07 April 2025
EMA/PRAC/89624/2025
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 07-10 April 2025

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

07 April 2025, 13:00 – 19:30, room 1C

08 April 2025, 08:30 – 19:30, room 1C

09 April 2025, 08:30 – 19:30, room 1C

10 April 2025, 08:30 – 16:00, room 1C

Organisational, regulatory and methodological matters (ORGAM)

24 April 2025, 09:00 – 12:00, via teleconference

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PRAC plenary session to be held 7-10 April 2025. See April 2025 PRAC minutes (to be published post May 2025 PRAC meeting).

1.2. Agenda of the meeting on 07-10 April 2025

Action: For adoption

1.3. Minutes of the previous meeting on 10-13 March 2025

Action: For adoption

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

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

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

3.1. Newly triggered procedures

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination procedures[1]

None

3.5. Others

None

4. Signals assessment and prioritisation[2]

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

4.1.1. Brodalumab – KYNTHEUM (CAP)

Applicant: LEO Pharma A/S

PRAC Rapporteur: Monica Martinez Redondo

Scope: Signal of pyoderma gangrenosum

Action: For adoption of PRAC recommendation

EPITT 20162 – New signal

Lead Member State(s): ES

4.1.2. Diazoxide (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of necrotising enterocolitis neonatal

Action: For adoption of PRAC recommendation

EPITT 20163 – New signal

Lead Member State(s): IT

4.1.3. Ibrutinib – IMBRUVICA (CAP)

Applicant: Janssen-Cilag International N.V.

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

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Signal of cough

Action: For adoption of PRAC recommendation

EPITT 20161 – New signal

Lead Member State(s): HR

4.2. Signals follow-up and prioritisation

4.2.1. Avelumab – BAVENCIO (CAP) - EMEA/H/C/004338/SDA/013; atezolizumab – TECENTRIQ (CAP) - EMEA/H/C/004143/SDA/028; cemiplimab – LIBTAYO (CAP) - EMEA/H/C/004844/SDA/014; dostarlimab – JEMPERLI (CAP) - EMEA/H/C/005204/SDA/008; durvalumab – IMFINZI (CAP) - EMEA/H/C/004771/SDA/015; ipilimumab – YERVOY (CAP) - EMEA/H/C/002213/SDA/050; nivolumab - OPDIVO- EMEA/H/C/003985/SDA/060; Nivolumab, relatlimab - OPDUALAG (CAP) - EMEA/H/C/005481/SDA/008; pembrolizumab – KEYTRUDA (CAP) - EMEA/H/C/003820/SDA/044; retifanlimab – ZYNYZ (CAP) - EMEA/H/C/006194/SDA/003; tislelizumab – TEVIMBRA (CAP) - EMEA/H/C/005919/SDA/005; toripalimab – LOQTORZI (CAP) - EMEA/H/C/006120/SDA/002; tremelimumab – IMJUDO (CAP) - EMEA/H/C/006016/SDA/005

Applicant: AstraZeneca AB (Imfinzi, Imjudo), Beigene Ireland Limited (Tevimbra), Bristol-Myers Squibb Pharma EEIG (Yervoy, Opdivo, Opdualag), GlaxoSmithKline (Ireland) Limited (Jemperli), Incyte Biosciences Distribution B.V. (Zynyz), Merck Europe B.V. (Bavencio), Merck Sharp & Dohme B.V. (Keytruda), Regeneron Ireland Designated Activity Company (Libtayo), Roche Registration GmbH (Tecentriq), TMC Pharma (EU) Limited (Loqtorzi)

PRAC Rapporteur: David Olsen

Scope: Signal of scleroderma, systemic scleroderma, morphea

Action: For adoption of PRAC recommendation

EPITT 20119 – Follow-up to November 2024

Lead Member State(s): NO

4.2.2. Emtricitabine, tenofovir disoproxil – EMTRICITABINE/TENOFOVIR DISOPROXIL KRKA, EMTRICITABINE/TENOFOVIR DISOPROXIL KRKA D.D., EMTRICITABINE/TENOFOVIR DISOPROXIL MYLAN, EMTRICITABINE/TENOFOVIR DISOPROXIL ZENTIVA, TRUVADA (CAP), NAP

Applicant(s): Gilead Sciences Ireland UC (Truvada, Emtricitabine/Tenofovir disoproxil Mylan), KRKA, d.d., Novo mesto (Emtricitabine/Tenofovir disoproxil Krka, Emtricitabine/tenofovir disoproxil Krka d.d.), Zentiva k.s. (Emtricitabine/Tenofovir disoproxil Zentiva), various

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Signal of trigeminal neuralgia

Action: For adoption of PRAC recommendation

EPITT 20121 – Follow-up to December 2024

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

Applicant(s): various

PRAC Rapporteur: Jo Robays

Scope: Signal of hearing and vestibular disorders

Action: For adoption of PRAC recommendation

EPITT 20120 – Follow-up to October 2024

Lead Member State(s): BE

4.2.4. Regorafenib - STIVARGA (CAP) - EMEA/H/C/002573/SDA/015

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Signal of nephrotic syndrome

Action: For adoption of PRAC recommendation

EPITT 20123 – Follow-up to December 2024

4.2.5. Regorafenib - STIVARGA (CAP) - EMEA/H/C/002573/SDA/016

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Signal of hyperammonaemia, hyperammonaemic encephalopathy

Action: For adoption of PRAC recommendation

EPITT 20147– Follow-up to February 2025

4.3. Variation procedure(s) resulting from signal evaluation

None

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Aflibercept (CAP MAA) - EMEA/H/C/006438

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

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

5.1.2. Aflibercept (CAP MAA) - EMEA/H/C/006282

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

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

5.1.3. Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human Wiskott-Aldrich syndrome protein (CAP MAA) - EMEA/H/C/006525, Orphan

Applicant: Fondazione Telethon Ets, ATMP

Scope (pre D-120 phase): Treatment of patients with Wiskott-Aldrich Syndrome (WAS)

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

5.1.4. Belantamab mafodotin (CAP MAA) - EMEA/H/C/006511, Orphan

Applicant: Glaxosmithkline Trading Services Limited

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

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

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

Applicant: Roche Registration GmbH, ATMP

Scope (pre D-180 phase): Treatment of ambulatory patients aged 3 to 7 years old with Duchenne muscular dystrophy

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

5.1.6. Denosumab (CAP MAA) - EMEA/H/C/006436

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

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

5.1.7. Denosumab (CAP MAA) - EMEA/H/C/006437

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

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

5.1.8. Emtricitabine, rilpivirine, tenofovir alafenamide (CAP MAA) - EMEA/H/C/006491

Scope (pre D-180 phase): Treatment of HIV-1

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

5.1.9. Macitentan (CAP MAA) - EMEA/H/C/006524

Scope (pre D-180 phase): Treatment of pulmonary arterial hypertension (PAH)

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

5.1.10. Macitentan (CAP MAA) - EMEA/H/C/006523

Scope (pre D-180 phase): Treatment of pulmonary arterial hypertension (PAH)

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

5.1.11. Mirdametinib (CAP MAA) - EMEA/H/C/006460, Orphan

Applicant: Springworks Therapeutics Ireland Limited

Scope (pre D-180 phase): Treatment of neurofibromatosis type 1

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

5.1.12. Nadofaragene firadenovec (CAP MAA) - EMEA/H/C/005856

Scope (pre D-120 phase): Treatment of adult patients with high-grade (HG), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC)

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

5.1.13. Nintedanib (CAP MAA) - EMEA/H/C/006486

Scope (pre D-180 phase): Treatment of Idiopathic Pulmonary Fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) and systemic sclerosis associated interstitial lung disease (SSc-ILD)

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

5.1.14. Ustekinumab (CAP MAA) - EMEA/H/C/006467

Scope (pre D-180 phase): Treatment of Crohn’s disease and ulcerative colitis, treatment of plaque psoriasis, arthritis psoriatic

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

5.1.15. Vimseltinib (CAP MAA) - EMEA/H/C/006363, Orphan

Applicant: Deciphera Pharmaceuticals (Netherlands) B.V.

