13 January 2025
EMA/PRAC/549682/2024
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 13-16 January 2025

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

13 January 2025, 10:30 – 19:30, via teleconference

14 January 2025, 08:30 – 19:30, via teleconference

15 January 2025, 08:30 – 19:30, via teleconference

16 January 2025, 08:30 – 16:00, via teleconference

Organisational, regulatory and methodological matters (ORGAM)

30 January 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 13-16 January 2025. See January 2025 PRAC minutes (to be published post February 2025 PRAC meeting).

1.2. Agenda of the meeting on 13-16 January 2025

Action: For adoption

1.3. Minutes of the previous meeting on 25-28 November 2024

Action: For adoption

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

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

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

3.1. Newly triggered procedures

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination 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. Ciltacabtagene autoleucel – CARVYKTI (CAP)

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Jo Robays

Scope: Signal of immune-mediated enterocolitis

Action: For adoption of PRAC recommendation

EPITT 20133 – New signal

Lead Member State(s): BE

4.1.2. Clozapine (NAP)

Applicant(s): various

PRAC Rapporteur: To be appointed

Scope: Signal of appendicitis

Action: For adoption of PRAC recommendation

EPITT 20139 – New signal

Lead Member State(s): IT

4.1.3. Clozapine (NAP)

Applicant: various

[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: To be appointed

Scope: Signal of new aspect of the known risk of neutropenia/agranulocytosis with potential impact on the risk management measures

Action: For adoption of PRAC recommendation

EPITT 20141 – New signal

Lead Member State(s): IT

4.1.4. Enzalutamide - ENZALUTAMIDE VIATRIS (CAP), XTANDI (CAP); NAP

Applicant(s): Astellas Pharma Europe B.V. (Xtandi), Viatris Limited (Enzalutamide Viatris), various

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Signal of laboratory test interference, cardioactive drug level increased

Action: For adoption of PRAC recommendation

EPITT 20134 – New signal

Lead Member State(s): ES

4.1.5. Omalizumab – OMLYCLO (CAP); XOLAIR (CAP)

Applicant: Celltrion Healthcare Hungary Kft. (Omlyclo), Novartis Europharm Limited (Xolair)

PRAC Rapporteur: Mari Thorn

Scope: Signal of hearing losses

Action: For adoption of PRAC recommendation

EPITT 20128 – New signal

Lead Member State(s): SE

4.1.6. Sertraline (NAP)

Applicant: various

PRAC Rapporteur: To be appointed

Scope: Signal of multiple acyl-coenzyme A dehydrogenase deficiency (MADD)

Action: For adoption of PRAC recommendation

EPITT 20125 – New signal

Lead Member State(s): NL

4.1.7. Sulfamethoxazole, trimethoprim (co-trimoxazole) (NAP)

Applicant: various

PRAC Rapporteur: To be appointed

Scope: Signal of circulatory shock

Action: For adoption of PRAC recommendation

EPITT 20135 – New signal

Lead Member State(s): HR

4.2. Signals follow-up and prioritisation

4.2.1. Afatinib - GIOTRIF (CAP) - EMEA/H/C/002280/SDA/009

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Mari Thorn

Scope: Signal of growth of eyelashes

Action: For adoption of PRAC recommendation

EPITT 19987 – Follow-up to December 2023[3]

4.2.2. Atezolizumab - TECENTRIQ (CAP) - EMEA/H/C/004143/SDA/026; Avelumab - BAVENCIO (CAP) - EMEA/H/C/004338/SDA/012; Cemiplimab - LIBTAYO (CAP) - EMEA/H/C/004844/SDA/013; Dostarlimab - JEMPERLI (CAP) - EMEA/H/C/005204/SDA/007; Durvalumab - IMFINZI (CAP) - EMEA/H/C/004771/SDA/013; Ipilimumab - YERVOY (CAP) - EMEA/H/C/002213/SDA/049; Nivolumab - OPDIVO (CAP) - EMEA/H/C/003985/SDA/058; Nivolumab, relatlimab - OPDUALAG (CAP) - EMEA/H/C/005481/SDA/007; Pembrolizumab - KEYTRUDA (CAP) - EMEA/H/C/003820/SDA/042; Retifanlimab - ZYNYZ (CAP) - EMEA/H/C/006194/SDA/002; Tislelizumab - TEVIMBRA (CAP) - EMEA/H/C/005919/SDA/004; Tremelimumab - IMJUDO (CAP) - EMEA/H/C/006016/SDA/004

Applicants: 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 (Libtayo), Roche Registration GmbH (Tecentriq)

