitor therapies in the treatment of rheumatoid arthritis (RA) and to compare this to a cohort of RA patients who are treated with non-biologic DMARDs (RABBIT-RA)

Action: For adoption of PRAC Assessment Report

7.4.5. Fremanezumab - AJOVY (CAP) - EMEA/H/C/004833/II/0047

Applicant: TEVA GmbH

PRAC Rapporteur: Kirsti Villikka

Scope: Submission of the final report from the PASS study TV48125-MH-50039 listed as a category 3 study in the RMP. This is a long-term, prospective, observational study to evaluate the safety, including cardiovascular safety, of fremanezumab in patients with migraine in routine clinical practice. The RMP version 6.0 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.6. [Infliximab - FLIXABI \(CAP\) - EMEA/H/C/004020/II/0084/G](#)

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Mari Thorn

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

C.I.13: Submission of the final report from study CEDUR listed as a category 3 study in the RMP. This is a nationwide German inflammatory bowel disease (IBD) registry to describe the long-term effectiveness of treatment with IBD therapies such as drug survival, effectiveness, side effects of treatment combination, and disease activity achieved

C.I.13: Submission of the final report from study CREDIT listed as a category 3 study in the RMP. This is a Czech Register of IBD Patients on Biological Therapy to monitor effectiveness of total population of IBD patients on biological medication in the Czech Republic and regular analytical evaluation of the effectiveness. The RMP version 13.0 has also been submitted

Action: For adoption of PRAC Assessment Report

7.4.7. [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

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

Applicant: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

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

Action: For adoption of PRAC Assessment Report

7.4.9. [Tacrolimus - ADVAGRAF \(CAP\) - EMEA/H/C/000712/WS2519/0071/G; MODIGRAF \(CAP\) - EMEA/H/C/000954/WS2519/0046/G](#)

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eamon O’Murchu

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

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

Action: For adoption of PRAC Assessment Report

7.4.10. 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-centre, 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

7.4.11. Tozinameran - COMIRNATY (CAP) - EMEA/H/C/005735/II/0206/G

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application comprised of 3 Type II variations as follows:

C.I.13: Submission of the final report from study C4591012 listed as a category 3 study in the RMP. This is a non-interventional post-emergency use authorisation active safety surveillance study among individuals in the Veteran’s Affairs health system receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) vaccine. The RMP version 11.2 has also been submitted.

C.I.11.b: Submission of an updated RMP version 11.2 in order to implement changes to an agreed post-authorisation study (C4591052 protocol amendments 1 & 2) in the RMP, where there is an impact on the description of the study.

C.I.11.b: Submission of an updated RMP version 11.2 in order to implement changes to an agreed post-authorisation study (C4591021 protocol amendment 4) in the RMP, where there is an impact on the description of the study.

In addition, the MAH took the opportunity to update the milestones for the two studies

C4591022 and C4591051 in the RMP

Action: For adoption of PRAC Assessment Report

7.4.12. Vonicog alfa - VEYVONDI (CAP) - EMEA/H/C/004454/II/0033

Applicant: Baxalta Innovations GmbH

PRAC Rapporteur: Mari Thorn

Scope: Submission of the final report from study TAK-577-4005 listed as a category 3 PASS in the RMP. This is a non-interventional retrospective cohort study that evaluated the safety of VEYVONDI in real-world clinical practice. The RMP version 5.0 has also been submitted

Action: For adoption of PRAC Assessment Report

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

7.5.1. Alemtuzumab - LEMTRADA (CAP) - EMEA/H/C/003718/ANX 010.9

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: Third interim report of Study DUT0008: non-interventional PASS to investigate drug utilisation and safety monitoring patterns for Lemtrada (alemtuzumab)

Action: For adoption of advice to CHMP

7.5.2. Apremilast - OTEZLA (CAP) - EMEA/H/C/003746/MEA 008.4

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Monica Martinez Redondo

Scope: Fourth yearly report for study CC 10004 PSA-012: evaluation of the long-term safety and safety outcomes for psoriatic arthritis patients treated with Otezla (apremilast) in the British Society for Rheumatology Psoriatic Arthritis Register (BSRBR-PsA)

Action: For adoption of advice to CHMP

7.5.3. Blinatumomab - BLINCYTO (CAP) - EMEA/H/C/003731/ANX 002.3

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Jana Lukacisinova

Scope: Interim study report for PASS Study 20150136: an observational study of blinatumomab safety and effectiveness, utilisation, and treatment practices

Action: For adoption of advice to CHMP

7.5.4. Damoctocog alfa pegol - JIVI (CAP) - EMEA/H/C/004054/MEA 003.5

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: From Initial MAA: Study 14149: EUHASS Registry (European Haemophilia Safety Surveillance); Quarterly listings, annual reports (1 year after the end of the reporting period (upon receipt from EUHASS))