Scope (pre D-180 phase): Treatment of adult patients with tenosynovial giant cell tumour (TGCT) who are not amenable to surgery

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. Adalimumab – IDACIO (CAP) - EMA/VR/0000246858

Applicant: Fresenius Kabi Deutschland GmbH

PRAC Rapporteur: Karin Bolin

Scope: Submission of an updated RMP version 6.2 in order to remove the Observational registry RABBIT listed as a category 3 study in the RMP

Action: For adoption of PRAC Assessment Report

5.2.2. Ciltacabtagene autoleucel - CARVYKTI (CAP) - EMEA/H/C/005095/II/0034, Orphan

Applicant: Janssen-Cilag International NV, ATMP

PRAC Rapporteur: Jo Robays

Scope: Submission of an updated RMP version 5.2 in order to add a new important identified risk of "Secondary malignancy of T-cell origin", to change the important potential risk of "Second primary malignancies" to "Second primary malignancy except secondary malignancy of T-cell origin", and to include an additional pharmacovigilance activity for testing of secondary malignancies of T-cell origin, following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040)

Action: For adoption of PRAC Assessment Report

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

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

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

Action: For adoption of PRAC Assessment Report

5.2.4. Eculizumab - SOLIRIS (CAP) - EMEA/H/C/000791/WS2125/0133; Ravulizumab - ULTOMIRIS (CAP) - EMEA/H/C/004954/WS2125/0047

Applicant: Alexion Europe SAS

PRAC Rapporteur: Monica Martinez Redondo

Scope: Submission of an updated RMP version 21.0 for SOLIRIS and RMP version 9.0 for ULTOMIRIS in order to revise the controlled distribution additional risk minimisation measures and to add a new post-authorisation safety study (PASS) intended to evaluate the effectiveness of the revised additional risk minimisation measures for minimising the risk of meningococcal infections in the EU, following the PRAC outcome for PSUSA/00001198/202310 for SOLIRIS. The Annex II is updated accordingly. In addition, the MAH introduced minor updates to the SmPC to align the wording with the updated Annex II

Action: For adoption of PRAC Assessment Report

5.2.5. Fenfluramine - FINTEPLA (CAP) - EMEA/H/C/003933/II/0028, Orphan

Applicant: UCB Pharma SA

PRAC Rapporteur: Martin Huber

Scope: Submission of a revised protocol for study EP0218 listed as an obligation in the Annex II of the Product Information. This is a Long-term Registry in approved indications for fenfluramine, with a specific focus on cardiovascular events and growth retardation. The RMP version 4.0 is updated accordingly. In addition, the MAH introduced minor amendments in the targeted follow-up questionnaire for cardiovascular adverse events

Action: For adoption of PRAC Assessment Report

5.2.6. Meningococcal group B vaccine (recombinant, adsorbed) – TRUMENBA (CAP) - EMA/VR/0000247141

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Submission of an updated RMP version 9.0 in order to propose the removal of "Use in co-administration with MMR and pneumococcal vaccines" as missing information from the safety concerns listed in the RMP and consequently, removal of the associated additional pharmacovigilance activity, study C3511006 (a Phase 3, randomized, controlled, open-label trial to assess the safety, tolerability, and immunogenicity of MenABCWY in healthy participants 12 to <24 months of age, and when administered concomitantly with MMR and pneumococcal vaccine in healthy participants ⩾12 to <16 months of age)

Action: For adoption of PRAC Assessment Report

5.2.7. Zoledronic acid - ZOMETA (CAP) - EMEA/H/C/000336/II/0104

Applicant: Phoenix Labs Unlimited Company

PRAC Rapporteur: Karin Erneholm

Scope: Submission of an updated RMP version 12.1 in order to update the list of safety concerns and missing information as per the guidance provided in the GVP V–Rev.2 and PSUSA/3149/202308

Action: For adoption of PRAC Assessment Report

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

5.3.1. Acalabrutinib - CALQUENCE (CAP) - EMEA/H/C/005299/II/0028

Applicant: AstraZeneca AB

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Extension of indication to include CALQUENCE in combination with venetoclax with or without obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL), based on interim results from study AMPLIFY (D8221C00001). This is a Randomized, Multicenter, Open-Label, Phase 3 Study to Compare the Efficacy and Safety of Acalabrutinib in Combination with Venetoclax with and without Obinutuzumab Compared to Investigator's Choice of Chemoimmunotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukemia Without del(17p) or TP53 Mutation (AMPLIFY). As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8 of the RMP has also been submitted

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

5.3.2. Afamelanotide - SCENESSE (CAP) - EMA/VR/0000247271

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to include the risk of "anaphylactic reactions" based on post-marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 9.15 has also been submitted

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

5.3.3. Tecovirimat - TECOVIRIMAT SIGA (CAP) - EMA/VR/0000244868

Applicant: Siga Technologies Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Update of section 4.5 of the SmPC in order to add drug-drug interaction information with calcium acetate, lanthanum carbonate, sevelamer carbonate, and sucroferric oxyhydroxide based on final results from study SIGA-246-023. This is a safety, tolerability, and efficacy study of 4 phosphate binders on tecovirimat in adults. The Package Leaflet has been updated accordingly. The RMP version 2.1 has also been submitted

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

5.3.4. Tezepelumab - TEZSPIRE (CAP) - EMA/VR/0000245013

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include treatment of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) for Tezspire, based on results from study WAYPOINT (D5242C00001); this

is a global, multicentre, randomised, double-blind, parallel-group, placebo-controlled study that evaluated the efficacy and safety of tezepelumab compared with placebo in the treatment of CRSwNP. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to update the PI and the Package Leaflet in accordance with the latest EMA excipients guideline

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

5.3.5. Tolvaptan - JINARC (CAP) - EMA/VR/0000246866

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Update of sections 4.2 and 5.1 of the SmPC in order to update information based on final results from study 156-12-299 listed as a category 1 study in the RMP. This is a 7.5-year, Multicentre, Non-interventional, Post-authorisation Safety Study for Patients Prescribed JINARC for Autosomal Dominant Polycystic Kidney Disease. This study was intended to explore the safety profile and usage of Jinarc when used in the real-world setting in Europe, particularly with relation to the risk of liver injury. The Package Leaflet is updated accordingly. The RMP version 15.1 has also been submitted. In addition, the MAH took the opportunity to update Annex II section D, to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4

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

5.3.6. Venetoclax - VENCLYXTO (CAP) - EMA/VR/0000246380

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Update of sections 4.2, 4.9 and 5.2 of the SmPC in order to inform no adjustment is needed in patients with ESRD requiring dialysis and to add information on the pharmacokinetics data for patients with ESRD requiring dialysis, based on final results from study M19-065, “Evaluation of the Pharmacokinetics and Safety of Venetoclax in Subjects with Impaired Renal Function”. The RMP version 10.0 has also been submitted

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

5.3.7. Zoonotic influenza vaccine (H5N8) (surface antigen, inactivated, adjuvanted)- ZOONOTIC INFLUENZA VACCINE SEQIRUS (CAP) - EMA/VR/0000249071

Applicant: Seqirus S.r.l.