PRAC Rapporteur: Bianca Mulder

Scope: Signal of thrombotic microangiopathy

Action: For adoption of PRAC recommendation

EPITT 20090 – Follow-up to July 2024

4.2.3. Lenvatinib - KISPLYX (CAP) - EMEA/H/C/004224/SDA/021; LENVIMA (CAP) - EMEA/H/C/003727/SDA/024

Applicant: Eisai GmbH

[3] Held 27–30 November 2023

PRAC Rapporteur: Mari Thorn

Scope: Signal of tumour lysis syndrome

Action: For adoption of PRAC recommendation

EPITT 20108 – Follow-up to September 2024

4.3. Variation procedure(s) resulting from signal evaluation

None

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Amino acids (CAP MAA) - EMEA/H/C/005557, Orphan

Applicant: Recordati Rare Diseases

Scope (pre D-180 phase): treatment of decompensation episodes in MSUD patients

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

5.1.2. Diflunisal (CAP MAA) - EMEA/H/C/006248, Orphan

Applicant: AO Pharma AB

Scope (pre D-180 phase): Treatment of ATTR amyloidosis

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

5.1.3. Ferric citrate coordination complex (CAP MAA) - EMEA/H/C/006402

Scope (pre D-180 phase): treatment of iron deficiency anaemia in adult chronic kidney disease (CKD) patients with elevated serum phosphorus levels

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

5.1.4. Trastuzumab (CAP MAA) - EMEA/H/C/006219

Scope (pre D-180 phase): treatment of metastatic and early breast cancer

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

5.1.5. Troriluzole (CAP MAA) - EMEA/H/C/006068, Orphan

Applicant: Biohaven Bioscience Ireland Limited

Scope (pre D-180 phase): treatment of adult patients with spinocerebellar ataxia genotype 3 (SCA3)

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. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - STRIMVELIS (CAP) - EMEA/H/C/003854/II/0040, Orphan

Applicant: Fondazione Telethon ETS, ATMP

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of an updated RMP version 7.0 in order to propose amendments to the STRIM-005 and STRIM-003 study protocols, as well as revised timelines for completion of both studies. In addition, the Annex II is updated accordingly

Action: For adoption of PRAC Assessment Report

5.2.2. Brexucabtagene autoleucel - TECARTUS (CAP) - EMEA/H/C/005102/WS2771/0054; Axicabtagene ciloleucel - YESCARTA (CAP) - EMEA/H/C/004480/WS2771/0084

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Submission of an updated RMP version 4.3 for Tecartus and version 11.1 for Yescarta following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040), and of a PASS protocol for a framework for the sampling and testing of secondary malignancies of T-cell origin

Action: For adoption of PRAC Assessment Report

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

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Gabriele Maurer

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

Action: For adoption of PRAC Assessment Report

5.2.4. Cetuximab - ERBITUX (CAP) - EMEA/H/C/000558/II/0103

Applicant: Merck Europe B.V.

PRAC Rapporteur: Mari Thorn

Scope: Submission of an updated RMP version 19.2 in order to re-classify important identified risks and important potential risks and to remove them from the summary of safety concerns, following the PRAC assessment for PSUSA/00000635/202309

Action: For adoption of PRAC Assessment Report

5.2.5. 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

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

Applicant: Pharming Group N.V

PRAC Rapporteur: Jan Neuhauser

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

Action: For adoption of PRAC Assessment Report

5.2.7. 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

5.2.8. Remdesivir - VEKLURY (CAP) - EMEA/H/C/005622/II/0062

Applicant: Gilead Sciences Ireland UC

PRAC Rapporteur: Eva Jirsová

Scope: Submission of the final report from study COVID-PR (CO-US-540-6127 listed as a category 3 study in the RMP. This is a non-interventional, patient-reporting, postmarketing cohort study designed to collect safety data from pregnant and recently pregnant women treated with monoclonal antibodies or antiviral drugs for mild, moderate, or severe COVID-

19 at any time from the first day of the last menstrual period to the end of pregnancy. The RMP version 8.2 is updated accordingly

Action: For adoption of PRAC Assessment Report

5.2.9. Zoledronic Acid – ZOLEDRONIC ACID ACCORD (CAP); NAP - EMA/VR/0000226953

Applicant(s): Accord Healthcare S.L.U., various

PRAC Rapporteur: Karin Erneholm

Scope: To align the RMP for Zoledronic Acid Accord with the RMP of the reference product. In addition for the nationally authorised products Zoledronic Acid Accord 4 mg/5 ml, 4 mg/100 ml concentrate for solution for infusion (product reference PT/H/0742/001/DC) the RMP is being merged with the RMP of the centrally authorised product