Action: For adoption of advice to CHMP

7.5.5. Etanercept - BENEPALI (CAP) - EMEA/H/C/004007/MEA 002.5

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Monica Martinez Redondo

Scope: Sixth interim report for an established nationwide register: British Society for Rheumatology Rheumatoid Arthritis Register (BSRBR-RA) for patients with rheumatological disorders treated with biologic agents, designed as a national prospective study whose primary purpose is to assess long-term toxicity from the use of these agents in routine practice [final report expected in 2027]

Action: For adoption of advice to CHMP

7.5.6. Etanercept - BENEPALI (CAP) - EMEA/H/C/004007/MEA 004.5

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Monica Martinez Redondo

Scope: Sixth annual interim report for study from the Anti-Rheumatic Treatment in Sweden (ARTIS) register: a national prospective, observational, uncontrolled cohort study evaluating the risk of selected adverse events (AEs) in rheumatoid arthritis (RA), juvenile idiopathic arthritis, and other rheumatic disease patients treated with etanercept [final report expected in 2027]

Action: For adoption of advice to CHMP

7.5.7. Etanercept - BENEPALI (CAP) - EMEA/H/C/004007/MEA 005.5

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Monica Martinez Redondo

Scope: Sixth annual interim report for study from the British Association of Dermatologists Biologic Interventions Register (BADBIR): a national prospective, observational cohort study of patients with psoriasis, which compares patients treated with biological interventions to a control group not exposed to biologicals [final report expected in 2027]

Action: For adoption of advice to CHMP

7.5.8. [Infliximab - REMSIMA \(CAP\) - EMEA/H/C/002576/MEA 020.5](#)

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Annual Recruitment Status Report for study CT-P13 4.8: an observational, prospective cohort study to evaluate safety of Remsima SC in patients with rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and psoriasis

Action: For adoption of advice to CHMP

7.5.9. [Inotersen - TEGSEDI \(CAP\) - EMEA/H/C/004782/MEA 001.10](#)

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Rhea Fitzgerald

Scope: Interim report covering the period of 18 September 2022 to 19 September 2023 for study TEG4001: a prospective, non-interventional, long-term, multinational cohort safety study of patients with hereditary transthyretin amyloidosis with polyneuropathy (hATTR-PN)

Action: For adoption of advice to CHMP

7.5.10. [Octocog alfa - KOVALTRY \(CAP\) - EMEA/H/C/003825/MEA 004.7](#)

Applicant: Bayer AG

PRAC Rapporteur: Gabriele Maurer

Scope: 14th Annual Report for Study 14149 (listed as a category 3 study in the RMP): evaluation of cases with adverse events (AEs) of special interest in the European Haemophilia Safety Surveillance (EUHASS) registry

Action: For adoption of advice to CHMP

7.5.11. [Plasmodium falciparum and hepatitis B vaccine \(recombinant, adjuvanted\) - MOSQUIRIX \(Art 58²⁶\) - EMEA/H/W/002300/MEA 015.1](#)

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Jean-Michel Dogné

Scope: From EMEA/H/W/002300/II/0020: Statistical Analysis Plan (SAP) of EPI-MAL-010 (205071) interim analysis and associated Tables, Figures and Listings (TFLs)

Action: For adoption of advice to CHMP

7.5.12. [Rurioctocog alfa pegol - ADYNOVI \(CAP\) - EMEA/H/C/004195/ANX 002.3](#)

Applicant: Baxalta Innovations GmbH

PRAC Rapporteur: Bianca Mulder

²⁶ 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)

Scope: Fourth progress report for PASS TAK-660-403 (imposed/non-interventional/cat. 3) to investigate the potential effects of PEG accumulation in the choroid plexus of the brain and other tissues/organs

Action: For adoption of advice to CHMP

7.5.13. Tofacitinib - XELJANZ (CAP) - EMEA/H/C/004214/MEA 014.7

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: First interim report for PASS A3921321: a PASS of the utilisation and prescribing patterns of Xeljanz (tofacitinib) in two European countries using administrative claims databases and national registries for assessment

Action: For adoption of advice to CHMP

7.6. Others

None

7.7. New Scientific Advice

None

7.8. Ongoing Scientific Advice

None

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

None

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Afamelanotide - SCENESSE (CAP) - EMEA/H/C/002548/S/0050 (without RMP)

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.2. Histamine dihydrochloride - CEPLENE (CAP) - EMEA/H/C/000796/S/0048 (without RMP)

Applicant: Laboratoires Delbert

PRAC Rapporteur: Eamon O'Murchu

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.3. Maralixibat - LIVMARLI (CAP) - EMEA/H/C/005857/S/0012 (without RMP)