PRAC Rapporteur: Amelia Cupelli

Scope: Extension of indication to include treatment of individuals 6 months of age and above for Zoonotic Influenza Vaccine Seqirus based on final results from study V87_30. This is a Phase 2, Randomized, Observer-Blind, Multicenter Study to Evaluate the Immunogenicity and Safety of Several Doses of Antigen and MF59 Adjuvant Content in a Monovalent H5N1 Pandemic Influenza Vaccine in Healthy Pediatric Subjects 6 Months to < 9

Years of Age. As a consequence, sections 4.1, 4.2, 4.6, 4.7, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the PI

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

5.3.8. Brentuximab vedotin - ADCETRIS (CAP) - EMEA/H/C/002455/II/0111

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication for ADCETRIS to include treatment for adult patients with previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone (BrECADD), based on final results from phase 3 study HD21 (NCT02661503). This study is titled Treatment Optimization Trial in the First-Line Treatment of Advanced-Stage Hodgkin Lymphoma; Comparison of 4-6 Cycles of Escalated BEACOPP With 4-6 Cycles of BrECADD. 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 20.0 of the RMP has also been submitted.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the SmPC

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

5.3.9. Clopidogrel - CLOPIDOGREL ZENTIVA (CAP) - EMEA/H/C/000975/II/0092

Applicant: Zentiva k.s.

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include, in combination with acetylsalicylic acid (ASA), patients with ST segment elevation acute myocardial infarction (STEMI) who are undergoing percutaneous coronary intervention (PCI) for CLOPIDOGREL ZENTIVA. As a consequence, sections 4.1, 4.2, 4.4 and 5.1 of the SmPC are updated. Version 0.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, introduce minor editorial changes to the PI and bring it in line with the latest QRD template version 10.4

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

5.3.10. Concizumab - ALHEMO (CAP) - EMA/VR/0000244862

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include treatment of haemophilia A without inhibitors and haemophilia B without inhibitors for ALHEMO based on final results from study NN7415-4307; this is an interventional study to investigate efficacy and safety of concizumab prophylaxis in patients with haemophilia A or B without inhibitors. As a consequence,

sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI

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

5.3.11. Crizotinib - XALKORI (CAP) - EMEA/H/C/002489/II/0084

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of the final report from study CRZ-NBALCL listed as a category 3 study in the RMP. This is a phase I/II study to evaluate the adverse effects of ocular toxicity and bone toxicity and impaired bone growth associated with crizotinib in paediatric and young adult patients with recurrent/refractory anaplastic lymphoma kinase-positive anaplastic large cell lymphoma or neuroblastoma. The RMP version 9.2 is updated accordingly

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

5.3.12. Damoctocog alfa pegol - JIVI (CAP) - EMEA/H/C/004054/II/0034

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment and prophylaxis of bleeding in previously treated patients ≥7 years of age with haemophilia A for JIVI, based on integrated analysis results from Part A of the Alfa-PROTECT study (21824) and PROTECT Kids main study (15912). Alfa-PROTECT is a Phase 3, single-group treatment, open-label study to evaluate the safety of BAY 94-9027 infusions for prophylaxis and treatment of bleeding in previously treated children aged 7 to <12 years with severe hemophilia A. PROTECT Kids is a multi-center, Phase 3, non-controlled, open-label trial to evaluate the pharmacokinetics, safety, and efficacy of BAY 94-9027 for prophylaxis and treatment of bleeding in previously treated children (age <12 years) with severe haemophilia A. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4

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

5.3.13. Damoctocog alfa pegol - JIVI (CAP) - EMEA/H/C/004054/X/0033/G

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Extension application to add a new strength of Jivi 4000 UI powder and solvent for solution for injection for treatment and prophylaxis of bleeding in previously treated patients ≥ 12 years of age with haemophilia A (congenital factor VIII deficiency).

Version 3.1 of the RMP has also been submitted.

In addition, the MAH has taken the opportunity to align the product information with the pre-specified language from the updated EC Excipient Guideline

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

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

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

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

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

5.3.15. Eltrombopag - REVOLADE (CAP) - EMEA/H/C/001110/II/0077

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Monica Martinez Redondo

Scope: Extension of indication to include second-line treatment of paediatric patients aged 2 years and above with acquired severe aplastic anaemia (SAA) for REVOLADE based on the ETB115E2201 (E2201) study primary analysis results; this is a paediatric phase II, open-label, uncontrolled, intra-patient dose escalation study to characterise the pharmacokinetics after oral administration of eltrombopag in paediatric patients with refractory, relapsed severe aplastic anaemia or recurrent aplastic anaemia. 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 56.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI

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

5.3.16. Florbetaben (^{18}F) - NEURACEQ (CAP) - EMA/VR/0000227744

Applicant: Life Molecular Imaging GmbH

PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include monitoring of the biological treatment response to pharmacological and non-pharmacological interventions for NEURACEQ, based on supporting literature. As a consequence, sections 4.1, 4.4 and 5.1 of the SmPC are updated. The Package Leaflet (PL) is updated in accordance. Version 6.91 of the RMP has also been

submitted. In addition, the MAH took the opportunity to include the proposal to discontinue the inclusion of a paper copy of the SmPC with the product package

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

5.3.17. Glucagon - BAQSIMI (CAP) - EMA/VR/0000244909

Applicant: Amphastar France Pharmaceuticals

PRAC Rapporteur: Eamon O'Murchu

Scope: Extension of indication to include treatment of severe hypoglycaemia in paediatric patients aged 1 and over with diabetes mellitus for BAQSIMI, based on final results from study I8R-MC-IGBO; this is an Open-Label, Multi-Center, Single-Dose Study to Assess the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of Nasal Glucagon in Paediatric Patients with Type 1 Diabetes Aged 1 to <4 years; As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce a correction in the Package Leaflet

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

5.3.18. Golimumab - SIMPONI (CAP) - EMEA/H/C/000992/II/0121

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Karin Bolin

Scope: Extension of indication to include treatment of paediatric ulcerative colitis for SIMPONI, based on results from study CNTO148UCO3003; this is a Phase 3 Randomized, Open-label Study to Assess the Efficacy, Safety, and Pharmacokinetics of Golimumab Treatment, a Human anti-TNFα Monoclonal Antibody, Administered Subcutaneously in Paediatric Participants with Moderately to Severely Active Ulcerative Colitis; As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. Version 28.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is updated in accordance with the latest EMA excipients guideline and aligned with the latest QRD template version 10.4

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

5.3.19. Ibrutinib - IMBRUVICA (CAP) - EMEA/H/C/003791/II/0092

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Extension of indication to include IMBRUVICA in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone (R-CHOP) for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are eligible for autologous stem cell transplantation (ASCT), based on results from study MCL3003. This is a randomized, 3-arm, parallel-group, open-label, international, multicenter Phase 3 study. The purpose of Study MCL3003 is to compare 3 alternating courses of R CHOP/R-DHAP

followed by ASCT (control Arm A), versus the combination with ibrutinib in induction and maintenance (experimental Arm A+I), or the experimental arm without ASCT (experimental Arm I) in participants with previously untreated MCL who are eligible for ASCT.
Consequently, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Version 23.1 of the RMP has also been submitted

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

5.3.20. Infliximab - REMSIMA (CAP) - EMEA/H/C/002576/X/0149

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension application to introduce a new pharmaceutical form (concentrate for solution for infusion) associated with a new strength (40 mg/ml)

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

5.3.21. Mercaptamine - CYSTADROPS (CAP) - EMEA/H/C/003769/II/0032, Orphan

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include treatment of children from 6 months of age for CYSTADROPS, based on final results from study CYT-C2-001. This is an Open-label, Single-arm, Multicenter Study to Assess the Safety of Cystadrops in Pediatric Cystinosis Patients from 6 Months to Less Than 2 Years Old. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II of the PI and the list of local representatives in the Package Leaflet

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

5.3.22. Mosunetuzumab - LUNSUMIO (CAP) - EMEA/H/C/005680/X/0015, Orphan

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Extension application to introduce a new pharmaceutical form (solution for injection) associated with two new strengths (5 mg and 45 mg) and new route of administration (subcutaneous use).
The RMP (version 3.0) is updated in accordance

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

5.3.23. Naloxone - NYXOID (CAP) - EMEA/H/C/004325/II/0019

Applicant: Mundipharma Corporation (Ireland) Limited

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the interim report from the PAES MR903-9501 listed as an obligation in the Annex II, supported by Real World Evidence from literature and European Take-Home Naloxone programs (THN) demonstrating the effectiveness of Nyxoid in a real-world setting. Study MR903-9501 is a non-interventional multi-national, prospective, mixed methods study of the effectiveness of naloxone (including intranasal Nyxoid) administration by lay people in reversing opioid overdose. The Annex II and the RMP version 3.0 are updated accordingly. In addition, the MAH took the opportunity to introduce minor administrative changes to the Package Leaflet