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

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Gabriele Maurer

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

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

5.3.3. Brexpiprazole - RXULTI (CAP) - EMEA/H/C/003841/II/0015

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Miroslava Gocova

Scope: Extension of indication to include treatment of schizophrenia in adolescent patients aged from 13 years to 17 years for RXULTI, based on results from the following clinical studies: one phase 1 dose-escalation trial (Trial 331-10-233) and two phase 3 clinical trials (Trial 331-10-234 and Trial 331-10-236). In addition, a paediatric extrapolation study was completed (Study 331-201-00185). These studies investigated the efficacy and safety of brexpiprazole in paediatric patients (13-17 years old) with schizophrenia. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, and to bring the PI in line with the latest QRD template version 10.4

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

5.3.4. Capivasertib - TRUQAP (CAP) - EMEA/H/C/006017/II/0001

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Hrabcik

Scope: Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update the posology recommendation and the warning regarding Diabetic Ketoacidosis (DKA) and add it to the list of adverse drug reactions (ADRs) with frequency uncommon based on a safety review. The Package Leaflet is updated accordingly. The RMP version 2 has also been submitted. In addition, the MAH took the opportunity to remove post authorisation measures which were added to Annex II in error, 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

5.3.5. COVID-19 mRNA vaccine - COMIRNATY (CAP) - EMA/VR/0000231586

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

C.I.11.b: Submission of an updated RMP version 13.1 in order to include Protocol amendment no. 5 where the study design and objectives were revised for an interventional study C4591048, a master phase 1/2/3 protocol to investigate the safety, tolerability, and immunogenicity of bivalent BNT162b2 RNA- based vaccine candidate(s) in healthy children, listed as a category 3 study in the RMP.

C.I.13: Submission of the final report from study C4591044 listed as a category 3 study in the RMP. This is an interventional randomized, active controlled, Phase 2/3 Study to Investigate the Safety, Tolerability, and Immunogenicity of Bivalent BNT162b RNA-Based Vaccine Candidates as A Booster Dose In COVID-19 Vaccine–Experienced Healthy Individuals. The RMP version 13.1 has also been submitted

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

5.3.6. 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

5.3.7. 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

5.3.8. 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.

B.III.2.b
B.II.b.2.a

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

5.3.9. Dapivirine - DAPIVIRINE VAGINAL RING 25 MG (Art 58[4]) - EMEA/H/W/002168/II/0027

Applicant: International Partnership for Microbicides Belgium AISBL

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include reducing the risk of HIV-1 infection via vaginal intercourse in HIV-uninfected women 16 years and older for Dapivirine Vaginal Ring 25 mg, based on final results from study MTN-034 (REACH) listed as a category 3 study in the RMP; this is a Phase 2a crossover trial evaluating the safety of and adherence to a vaginal matrix ring containing dapivirine and oral emtricitabine/tenofovir disoproxil fumarate in an adolescent and young adult female population. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 1.5 of the RMP has also been submitted

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

5.3.10. Daratumumab - DARZALEX (CAP) - EMEA/H/C/004077/II/0076, Orphan

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Carla Torre

Scope: Extension of indication for Darzalex in combination with bortezomib, lenalidomide and dexamethasone for the treatment of newly diagnosed multiple myeloma, to include also adult patients who are not eligible for stem cell transplant (SCT), based on the results of the final PFS analysis from Study CEPHEUS (54767414MMY3019), a randomised, open-label, active-controlled, multicenter phase 3 study in adult participants, comparing the clinical outcome of D-VRd with VRd in participants with untreated multiple myeloma for whom stem cell transplant is not planned as initial therapy, in terms of the primary endpoint of MRD negativity rate in participants with CR or better rate and major secondary endpoints of CR or better rate, PFS and sustained MRD negativity.
As a consequence, SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 are updated and the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the contact details of the local representatives in the Package Leaflet.
An updated RMP version 11.1 has also been submitted

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

5.3.11. Darolutamide - NUBEQA (CAP) - EMEA/H/C/004790/II/0024

Applicant: Bayer AG

PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include in combination with androgen deprivation therapy (ADT) the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) for NUBEQA, based on final results from study 21140 (ARANOTE); this is a randomized, double-blind, placebo-controlled Phase 3 study of darolutamide to demonstrate the superiority of darolutamide in addition to ADT over placebo plus ADT in patients with

[4] 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)

mHSPC. 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 5.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and update the Package Leaflet to more patient friendly wording based on patient council feedback

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

5.3.12. Durvalumab - IMFINZI (CAP) - EMEA/H/C/004771/II/0073

Applicant: AstraZeneca AB

PRAC Rapporteur: David Olsen

Scope: Extension of indication to include IMFINZI in combination with cisplatin-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, for the treatment of adults with muscle invasive bladder cancer (MIBC), based on an ongoing pivotal study D933RC00001 (NIAGARA); this is a phase 3, randomized, open-label, multi-center, global study to determine the efficacy and safety of durvalumab in combination with gemcitabine+cisplatin for neoadjuvant treatment followed by durvalumab alone for adjuvant treatment in patients with muscle-invasive bladder cancer. As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. The RMP version 13 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and update the PI according to the Excipients Guideline