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.2. Conditional renewals of the marketing authorisation

8.2.1. Budesonide - KINPEYGO (CAP) - EMEA/H/C/005653/R/0010 (without RMP)

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.2. Talquetamab - TALVEY (CAP) - EMEA/H/C/005864/R/0005 (without RMP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.3. Teclistamab - TECVAYLI (CAP) - EMEA/H/C/005865/R/0010 (without RMP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jana Lukacisinova

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Cannabidiol - EPIDYOLEX (CAP) - EMEA/H/C/004675/R/0031 (with RMP)

Applicant: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.2. Gilteritinib - XOSPATA (CAP) - EMEA/H/C/004752/R/0017 (without RMP)

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Idelalisib - ZYDELIG (CAP) - EMEA/H/C/003843/R/0059 (with RMP)

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Levodopa - INBRIJA (CAP) - EMEA/H/C/004786/R/0022 (without RMP)

Applicant: Acorda Therapeutics Ireland Limited

PRAC Rapporteur: Barbara Kovacic Bytyqi

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. Semaglutide – RYBELSUS (CAP) - EMEA/H/C/4953/X/0038

Applicant: Novo Nordisk A/S

PRAC Rapporteur (for product): Mari Thorn

PRAC Rapporteur (for procedure): Bianca Mulder

Scope: Consultation of PRAC on a DHPC and communication plan in the framework of a line extension to introduce new strengths of tablets for Rybelsus (semaglutide)

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. Ibuprofen; ibuprofen lysine; ibuprofen, caffeine; ibuprofen, pseudoephedrine hydrochloride; ibuprofen, drotaverine hydrochloride (NAP) - CZ/H/XXXX/WS/075

Applicant(s): Opella Healthcare Czech s.r.o

PRAC Lead: Jana Lukacisinova

Scope: PRAC consultation on work sharing variation to update the product information of ibuprofen-containing products in order to add a risk of renal tubular acidosis and hypokalaemia and overdose based on the MHRA review, on request of Czech Republic

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. Mandate of PRAC Chairperson and Vice-Chairperson – call for nominations

Action: For information

12.1.2. PRAC membership

Action: For information

12.1.3. 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. EMA review of seasonal influenza vaccines enhanced safety surveillance systems - interim guidance

PRAC leads: Jean Michel Dogné, Nathalie Gault, Gabriele Mauer, Maria del Pilar Rayon, David Olsen

Action: For discussion

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

Action: For discussion

12.4.3. PRAC strategic review and learning meeting (SRLM) under the Belgium presidency of the European Union (EU) Council – Hulpe, Belgium, 27 - 29 May 2024 - agenda

PRAC lead: Jean-Michel Dogné, Jo Robays

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

12.6.1. PRAC and WHO pharmacovigilance team enhanced engagement and collaboration in Article 58 procedures

PRAC lead: Sabine Straus**Action:** For discussion

12.7. PRAC work plan

None

12.8. Planning and reporting

12.8.1. Marketing authorisation applications (MAA) forecast for 2024 – planning update dated Q1 2024

Action: For discussion

12.8.2. MAAs 3-year forecast report for March 2024 - December 2026

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 Lukačšínová

Action: For discussion

12.10.3. PSURs repository

None

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

Action: For adoption

12.11. Signal management

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

None

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

12.20.1. Good pharmacovigilance practice (GVP) module XVI on 'Risk minimisation measures: selection of tools and effectiveness indicators' – revision 3 on principles and methods to evaluate the effectiveness of risk minimisation measures (RMM)

PRAC lead: Sabine Straus

Action: For discussion

12.21. Others

12.21.1. EU NTC training webinar on the regulatory/Health Technology Assessment (HTA) interface under the HTA Regulation

Action: For discussion

12.21.2. Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling – concept paper on revision of the guideline

PRAC lead: Ulla Wändel Liminga

Action: For discussion

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

PRAC lead: Liana Martirosyan

Action: For discussion

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

Action: For discussion

13. Any other business

Next meeting on: 13-16 May 2024

14. Explanatory notes

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

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

(Items 2 and 3 of the PRAC agenda)

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

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

Signals assessment and prioritisation

(Item 4 of the PRAC agenda)

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

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

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

Risk Management Plans (RMPs)

(Item 5 of the PRAC agenda)

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

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

Assessment of Periodic Safety Update Reports (PSURs)

(Item 6 of the PRAC agenda)

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

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

Post-authorisation Safety Studies (PASS)

(Item 7 of the PRAC agenda)

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

Product related pharmacovigilance inspections

(Item 9 of the PRAC agenda)

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

For a list of acronyms and abbreviations, see:

[List of abbreviations used in EMA human medicines scientific committees and CMDh documents, and in Pharmacovigilance Risk Assessment Committee \(PRAC\)](#)

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