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

5.3.24. Nirmatrelvir, ritonavir - PAXLOVID (CAP) - EMEA/H/C/005973/II/0061/G

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: A grouped application comprised of a Type II Variation and a Type IB Variation, as follows:

Type II (C.I.6.a): Extension of indication to include treatment of coronavirus disease 2019 (COVID-19) in paediatric patients 6 years of age and older weighing at least 20 kg for PAXLOVID, based on the final analysis of Cohorts 1 and 2 from pivotal Study C4671026; this is a Phase 2/3, Interventional Safety, Pharmacokinetics, and Efficacy, Open-Label, Multi-Center, Single-Arm Study to Investigate Orally Administered PF 07321332 (Nirmatrelvir)/Ritonavir in Nonhospitalized Symptomatic Pediatric Participants With COVID-19 Who Are at Risk of Progression to Severe Disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. 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

5.3.25. Nusinersen - SPINRAZA (CAP) - EMEA/H/C/004312/X/0038, Orphan

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Karin Bolin

Scope: Extension application to add a new strength of 28 mg and 50 mg.
The RMP (version 12.x) is updated in accordance (version 12.2 is under assessment in procedure EMEA/H/C/004312/II/0034/G)

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

5.3.26. Obinutuzumab - GAZYVARO (CAP) - EMA/VR/0000244907

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of adult patients with active lupus nephritis who are receiving standard therapy for GAZYVARO, based on results from study

Regency (CA41705). This is an ongoing, Phase III, randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy and safety of obinutuzumab administered at standard infusion rates in patients with ISN/RPS 2003 Class III or IV lupus nephritis treated with standard-of-care therapy.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet

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

5.3.27. Olipudase alfa - XENPOZYME (CAP) - EMEA/H/C/004850/II/0012/G, Orphan

Applicant: Sanofi B.V.

PRAC Rapporteur: Martin Huber

Scope: A grouped application consisting of:
C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study DFI12712 ASCEND, listed as a category 3 study in the RMP; this is a Phase 2/3, multicenter, randomised, double-blinded, placebo-controlled, repeat-dose study to evaluate the efficacy, safety, pharmacodynamics and pharmacokinetics of olipudase alfa in patients with AMSD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the SmPC.

C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study LTS13632 listed as a category 3 study in the RMP; this is a long-term study the ongoing safety and efficacy of olipudase alfa in patients with ASMD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted.

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

5.3.28. Pembrolizumab - KEYTRUDA (CAP) - EMA/VR/0000245108

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include, KEYTRUDA as monotherapy, for the treatment of resectable locally advanced head and neck squamous cell carcinoma (HNSCC) as neoadjuvant treatment, continued as adjuvant treatment in combination with radiation therapy with or without platinum-containing chemotherapy and then as monotherapy in adults, based on the results of study P689V01MK3475 (KEYNOTE-689); this is a Phase 3, randomised, open-label study evaluating pembrolizumab as neoadjuvant therapy and in combination with standard of care as adjuvant therapy for stage III or IVA, resectable, locoregionally advanced head and neck squamous cell carcinoma. Consequently, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 48.1 has also been submitted. In addition, the MAH took the opportunity to introduce some minor editorial changes to the PI

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

5.3.29. Ranibizumab - EPRUVY (CAP) - EMEA/H/C/006528/II/0002/G

Applicant: MIDAS Pharma GmbH

PRAC Rapporteur: Karin Bolin

Scope: Quality variations. The product information and the RMP (version 2.0) are updated consequentially

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

5.3.30. Ranibizumab - RANIVISIO (CAP) - EMEA/H/C/005019/II/0017/G

Applicant: Midas Pharma GmbH

PRAC Rapporteur: Karin Bolin

Scope: Quality variations. The product information and the RMP (version 2.0) are updated consequentially

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

5.3.31. Ranibizumab - RIMMYRAH (CAP) - EMA/VR/0000246182

Applicant: QILU Pharma Spain S.L.

PRAC Rapporteur: Karin Bolin

Scope: Quality variation. The RMP version 1.1 has also been submitted

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

5.3.32. Remdesivir - VEKLURY (CAP) - EMEA/H/C/005622/II/0053/G

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Eva Jirsová

Scope: Grouped application comprising two extensions of indication to include treatment of paediatric patients weighing at least 1.5 kg for VEKLURY, based on final results from study GS-US-540-5823; this is a Phase 2/3 single-arm, open-label study to evaluate the safety, tolerability, pharmacokinetics, and efficacy of remdesivir in participants from birth to < 18 years of age with COVID-19; As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted

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

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

Applicant: Bayer AG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength (0.15 mg/ml granules for oral suspension) for the Pulmonary arterial hypertension

(PAH) paediatric indication. As a consequence, the film coated tablets presentations are updated to accommodate the new pharmaceutical form. In addition, contact details for local representatives of Belgium, Luxembourg, Greece and Ireland, have also been updated

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

5.3.34. Ritonavir - NORVIR (CAP) - EMA/VR/0000249795

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

Type II (C.I.6.a): To modify the approved therapeutic indication to reflect current clinical use as a pharmacokinetic enhancer of other antiretroviral products only. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.8 and 5.1 of the SmPC. The Package Leaflet is updated accordingly. The updated RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI

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

5.3.35. Selpercatinib - RETSEVMO (CAP) - EMA/VR/0000247142

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Update of section 5.3 of the SmPC in order to update information on carcinogenesis based on results from a non-clinical 2-year carcinogenicity study of selpercatinib in rats. The RMP version 11.1 has also been submitted

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

5.3.36. Selumetinib - KOSELUGO (CAP) - EMEA/H/C/005244/X/0018/G, Orphan

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Extension application to introduce a new pharmaceutical form (Granules in capsules for opening) associated with new strengths (5 mg and 7.5 mg capsule) grouped with a Type II variation (C.I.4) to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to align the SmPC and labelling of Koselugo capsules and Koselugo granules in capsules for opening. The Package Leaflet and Labelling are updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet

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

5.3.37. Selumetinib - KOSELUGO (CAP) - EMA/VR/0000245231

Applicant: AstraZeneca AB

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication for KOSELUGO to include treatment of adults based on results from study D134BC00001 (KOMET). This is a phase III, multicentre, international study with a parallel, randomised, double-blind, placebo-controlled, 2 arm design that assesses efficacy and safety of selumetinib in adult participants with NF1 who have Symptomatic Inoperable Plexiform Neurofibromas.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC. As part of the application the MAH is requesting a 1-year extension of the market protection

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

5.3.38. Tasimelteon - HETLIOZ (CAP) - EMEA/H/C/003870/II/0040, Orphan

Applicant: Vanda Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include the treatment of nighttime sleep disturbances in adults with Smith Magenis Syndrome (SMS) for HETLIOZ, based on results from study VP-VEC-162-2401. This is a double-blind, randomized, two-period crossover study evaluating the effects of tasimelteon vs. placebo on sleep disturbances of individuals with Smith-Magenis Syndrome (SMS). As a consequence, sections 4.1, 4.5, 5.1, 5.2 and 5.3 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. The RMP version 5.0 has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection

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

5.3.39. Ustekinumab - OTULFI (CAP) - EMEA/H/C/006544/II/0001/G

Applicant: Fresenius Kabi Deutschland GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Quality variations. The product information and the RMP (v 1.0) are updated consequentially

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

5.3.40. Vutrisiran - AMVUTTRA (CAP) - EMEA/H/C/005852/II/0015, Orphan

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include treatment of wild-type or hereditary transthyretin-mediated amyloidosis in adult patients with cardiomyopathy (ATTR-CM), based on primary analysis results from study HELIOS-B (ALN-TTRSC02-003); a Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of Vutrisiran in Patients With Transthyretin Amyloidosis With Cardiomyopathy (ATTR Amyloidosis With