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

5.3.13. 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

5.3.14. Faricimab - VABYSMO (CAP) - EMEA/H/C/005642/II/0016

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Update of section 5.1 of the SmPC to reflect the long-term safety profile of faricimab in patients with diabetic macular edema (DME) based on the final results from study GR41987 (Rhone-X) listed as a category 3 study of the RMP. Rhone-X was a phase III interventional, multicenter, open-label extension study to evaluate the long-term safety and tolerability of faricimab in patients with diabetic macular edema. The RMP version 7.0 has also been submitted

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

5.3.15. Formoterol, glycopyrronium bromide, budesonide - RILTRAVA AEROSPHERE (CAP) - EMEA/H/C/005311/WS2780/0017; Formoterol, glycopyrronium bromide, budesonide - TRIXEO AEROSPHERE (CAP) - EMEA/H/C/004983/WS2780/0024

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Type II var

- B.II.a.3.b.2 The change is reflected in the PI and it is supported by non clinical and clinical data. The RMP version 2 has also been submitted.

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

5.3.16. Glofitamab - COLUMVI (CAP) - EMEA/H/C/005751/II/0005, Orphan

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jana Lukacisinova

Scope: Extension of indication to include in combination with gemcitabine and oxaliplatin the treatment of adult patients with relapse or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are not candidates for autologous stem cell transplant (ASCT) for COLUMVI, based on results of primary and updated analyses from study GO41944 (STARGLO) listed as a Specific Obligation in the Annex II of the Product Information, as well supportive data from the Phase Ib study GO41943. Study GO41944 (STARGLO) is a Phase III, open-label, multicenter, randomized study of glofitamab in combination with GemOx (Glofit-GemOx) vs. rituximab in combination with GemOx (R-GemOx) in patients with R/R DLBCL. 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 Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet. As part of the application, the MAH is requesting a 1-year extension of the market protection

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

5.3.17. Herpes zoster vaccine (recombinant, adjuvanted) – SHINGRIX (CAP) - EMA/VR/0000235389

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Sonja Hrabcik

Scope: Update of sections 4.4 and 5.1 of the SmPC to include the final results of study ZOSTER-062, listed as a category 3 study in the RMP. This is a phase III, randomized, observer-blind, placebo controlled, multicenter clinical trial to assess Herpes Zoster recurrence and the reactogenicity, safety and immunogenicity of Shingrix when administered intramuscularly on a 0 and 2 month schedule to adults ⩾ 50 years of age with a prior episode of Herpes Zoster. The RMP version 9.0 has also been submitted. In addition, the MAH took the opportunity to implement a minor editorial change to Annex II of the PI

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

5.3.18. Herpes zoster vaccine (recombinant, adjuvanted) - SHINGRIX (CAP) - EMEA/H/C/004336/II/0076

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Sonja Hrabcik

Scope: Update of sections 4.8 and 5.1 of the SmPC to include the final results of study ZOSTER-049, listed as a category 3 study in the RMP. This is a Phase 3b, open label, multi-country, long-term follow-up study that assessed the prophylactic efficacy, safety, and immunogenicity persistence of Shingrix in adults ≥50 years of age at the time of primary vaccination in studies ZOSTER 006 and ZOSTER-022. The study also assessed 1 or 2 additional doses of Shingrix on a 0 or 0, 2-month schedule in two subgroups of older adults. The updated RMP version 8.0 is also included. In addition, the MAH took the opportunity to implement editorial changes to the SmPC, Labelling and 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

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

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Bianca Mulder

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

Extension of indication to include a new indication for OPDIVO in combination with ipilimumab as first line treatment of adult patients with unresectable or advanced hepatocellular carcinoma (HCC) based on study CA2099DW. This is a phase 3 randomised, multi-centre, open label study of Nivolumab in combination with Ipilimumab compared to Sorafenib or Lenvatinib as first-line treatment in participants with advanced HCC. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 41.0 of the RMP has also been submitted.

Extension of indication to include a new indication for YERVOY in combination with ipilimumab as first line treatment of adult patients with unresectable or advanced hepatocellular carcinoma (HCC) based on study CA2099DW. This is a phase 3 randomised, multi-centre, open label study of Nivolumab in combination with Ipilimumab compared to Sorafenib or Lenvatinib as first-line treatment in participants with advanced HCC. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 44.0 of the RMP has also been submitted

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

5.3.20. Iptacopan - FABHALTA (CAP) - EMEA/H/C/005764/II/0001, Orphan

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Lina Seibokiene

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

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

5.3.21. Lenacapavir - SUNLENCA (CAP) - EMEA/H/C/005638/II/0022/G

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Grouping of two type II variations:

- Update of section 5.1 of the SmPC to include efficacy and resistance data based on week 156 interim data from Study GS-US-200-4625; a phase 2/3 study to evaluate the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with an optimized background regimen in heavily treatment experienced people living with HIV-1 infection with multidrug resistance (category 3 study in the RMP). Additionally, upon request by the CHMP following the assessment of II/0013, the MAH proposes to update section 4.8 of the SmPC to include information related to injection site nodules and induration that were non-resolved at the end of follow-up.
- Provision of the final study report of Study GS-US-200-4334: a phase 2 randomized, open label, active controlled study evaluating the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with other antiretroviral agents in people living with HIV (category 3 study in the RMP).

An updated RMP version 2.1 was included as part of the application

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

5.3.22. Lisocabtagene maraleucel, lisocabtagene maraleucel - BREYANZI (CAP) - EMEA/H/C/004731/II/0043/G

Applicant: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: A grouped application consisting of:

C.I.6 (Type II): Extension of indication for Breyanzi to include treatment of adult patients with 3rd line + follicular lymphoma (FL) based on final results from the pivotal study JCAR017-FOL-001 (FOL-001, TRANSCEND-FL). This is a phase 2, open-label, single-arm, multicohort, multicenter study to evaluate efficacy and safety of JCAR017 in adult subjects with relapsed or refractory (r/r) follicular Lymphoma (FL) or marginal zone lymphoma (MZL). As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP is being submitted. Furthermore, as part of the application the MAH is requesting a 1-year extension of the market protection.

B.II.d.1.e (Type II)
B.II.d.1.a (Type IB)
B.II.d.1.a (Type IB)

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

5.3.23. Lutetium (^{177}Lu) vipivotide tetraxetan - PLUVICTO (CAP) - EMEA/H/C/005483/II/0022

Applicant: Novartis Europharm Limited

PRAC Rapporteur: John Joseph Borg

Scope: Update of section 4.8 of the SmPC in order to update safety information based on final results from study PSMA-617-01 (CAAA617A12301 – VISION) listed as a category 3 study in the RMP; this is an international, prospective, open-label, multicenter, randomized Phase 3 study of 177Lu-PSMA-617 in the treatment of patients with progressive PSMA-positive metastatic castration-resistant prostate cancer. The Package Leaflet is updated accordingly. The RMP version 2.0 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

5.3.24. Melatonin - SLENYTO (CAP) - EMEA/H/C/004425/II/0028

Applicant: RAD Neurim Pharmaceuticals EEC SARL

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension of indication to include treatment of insomnia in children and adolescents aged 2-18 with Attention-Deficit Hyperactivity Disorder (ADHD), where sleep hygiene measures have been insufficient, based on results from phase III study NEU_CH_7911 and literature. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted

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

5.3.25. 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

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

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Gabriele Maurer

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

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

5.3.27. Nusinersen - SPINRAZA (CAP) - EMEA/H/C/004312/II/0034/G, Orphan

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Karin Bolin

Scope: A grouped application consisting of:
C.I.4: Update of sections 5.1 and 5.2 of the SmPC based on final results from study CS11 (SHINE) listed as a PAES in the Annex II. The Annex II and the RMP v12.1 are updated accordingly. SHINE is a phase III, open-label extension study for patients with Spinal Muscular Atrophy (SMA) who previously participated in investigational studies of ISIS 396443.
C.I.4: Update of section 5.1 of the SmPC based on interim results from study CS5 (NURTURE, 232SM201). NURTURE is a Phase II, open-label study to assess the efficacy, safety, tolerability, and pharmacokinetics of multiple doses of nusinersen delivered intrathecally to patients with genetically diagnosed and presymptomatic SMA.
C.I.4: Update of section 5.1 of the SmPC in order to relocate the updated information regarding immunogenicity from SmPC section 4.8 to section 5.1 as per applicable CHMP guidance. The data has been revised based on an updated integrated analysis across several studies.
C.I.4: Update of section 5.1 of the SmPC based on the outcome of a systematic literature review (SLR) and Natural History data from an International SMA registry (ISMAR)

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

5.3.28. Odevixibat - BYLVAY (CAP) - EMEA/H/C/004691/II/0022/G, Orphan

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application including two type II variations:
- Update of sections 4.2, 4.4, 4.8, and 5.1 of the SmPC based on the clinical study report for the completed 72 weeks of Study A4250-008; an open-label, phase III study to evaluate the long-term efficacy and safety of odevixibat in children with PFIC (category 3 study in the RMP; MEA 002).
The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and the Package Leaflet. An updated RMP version 6.1 is included in this submission.
- Submission of the clinical study report for Study A4250-J001; a Phase I PK study in healthy Japanese adult male patients