Cardiomyopathy). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. An updated version 1.3 of the RMP has also been submitted

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

5.3.41. Zanubrutinib - BRUKINSA (CAP) - EMEA/H/C/004978/X/0023

Applicant: BeiGene Ireland Ltd

PRAC Rapporteur: Bianca Mulder

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (160 mg film-coated tablets)

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

6. Periodic safety update reports (PSURs)

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

6.1.1. Abrocitinib - CIBINQO (CAP) - PSUSA/00010976/202409

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.2. Aprocitentan - JERAYGO (CAP) - PSUSA/00011067/202409

Applicant: Idorsia Pharmaceuticals Deutschland GmbH

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.3. Bedaquiline - SIRTURO (CAP) - PSUSA/00010074/202409

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.4. Cabotegravir[3] - APRETUDE (CAP) - PSUSA/00000116/202409

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.5. Caplacizumab - CABLIVI (CAP) - PSUSA/00010713/202408

Applicant: Ablynx NV

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.6. Cenobamate - ONTOZRY (CAP) - PSUSA/00010921/202409

Applicant: Angelini S.p.A.

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.7. Chlormethine - LEDAGA (CAP) - PSUSA/00010587/202408

Applicant: Helsinn Birex Pharmaceuticals Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.8. Cholic acid[4] - ORPHACOL (CAP) - PSUSA/00010208/202409

Applicant: Theravia

PRAC Rapporteur: Maria Poulianiti

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.9. Cipaglucosidase alfa - POMBILITI (CAP) - PSUSA/00011047/202409

Applicant: Amicus Therapeutics Europe Limited

[3] Indicated for pre-exposure prophylaxis of HIV-1 infection

[4] For oxosteroid-reductase or hydroxy-steroid dehydrogenase deficiency indication only

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.10. Deferiprone - FERRIPROX (CAP) - PSUSA/00000940/202408

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.11. Deucravacitinib - SOTYKTU (CAP) - PSUSA/00011046/202409

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.12. Duvelisib - COPIKTRA (CAP) - PSUSA/00010939/202409

Applicant: Secura Bio Limited

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.13. Ebola vaccine (MVA-BN-Filo [recombinant]) - MVABEA (CAP); Ebola vaccine (Ad26.ZEBOV-GP [recombinant]) ZABDENO (CAP) - PSUSA/00010857/202409

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.14. Eliglustat - CERDELGA (CAP) - PSUSA/00010351/202408

Applicant: Sanofi B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.15. Epcoritamab - TEPKINLY (CAP) - PSUSA/00000107/202409

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.16. Filgotinib - JYSELECA (CAP) - PSUSA/00010879/202409

Applicant: Alfasigma S.p.A.

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.17. Fruquintinib - FRUZAQLA (CAP) - PSUSA/00011069/202409

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.18. Ganaxolone - ZTALMY (CAP) - PSUSA/00000093/202409

Applicant: Marinus Pharmaceuticals Emerald Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.19. Gilteritinib - XOSPATA (CAP) - PSUSA/00010832/202409

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. Glofitamab - COLUMVI (CAP) - PSUSA/00000067/202409

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jana Lukacisinova

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.21. Gozetotide - LOCAMETZ (CAP) - PSUSA/00011030/202409

Applicant: Novartis Europharm Limited

PRAC Rapporteur: John Joseph Borg

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.22. Idebenone[5] - RAXONE (CAP) - PSUSA/00010412/202409

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.23. Influenza vaccine (intranasal, live attenuated) - FLUENZ (CAP); FLUENZ TETRA (CAP) - PSUSA/00001742/202408

Applicant: AstraZeneca AB

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.24. Isavuconazole - CRESEMBA (CAP) - PSUSA/00010426/202409

Applicant: Basilea Pharmaceutica Deutschland GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.25. Lacosamide - LACOSAMIDE UCB (CAP); VIMPAT (CAP) - PSUSA/00001816/202408

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[5] For centrally authorised product(s) only

6.1.26. Lorlatinib - LORVIQUA (CAP) - PSUSA/00010760/202409

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.27. Loxapine[6] - ADASUVE (CAP) - PSUSA/00010113/202408

Applicant: Ferrer Internacional s.a.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.28. Lutetium (^{177}LU) vipivotide tetraxetan - PLUVICTO (CAP) - PSUSA/00011031/202409

Applicant: Novartis Europharm Limited

PRAC Rapporteur: John Joseph Borg

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.29. Mecasermin - INCRELEX (CAP) - PSUSA/00001942/202408

Applicant: Ipsen Pharma

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.30. Mepolizumab - NUCALA (CAP) - PSUSA/00010456/202409

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.31. Miglustat[7] - OPFOLDA (CAP) - PSUSA/00000077/202409

Applicant: Amicus Therapeutics Europe Limited

[6] Pre-dispensed inhalation powder only
[7] For treatment of Pompe disease only

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.32. Momelotinib - OMJJARA (CAP) - PSUSA/00000263/202409

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.33. Moroctocog alfa - REFACTO AF (CAP) - PSUSA/00002089/202408

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. Naloxegol - MOVENTIG (CAP) - PSUSA/00010317/202409

Applicant: Gruenenthal GmbH (Moventig)

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.35. Naltrexone hydrochloride, bupropion hydrochloride - MYSIMBA (CAP) - PSUSA/00010366/202409

Applicant: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.36. Nivolumab, relatlimab - OPDUALAG (CAP) - PSUSA/00011018/202409

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.37. Ofatumumab - KESIMPTA (CAP) - PSUSA/00010927/202409

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.38. Pembrolizumab - KEYTRUDA (CAP) - PSUSA/00010403/202409

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. Pralsetinib - GAVRETO[8] - PSUSA/00010961/202409

Applicant: Blueprint Medicines (Netherlands) B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For discussion

6.1.40. Retifanlimab - ZYNYZ (CAP) - PSUSA/00011059/202409

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. Rezafungin - REZZAYO (CAP) - PSUSA/00000221/202409

Applicant: Mundipharma GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.42. Ruxolitinib[9] - OPZELURA (CAP) - PSUSA/00011052/202409

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Adam Przybylkowski

[8] European Commission (EC) decision on the marketing authorisation (MA) withdrawal of Truberzi dated 18 December 2020
[9] For non-segmental vitiligo only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.43. Sebelipase alfa - KANUMA (CAP) - PSUSA/00010422/202408

Applicant: Alexion Europe SAS

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Sodium thiosulfate - PEDMARQSI (CAP) - PSUSA/00000066/202409

Applicant: Norgine B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Somapacitan - SOGROYA (CAP) - PSUSA/00010920/202408

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Sotatercept - WINREVAIR (CAP) - PSUSA/00011076/202409

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Spesolimab - SPEVIGO (CAP) - PSUSA/00011033/202409

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. Teduglutide - REVESTIVE (CAP) - PSUSA/00009305/202408

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

6.1.49. Vibegron - OBGEMSA (CAP) - PSUSA/00011068/202409

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.50. Zilucoplan - ZILBRYSQ (CAP) - PSUSA/00000169/202409

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.51. Zolbetuximab - VYLOY (CAP) - PSUSA/00011095/202409

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Bianca Mulder

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. Asparaginase, crisantaspase (L-asparaginase from Erwinia chrysanthemi) - ENRYLAZE (CAP); NAP - PSUSA/00003161/202408

Applicants: Jazz Pharmaceuticals Ireland Limited (Enrylaze), various

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.2. Epoetin alfa - ABSEAMED (CAP); BINOCRIT (CAP); EPOETIN ALFA HEXAL (CAP); NAP - PSUSA/00001237/202408