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

5.3.29. 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

5.3.30. Omalizumab - OMLYCLO (CAP) - EMEA/H/C/005958/II/0004/G

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Mari Thorn

Scope: - to introduce a new alternative delivery device in addition to the already authorised pre-filled syringe (PFS), (Type II - B.II.e.1.b.2);
(Type IAIN - B.II.e.5.a.1);
(Type IAIN - B.II.e.5.a.1)

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

5.3.31. Pegcetacoplan - ASPAVELI (CAP) - EMEA/H/C/005553/II/0028, Orphan

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: Update of section 4.8 of the SmPC in order to add urticaria/hives to the list of adverse drug reactions (ADRs) with frequency "common" and to add anaphylactic reaction and anaphylactic shock to the list of ADRs with frequency "uncommon", based on post-marketing data and literature; the Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted

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

5.3.32. Pegunigalsidase alfa - ELFABRIO (CAP) - EMEA/H/C/005618/II/0007

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC in order to introduce an alternative posology regimen based on results from study PB-102-F50 (BRIGHT) and interim results from its extension study CLI-06657AA1-03 (formerly presented as PB-102-F51), as well as results of the observational patient reporting outcome study CLI-06657AA1-05. CLI-06657AA1-03 is an Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Pegunigalsidase Alfa (PRX-102) 2 mg/kg Administered by Intravenous Infusion Every 4 Weeks in Patients with Fabry Disease. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4

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

5.3.33. Pirtobrutinib - JAYPIRCA (CAP) - EMEA/H/C/005863/II/0002

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of adult patients with chronic lymphocytic leukemia (CLL) who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor for JAYPIRCA, based on interim results from study LOXO-BTK-20020 (BRUIN CLL-321); this is a phase 3 open-label, randomized study of LOXO-305 versus investigator's choice of idelalisib plus rituximab or bendamustine plus rituximab in BTK inhibitor pretreated CLL/SLL.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection

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

5.3.34. Pyronaridine, artesunate - PYRAMAX (Art 58[5]) - EMEA/H/W/002319/II/0036

Applicant: Shin Poong Pharmaceutical Co., Ltd.

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

PRAC Rapporteur: Tiphaine Vaillant

Scope: Update of sections 4.4 and 4.6 of the SmPC with revised recommendations for treatment during pregnancy. The Package Leaflet has been updated accordingly. An updated RMP version 18 was provided as part of the application

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

5.3.35. Ranibizumab - RANIBIZUMAB MIDAS (CAP) - EMEA/H/C/006528/II/0002/G

Applicant: MIDAS Pharma GmbH

PRAC Rapporteur: Karin Bolin

Scope: Type II - B.II.e.1.b.2
2x Type II (B.II.b.1.c)
Type II (B.II.b.3.c)
Type IB - B.II.b.1.z
4x Type IB (B.II.b.2.a)
Type IB (B.II.d.2.a)
6x Type IA (B.II.d.1.c)
Type IAIN (B.II.e.6.a)
Type IAIN (B.II.f.1.a.1)

The product information and the RMP (version 2.0) is updated consequentially

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

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

Applicant: Midas Pharma GmbH

PRAC Rapporteur: Karin Bolin

Scope: Type II - B.II.e.1.b.2

2x Type II (B.II.b.1.c)
Type II (B.II.b.3.c)
Type IB - B.II.b.1.z .
4x Type IB (B.II.b.2.a)
Type IB (B.II.d.2.a)
6x Type IA (B.II.d.1.c)
Type IAIN (B.II.e.6.a)
Type IAIN (B.II.f.1.a.1)
The product information and the RMP (version 2.0) is updated consequentially

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

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

Applicant: Vifor France

PRAC Rapporteur: Martin Huber

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

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

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

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include treatment of paediatric patients aged from birth to less than 12 years for SIVEXTRO, based on final results from studies MK-1986-013, MK-1986-014 and MK-1986-018. MK-1986-013 is a single-dose trial to evaluate pharmacokinetics (PK) and safety of oral and intravenous (IV) administration of tedizolid phosphate in patients from 2 years to <12 years of age; MK-1986-014 is an open-label, multicentre, 2-part, single and multiple dose study to assess the PK of tedizolid phosphate and its active metabolite, tedizolid, and the safety of tedizolid phosphate following single and multiple dose IV and single oral dose. MK-1986-018 is a randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in patients from birth to less than 12 years of age; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement minor editorial corrections

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

5.3.40. Tisagenlecleucel - KYMRIAH (CAP) - EMEA/H/C/004090/II/0092, Orphan,

Applicant: Novartis Europharm Limited, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Update of section 4.2 of the SmPC in order to update the 'monitoring after infusion' recommendations, based on existing clinical trial data as well as literature references reporting real word experience. The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to introduce a minor change to the HCP educational programme in the Annex II in order to enhance readability

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

5.3.41. Tislelizumab - TEVIMBRA (CAP) - EMEA/H/C/005919/II/0016

Applicant: Beigene Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include first-line treatment of adult patients with extensive-stage Small Cell Lung Cancer (SCLC) for Tevimbra in combination with etoposide and platinum chemotherapy based on final results from study BGB-A317-312; a phase 3, randomized, double-blind, placebo-controlled study of platinum plus etoposide with or without tislelizumab in patients with untreated extensive-stage small cell lung cancer. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The MAH also took the opportunity to make editorial changes to the SmPC, Annex II and Package Leaflet.
The supportive studies BGB-A317-309 and BGB-A317-315 are provided for the purpose of updating the safety data package as well as updated data (latest CSR versions with new data cut-off) from the monotherapy pool (tislelizumab used at 200mg Q3W) consisting of the studies 001, 102, 203, 204, 208, 209, 301, 302, and 303 and from the combination with chemotherapy pool consisting of the studies 205, 206, 304, 305, 306, 307 and 312.
Version 2.4 of the RMP has also been submitted

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

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

Applicant: Fresenius Kabi Deutschland GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Type II - B.II.e.1.b.2
Type II - B.II.b.3.c
Type IB - B.II.d.1.z
Type IAIN - B.II.b.1.a

The product information and the RMP (v 1.0) is updated consequentially

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

5.3.43. Ustekinumab - PYZCHIVA (CAP) - EMEA/H/C/006183/II/0005/G

Applicant: Samsung Bioepis NL B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Type II B.IV.1.c

Type IB C.I.2.a To update section 4.6 Fertility, Pregnancy and lactation of the SmPC to update information on pregnancy following assessment of the same change for the reference product Stelara (EMEA/H/C/000958).

An updated RMP (version 4.0) is provided

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

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

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy or have medical contraindications to such therapies for STELARA, based on final results from study CNTO1275CRD3004. This is a Phase 3 Study of the Efficacy, Safety, and Pharmacokinetics of Ustekinumab as Open label Intravenous Induction Treatment Followed by Randomized Double blind Subcutaneous Ustekinumab Maintenance in Pediatric Participants with Moderately to Severely Active Crohn’s Disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 29.1 of the RMP has also been submitted

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

5.3.45. Ustekinumab - WEZENLA (CAP) - EMEA/H/C/006132/II/0003/G

Applicant: Amgen Technology (Ireland) Unlimited Company

PRAC Rapporteur: Rhea Fitzgerald

Scope: B.IV.1.c (Type II)
B.IV.1.c (Type II)

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

5.3.46. 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. As part of the application the MAH applied for +1 year of additional market protection

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. Abiraterone - ABIRATERONE MYLAN (CAP); ZYTIGA (CAP) - PSUSA/00000015/202404

Applicant: Mylan Pharmaceuticals Limited (Abiraterone Mylan), Janssen-Cilag International N.V. (Zytiga)

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.2. Adagrasib - KRAZATI (CAP) - PSUSA/00000214/202406

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.3. Alpelisib - PIQRAY (CAP) - PSUSA/00010871/202405

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.4. Amivantamab - RYBREVANT (CAP) - PSUSA/00010977/202405

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.5. Apixaban - ELIQUIS (CAP) - PSUSA/00000226/202405

Applicant: Bristol-Myers Squibb / Pfizer EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.6. Arpraziquantel - ARPRAZIQUANTEL (Art 58[6]) - EMEA/H/W/004252/PSUV/0001

Applicant: Merck Europe B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUR procedure

Action: For adoption of recommendation to CHMP

6.1.7. Atezolizumab - TECENTRIQ (CAP) - PSUSA/00010644/202405

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.8. Avatrombopag - DOPTELET (CAP) - PSUSA/00010779/202405

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.9. Azacitidine - VIDAZA (CAP) - PSUSA/00000274/202405

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

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

6.1.10. Azacitidine[7] - ONUREG (CAP) - PSUSA/00010935/202405

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.11. Basiliximab - SIMULECT (CAP) - PSUSA/00000301/202404

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.12. Binimetinib - MEKTOVI (CAP) - PSUSA/00010717/202406

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.13. Budesonide[8] - KINPEYGO (CAP) - PSUSA/00011007/202406

Applicant: STADA Arzneimittel AG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.14. Cannabidiol[9] - EPIDYOLEX (CAP) - PSUSA/00010798/202406

Applicant: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.15. Cefepime, enmetazobactam - EXBLIFEP (CAP) - PSUSA/00000305/202406

Applicant: Advanz Pharma Limited

[7] Oral formulations only
[8] For centrally authorised products indicated for primary immunoglobulin A nephropathy only
[9] For centrally authorised products only

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.16. Cholera vaccine, oral, live - VAXCHORA (CAP) - PSUSA/00010862/202406

Applicant: Bavarian Nordic A/S

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.17. Dabrafenib - FINLEE (CAP); TAFINLAR (CAP) - PSUSA/00010084/202405

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.18. Delafloxacin - QUOFENIX (CAP) - PSUSA/00010822/202406

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

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.19. Efgartigimod alfa - VYVGART (CAP) - PSUSA/00011014/202406

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.20. Efmoroctocog alfa - ELOCTA (CAP) - PSUSA/00010451/202406

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.21. Elacestrant - ORSERDU (CAP) - PSUSA/00000120/202406

Applicant: Stemline Therapeutics B.V.