Applicants: Medice Arzneimittel Pütter GmbH & Co. KG (Abseamed), Hexal AG (Epoetin alfa Hexal), Sandoz GmbH (Binocrit), various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.3. Glycopyrronium[10] - SIALANAR (CAP); NAP - PSUSA/00010529/202409

Applicant(s): Proveca Pharma Limited, various

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.4. Measles, mumps, rubella, varicella vaccines (live) - PROQUAD (CAP); NAP - PSUSA/00001936/202409

Applicants: Merck Sharp & Dohme B.V. (ProQuad), various

PRAC Rapporteur: Gabriele Maurer

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. Ciclesonide (NAP) - PSUSA/00000742/202408

Applicant(s): various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.2. Dalteparin sodium (NAP) - PSUSA/00000922/202408

Applicant(s): various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Dexamfetamine (NAP) - PSUSA/00000986/202409

Applicant(s): various

[10] For severe sialorrhoea indication only

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.4. Estrogen, medroxyprogesterone (NAP) - PSUSA/00000582/202408

Applicant(s): various

PRAC Lead: Jana Lukačišinová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. Etonogestrel (NAP) - PSUSA/00001331/202409

Applicant(s): various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.6. Hydrocortisone[11] (NAP) - PSUSA/00010856/202408

Applicant(s): various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.7. Hydrocortisone[12] (NAP) - PSUSA/00010855/202408

Applicant(s): various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. Lercanidipine (NAP) - PSUSA/00001841/202408

Applicant(s): various

PRAC Lead: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

[11] For all formulations apart from systemic use
[12] For systemic formulations except for products indicated in adrenal insufficiency in a modified release tablet formulation and except for centrally authorised products for adrenal insufficiency, paediatric use only

6.3.9. Meropenem (NAP) - PSUSA/00001989/202408

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. Oxcarbazepine (NAP) - PSUSA/00002235/202408

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. Rilmenidine (NAP) - PSUSA/00002643/202408

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. Sotalol (NAP) - PSUSA/00002774/202408

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. Thallium [201TL] (NAP) - PSUSA/00002920/202408

Applicant(s): various

PRAC Lead: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.4. Follow-up to PSUR/PSUSA procedures

None

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Burosumab - CRYSVITA (CAP) - EMA/VR/0000246754

Applicant: Kyowa Kirin Holdings B.V.

PRAC Lead: Gabriele Maurer

Scope: Update of section 4.6 of the SmPC in order to add a statement on how long contraception should be continued after burosumab treatment has been discontinued, as requested in procedure PSUSA/00010669/202402. The Package Leaflet is updated accordingly

Action: For adoption of PRAC Assessment Report

6.5.2. Mogamulizumab - POTELIGEO (CAP) - EMEA/H/C/004232/II/0026, Orphan

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Update of section 4.8 of the SmPC in order to add 'granuloma' to the list of adverse drug reactions (ADRs) with frequency 'unknown', based on post marketing data; the Package Leaflet is updated accordingly

Action: For adoption of PRAC Assessment Report

6.5.3. Rituximab – BLITZIMA (CAP); TRUXIMA (CAP) - EMA/VR/0000244743

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Lead: Karin Erneholm

Scope: C.I.2.a: To update sections 4.1, 4.2, 4.3, 4.8, 5.1, 6.2, 6.4 and 6.5 of the SmPC in order to introduce several structural and editorial changes to align with the current SmPC guideline and to remove the educational materials for HCPs and patients, following the request by the PRAC in the AR for the PSUSA procedure EMA/PRAC/257005/2023. The Annex II, Labelling and Package Leaflet are updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI in line with the same changes to the reference product.

C.I.11.z: To update the RMP following the assessment of PSUR EMEA/H/C/PSUSA/00002652/202311

Action: For adoption of PRAC Assessment Report

6.6. Expedited summary safety reviews[13]

None

[13] 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

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[14]

7.1.1. Cabotegravir - VOCABRIA; rilpivirine - REKAMBYS (CAP) - EMA/PASS/0000247696

Applicants: Janssen-Cilag International N.V. (Rekambys), ViiV Healthcare B.V. (Vocabria)

PRAC Rapporteur: Liana Martirosyan

Scope: Drug Utilization, Adherence, Effectiveness and Resistance: A Prospective Observational Cohort Study in People living with HIV (PLWH) initiating ARV regimen of CAB+RPV LA in Collaboration with EuroSIDA

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

7.1.2. rADAMTS13 - ADZYNMA (CAP) - EMA/PASS/0000253115

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Maia Uusküla

Scope: A Post-Authorization Safety Study (PASS) to Further Evaluate Real-World Safety in Patients with Congenital Thrombotic Thrombocytopenic Purpura (cTTP) Treated with Adzynma

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

7.1.3. Valproate (NAP) - EMEA/H/N/PSP/J/0108.1

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

PRAC Rapporteur: Liana Martirosyan

Scope: MAH's response to PSP/0108 [Paternal exposure to valproate, further investigation on the risk of Neuro Developmental Disorders (NDD) and Congenital Malformation (CM) in Offspring: A Non-Interventional Post-Authorization Safety Study (PASS)] as per the request for supplementary information (RSI) adopted in Oct 2024

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

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[15]

7.2.1. Beclometasone, formoterol, glycopyrronium bromide – RIARIFY (CAP) - EMA/PAM/0000247638

Applicant: Chiesi Farmaceutici S.p.A.

[14] In accordance with Article 107n of Directive 2001/83/EC
[15] 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: Jan Neuhauser

Scope: Revised protocol for a PASS study, non-interventional study titled: "MulTinational database cohoRt study to assess adverse cardIovascular and cereBrovascular outcomes in patiEnts (TRIBE) with chronic obstructive pulmonary disease initiating a fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via dry powder inhaler (DPI) compared to pressurized metered dose inhaler (pMDI)" (study code No.: CLI-05993BA1-05 CLI-05993BA1-05 (TRIBE)

Action: For adoption of advice to CHMP

7.2.2. Beclometasone, formoterol, glycopyrronium bromide –TRIMBOW (CAP) - EMA/PAM/0000247269

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Revised protocol for a PASS study, non-interventional study titled: "MulTinational database cohoRt study to assess adverse cardIovascular and cereBrovascular outcomes in patiEnts (TRIBE) with chronic obstructive pulmonary disease initiating a fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via dry powder inhaler (DPI) compared to pressurized metered dose inhaler (pMDI)" (study code No.: CLI-05993BA1-05 CLI-05993BA1-05 (TRIBE)

Action: For adoption of advice to CHMP

7.2.3. Beclometasone, formoterol, glycopyrronium bromide – TRYDONIS - EMA/PAM/0000247627

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Revised protocol for a PASS study, non-interventional study titled: "MulTinational database cohoRt study to assess adverse cardIovascular and cereBrovascular outcomes in patiEnts (TRIBE) with chronic obstructive pulmonary disease initiating a fixed triple therapy containing beclometasone dipropionate, formoterol fumarate and glycopyrronium administered via dry powder inhaler (DPI) compared to pressurized metered dose inhaler (pMDI)" (study code No.: CLI-05993BA1-05 CLI-05993BA1-05 (TRIBE)

Action: For adoption of advice to CHMP

7.2.4. Emicizumab – HEMLIBRA (CAP) - EMA/PAM/0000248363

Applicant: Roche Registration GmbH

PRAC Rapporteur: Amelia Cupelli

Scope: Revised protocol (version 3.0) of the protocol for study BO44691 which is a long term non-interventional safety study of Emicizumab treatment in patients with moderate haemophilia A and severe bleeding phenotype for PRAC review as a 'standalone' post-authorisation measure (PAM) application [EMEA/H/C/00406/MEA/012.3]

Action: For adoption of advice to CHMP

7.2.5. Etranacogene dezaparvovec – HEMGENIX (CAP) - EMA/PAM/0000248926

Applicant: CSL Behring GmbH, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Protocol for PASS CSL222_5001: Survey to evaluate the effectiveness of additional risk minimization measures (aRMMs) for Hemgenix among prescribers in the EU

Action: For adoption of advice to CAT and CHMP

7.2.6. Golimumab – SIMPONI (CAP) - EMA/PAM/0000248923

Applicant: Janssen Biologics B.V.

PRAC Rapporteur: Karin Bolin

Scope: PASS No. MK-8259-050: An observational post-approval safety study of golimumab in treatment of poly-articular Juvenile Idiopathic Arthritis (pJIA) using the German Biologics JIA Registry (BiKeR)

Action: For adoption of advice to CHMP

7.2.7. Human thrombin, human fibrinogen – TACHOSIL (CAP) - EMA/PAM/0000247840

Applicant: Corza Medical GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Revised protocol for PASS PasTel: Short- and long-term safety evaluation of TachoSil in paediatric population

Action: For adoption of advice to CHMP

7.2.8. Talimogene laherparepvec – IMLYGIC (CAP) - EMA/PAM/0000247962

Applicant: Amgen Europe B.V.G, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: A post-marketing, prospective cohort study of patients treated with talimogene laherparepvec in clinical practice to characterize the risk of herpetic illness among patients, close contacts, and healthcare providers; and long term safety in treated patients

Action: For adoption of advice to CAT and CHMP

7.2.9. Ublituximab – BRIUMVI (CAP) - EMA/PAM/0000246081

Applicant: Neuraxpharm Pharmaceuticals S.L.

PRAC Rapporteur: Liana Martirosyan

Scope: Revised protocol for PASS No. TG1101-RMS403 A registry study of pregnancy and infant outcomes in patients treated with ublituximab to characterise the safety of ublituximab use in pregnancy, including maternal, foetal and neonate/infant outcomes, in female patients with relapsing forms of multiple sclerosis

Action: For adoption of advice to CHMP

7.2.10. Velaglucerase alfa – VPRIV (CAP) - EMA/PAM/0000248394

Applicant: Takeda Pharmaceuticals International AG

PRAC Rapporteur: Martin Huber

Scope: Response to MEA/030: Study TAK-669-4018: A Survey among Patients, Caregivers and Home Infusion Nurses based in the European Union to Assess their Awareness and Understanding of Educational Materials (EM) Supporting VPRIV Infusion at Home.

Objectives: To determine whether patients/caregivers and home infusion nurses appropriately understand and implement the EM associated with VPRIV home infusion. Specifically, to assess the proportion of patients/caregivers and home infusion nurses who are aware of the EM; who understand the EM; and who use the EM

Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)[16]

7.3.1. Alemtuzumab – LEMTRADA (CAP) - EMEA/H/C/PSR/S/0050

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: Final study report for a non-interventional post-authorisation safety study to investigate drug utilisation and safety monitoring patterns for Lemtrada (alemtuzumab)

Action: For adoption of recommendation to CMDh

7.3.2. Alemtuzumab – LEMTRADA (CAP) - EMEA/H/C/PSR/S/0051

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: Final study report for a non-interventional post-authorisation safety study to investigate the risk of mortality in multiple sclerosis patients treated with alemtuzumab (Lemtrada) relative to comparable multiple sclerosis patients using other disease modifying therapies: a cohort study

Action: For adoption of recommendation to CMDh

7.3.3. Methylphenidate hydrochloride (NAP) - EMA/PASS/0000248031

Applicant(s): Medice Arzneimittel Puetter GmbH & Co. KG (Medikinet)

PRAC Rapporteur: Martin Huber

Scope: Final study report for a multi-centre, observational, prospective PASS to evaluate the safety concerns of long-term cardiovascular and psychiatric risks within the adult

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

attention deficit/hyperactivity disorder (ADHD) population taking Medikinet retard according to normal standard clinical practice

Action: For adoption of recommendation to CMDh

7.4. Results of PASS non-imposed in the marketing authorisation(s)[17]

7.4.1. Avelumab - BAVENCIO (CAP) - EMA/VR/0000244307

Applicant: Merck Europe B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Submission of the final report from study MS100070-0031 listed as a category 3 PASS in the RMP. This is a non-interventional cohort efficacy and safety study to assess the characteristics and management of patients with Merkel cell carcinoma (MCC) in Germany

Action: For adoption of PRAC Assessment Report

7.4.2. Deferasirox - EXJADE (CAP) - EMEA/H/C/000670/II/0090

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of section 4.2 of the SmPC in order to update information on posology based on the non-interventional study CICL670A2429 listed as a category 3 study in the RMP. This is a survey to assess physicians' knowledge of Exjade posology and biological monitoring recommendations as described in the Educational Materials (EMs)

Action: For adoption of PRAC Assessment Report

7.4.3. Eliglustat - CERDELGA (CAP) - EMA/VR/0000245058

Applicant: Sanofi B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Submission of the final report from study ELIGLC06913 listed as a category 3 PASS in the RMP. This is a drug utilisation study of eliglustat for the treatment of Gaucher Disease Type 1 in Europe using electronic healthcare records

Action: For adoption of PRAC Assessment Report

7.4.4. Etanercept - ENBREL (CAP) - EMEA/H/C/000262/II/0255

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Monica Martinez Redondo

Scope: Update of sections 4.2 and 4.4 of the SmPC in order to remove information regarding the Patient Card, based on final results from study B1801309 (BSR Register of

[17] 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

Anti-TNF Treated Patients and Prospective Surveillance Study for Adverse Events: Enbrel). This is a non-interventional PASS study listed as a category 3 study in the RMP. The Annex II and Package Leaflet are updated accordingly. The RMP version 7.7 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI as well as to update the list of local representatives in the Package Leaflet and align the PI with the QRD version 10.4

Action: For adoption of PRAC Assessment Report

7.4.5. Influenza quadrivalent vaccine (rDNA[18]) - SUPEMTEK TETRA (CAP) - EMEA/H/C/005159/II/0020

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Zoubida Amimour

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

Action: For adoption of PRAC Assessment Report

7.4.6. Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - MOSQUIRIX (Art 58[19]) - EMEA/H/W/002300/II/0085/G

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Jean-Michel Dogné

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

C.I.4: Update of sections 4.4 and 5.1 of the SmPC in order to remove meningitis from the list of important potential risks and add effectiveness data based on EPI-MAL-003 study listed as a category 3 study in the RMP. This is a prospective study to evaluate the safety, effectiveness and impact of the RTS,S/AS01E vaccine in young children in sub-Saharan Africa countries. The Package Leaflet is updated accordingly.
The RMP version 6.0 has also been submitted.

C.I.13: Submission of the final report from study MVPE (Malaria Vaccine Pilot Evaluation) listed as a category 3 study in the RMP. This is a observational study in the context of a cluster-randomized pilot implementation in order to assess the feasibility of delivery, safety, and impact on mortality of the RTS,S/AS01E malaria vaccine delivered through the routine immunization services in Kenya, Malawi, and Ghana over 4 years.

Action: For adoption of PRAC Assessment Report

[18] Ribosomal deoxyribonucleic acid
[19] 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)

7.4.7. Mepolizumab - NUCALA (CAP) - EMEA/H/C/003860/II/0071

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of the final report from the Mepolizumab (Nucala) Pregnancy Exposure Study 200870: a VAMPSS post marketing surveillance study of Mepolizumab safety in pregnancy, listed as a category 3 study in the RMP. This is a non-interventional study to monitor planned and unplanned pregnancies exposed to mepolizumab and to evaluate the possible teratogenic effect of this medication relative to the pregnancy outcomes of major birth defects, preterm delivery, small for gestational age infants and spontaneous abortion or stillbirth. The RMP version 13.0 has also been submitted.

Action: For adoption of PRAC Assessment Report

7.4.8. Venetoclax - VENCLYXTO (CAP) - EMA/VR/0000245044

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Submission of the final report from study P22-907 listed as a category 3 PASS in the RMP. This is a non-interventional cross-sectional study evaluating the effectiveness of venetoclax risk minimisation measures among haematologists in Europe

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. Burosumab – CRYSVITA (CAP) - EMA/PAM/0000248012

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: First adult interim report for PASS EUPAS32190: Non-interventional Post-Authorisation Safety Study of Burosumab in the Treatment of Children >1 year of age, Adolescents and Adults with X linked Hypophosphataemia (protocol number 2019-36-EU-CRY)

Action: For adoption of advice to CHMP

7.5.2. COVID-19 vaccine (recombinant, adjuvanted) – NUVAXOVID (CAP) - EMA/PAM/0000244397

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Revised Second Interim Report for PASS 2019nCoV-402: UK A Study Using the Clinical Practice Research Datalink (CPRD): A surveillance study to characterise the safety profile of Nuvaxovid in adults aged 18 years and older in the real-world setting using the UK

CPRD

Action: For adoption of advice to CHMP

7.5.3. Nirmatrelvir, ritonavir - PAXLOVID (CAP) - EMEA/H/C/005973/MEA 008.2

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: From Initial MAA:
First Interim Report for PASS C4671037
Title: Use and safety of Paxlovid in pregnant and breastfeeding women

Action: For adoption of advice to CHMP

7.5.4. Nirmatrelvir, ritonavir - PAXLOVID (CAP) - EMEA/H/C/005973/MEA 009.3

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: From Initial MAA:
First Interim Report for PASS C4671047
Use and safety of Paxlovid during pregnancy and among patients with moderate or severe hepatic or renal impairment

Action: For adoption of advice to CHMP

7.5.5. Ofatumumab – KESIMPTA (CAP) - EMA/PAM/0000243996

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Third Interim Report for PASS Study COMB157G2407: Evaluation of pregnancy and infant outcomes in Kesimpta patients using Pregnancy outcomes Intensive Monitoring (PRIM) data – The Kesimpta-PRIM study

Action: For adoption of advice to CHMP

7.5.6. Rurioctocog alfa pegol – ADYNOVI (CAP) - EMA/PAM/0000248808

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Bianca Mulder

Scope: 5th interim/progress report (dated 15 January 2025, with a data cut-off of 12 November 2024) for the ongoing Adynovi post-authorisation safety study (PASS) TAK-660-403 (EUPAS35698) which is a non-interventional, imposed study aimed 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

7.5.7. Tofacitinib – XELJANZ (CAP) - EMA/PAM/0000247897

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Response to MEA 017.4 - an RSI adopted on 12.12.2024 following assessment of Interim Report from Study A3921352

Study A3921352 is an active surveillance, post-authorization study to characterize the safety of tofacitinib in patients with moderately to severely active ulcerative colitis in the real-world setting using data from the United Registries for Clinical Assessment and Research (UR-CARE) in the European Union (EU)

Action: For adoption of advice to CHMP

7.6. Others

7.6.1. Anifrolumab – SAPHNELO (CAP) - EMA/PAM/0000245373

Applicant: AstraZeneca AB

PRAC Rapporteur: Liana Martirosyan

Scope: Progress report for ROSE study (D3461R00028): A non-interventional multi-database post-authorisation study to assess pregnancy-related safety data from women with Systemic Lupus Erythematosus exposed to anifrolumab

Action: For adoption of advice to CHMP

7.6.2. Damoctocog alfa pegol – JIVI (CAP) - EMA/PAM/0000245659

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: 16th Annual Report for Study 14149: EUHASS Registry (European Haemophilia Safety Surveillance)

Action: For adoption of advice to CHMP

7.6.3. Ganaxolone – ZTALMY (CAP) - EMA/PAM/0000246069

Applicant: Marinus Pharmaceuticals Emerald Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Study LLF001 (CANDID observational study): Milestone report to be provided after 50 participants have completed the first-year visit

Action: For adoption of advice to CHMP

7.6.4. Infliximab – REMSIMA (CAP) - EMA/PAM/0000245463

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Kimmo Jaakkola

Scope: MAH's responses to MEA 020.5 Annual Recruitment Status Report from Study CT-P13 4.8

An observational, prospective cohort study to evaluate safety of Remsima SC in patients with RA, AS, PsA and Ps

RSI as adopted in April 2024

Action: For adoption of advice to CHMP

7.6.5. Octocog alfa – KOVALTRY (CAP) - EMA/PAM/0000246076

Applicant: Bayer AG

PRAC Rapporteur: Gabriele Maurer

Scope: Study 14149: 16th Annual Report and Product Specific EUHASS Report

Action: For adoption of advice to CHMP

7.7. New Scientific Advice

7.8. Ongoing Scientific Advice

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

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

8.1. Annual reassessments of the marketing authorisation

8.1.1. Histamine dihydrochloride - CEPLENE (CAP) - EMEA/H/C/000796/S/0049 (without RMP)

Applicant: Laboratoires Delbert

PRAC Rapporteur: Eamon O'Murchu

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.2. Maralixibat - LIVMARLI (CAP) - EMEA/H/C/005857/S/0019 (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. Fidanacogene elaparvovec - BEQVEZ (CAP) - EMA/R/0000247045

Applicant: Pfizer Europe MA EEIG, ATMP

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CAT and CHMP

8.2.2. Imlifidase – IDEFIRIX (CAP) - EMA/R/0000249767

Applicant: Hansa Biopharma AB

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.3. Meningococcal Group A, C, W and Y conjugate vaccine – MENQUADFI (CAP) - EMA/R/0000245024

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Jean-Michel Dogné

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.4. Talquetamab – TALVEY (CAP) - EMA/R/0000249367

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.5. Teclistamab – TECVAYLI (CAP) - EMA/R/0000249306

Applicant: Janssen Cilag International

PRAC Rapporteur: Jana Lukacisinova

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Bevacizumab - AYBINTIO (CAP) - EMEA/H/C/005106/R/0022 (without RMP)

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.2. Fampridine – FAMPRIDINE ACCORD (CAP) - EMA/R/0000243787

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Formoterol / Glycopyrronium bromide / Budesonide – TRIXEO AEROSPHERE (CAP) - EMA/R/0000245136

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Idebenone - RAXONE (CAP) - EMEA/H/C/003834/R/0043 (without RMP)

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Amelia Cupelli

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.5. Lumasiran – OXLUMO (CAP) - EMA/R/0000245133

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

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

Applicant: Rayner Surgical (Ireland) Limited

PRAC Rapporteur: Jan Neuhauser

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspections

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

9.3. Others

None

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

10.1. Safety related variations of the marketing authorisation

None

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

None

10.3. Other requests

None

10.4. Scientific Advice

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

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

11.1. Safety related variations of the marketing authorisation

None

11.2. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC Best Practice Guide - Recommendations on efficiency of plenary meetings - Revision 2

PRAC lead: Martin Huber

Action: For adoption

12.1.2. PRAC membership

Action: For information

12.1.3. Vote by proxy

Action: For information

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

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

None

12.4. Cooperation within the EU regulatory network

12.4.1. European medicines agencies network strategy (EMANS) to 2028

Action: For information

12.4.2. Exchange of views with European Commission on Pharmaceutical Legislation Reform

Action: For discussion

12.5. Cooperation with International Regulators

12.5.1. International Coalition of Medicines Regulatory Authorities (ICMRA) Working Group on Real World Evidence (RWE) for Public Health Emergencies: mandate, general principles and process for conducting collaboratives studies

Action: For discussion

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

None

12.7. PRAC work plan

None

12.8. Planning and reporting

None

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)

None

12.10.3. PSURs repository

None

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

None

12.11. Signal management

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

PRAC lead: Martin Huber

Action: For discussion

12.12. 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

None

12.21. Others

12.21.1. Onboarding/offboarding experience of Committee/CMD members and alternates

Action: For discussion

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

Action: For discussion

12.21.3. Replacement of Annex C – Use of the IRIS NCA Dashboard to extract the relevant information

Action: For information

13. Any other business

None

14. Explanatory notes

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

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

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

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

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as

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

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

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

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

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

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

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

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

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

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