PRAC Rapporteur: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.22. Eladocagene exuparvovec - UPSTAZA (CAP) - PSUSA/00011004/202406

Applicant: PTC Therapeutics International Limited, ATMP

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.23. Encorafenib - BRAFTOVI (CAP) - PSUSA/00010719/202406

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.24. Entrectinib - ROZLYTREK (CAP) - PSUSA/00010874/202406

Applicant: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.25. Etranacogene dezaparvovec - HEMGENIX (CAP) - PSUSA/00011037/202405

Applicant: CSL Behring GmbH, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.26. Fenfluramine - FINTEPLA (CAP) - PSUSA/00010907/202406

Applicant: UCB Pharma SA

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.27. Fexinidazole - FEXINIDAZOLE WINTHROP (Art 58[10]) - EMEA/H/W/002320/PSUV/0020

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUR procedure

Action: For adoption of recommendation to CHMP

6.1.28. Fluticasone furoate, vilanterol - RELVAR ELLIPTA (CAP); REVINTY ELLIPTA (CAP) - PSUSA/00010099/202405

Applicant: GlaxoSmithKline (Ireland) Limited

PRAC Rapporteur: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.29. Formoterol fumarate dihydrate, glycopyrronium bromide, budesonide - RILTRAVA AEROSPHERE (CAP); TRIXEO AEROSPHERE (CAP) - PSUSA/00010908/202406

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.30. Galsulfase - NAGLAZYME (CAP) - PSUSA/00001515/202405

Applicant: BioMarin International Limited

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.31. Givosiran - GIVLAARI (CAP) - PSUSA/00010839/202405

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

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

6.1.32. Hydroxycarbamide[11] - SIKLOS (CAP); XROMI (CAP) - PSUSA/00001692/202406

Applicant: Theravia (Siklos), Nova Laboratories Ireland Limited (Xromi)

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.33. Imatinib - GLIVEC (CAP) - PSUSA/00001725/202405

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.34. Indacaterol, glycopyrronium, mometasone - ENERZAIR BREEZHALER (CAP); ZIMBUS BREEZHALER (CAP) - PSUSA/00010861/202407

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.35. Indacaterol, mometasone furoate - ATECTURA BREEZHALER (CAP); BEMRIST BREEZHALER (CAP) - PSUSA/00010850/202405

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.36. Inebilizumab - UPLIZNA (CAP) - PSUSA/00010996/202406

Applicant: Horizon Therapeutics Ireland DAC

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.37. Insulin lispro - HUMALOG (CAP); INSULIN LISPRO SANOFI (CAP); LIPROLOG (CAP); LYUMJEV (CAP) - PSUSA/00001755/202404

Applicant: Eli Lilly Nederland B.V. (Humalog, Liprolog, Lyumjev), Sanofi Winthrop Industrie

[11] For centrally authorised product only

(Insulin lispro Sanofi)

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.38. Interferon beta-1a[12] - AVONEX (CAP) - PSUSA/00010725/202405

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.39. Iptacopan - FABHALTA (CAP) - PSUSA/00011054/202406

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.40. Laronidase - ALDURAZYME (CAP) - PSUSA/00001830/202404

Applicant: Sanofi B.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.41. Larotrectinib - VITRAKVI (CAP) - PSUSA/00010799/202405

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.42. Latanoprost, netarsudil - ROCLANDA (CAP) - PSUSA/00010905/202406

Applicant: Santen Oy

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

[12] Intramuscular use

Action: For adoption of recommendation to CHMP

6.1.43. Lonafarnib - ZOKINVY (CAP) - PSUSA/00011005/202405

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.44. Lumacaftor, ivacaftor - ORKAMBI (CAP) - PSUSA/00010455/202405

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.45. Luspatercept - REBLOZYL (CAP) - PSUSA/00010860/202406

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.46. Maribavir - LIVTENCITY (CAP) - PSUSA/00011024/202405

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.47. Migalastat - GALAFOLD (CAP) - PSUSA/00010507/202405

Applicant: Amicus Therapeutics Europe Limited

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.48. Mosunetuzumab - LUNSUMIO (CAP) - PSUSA/00010999/202406

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.49. Nusinersen - SPINRAZA (CAP) - PSUSA/00010595/202405

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.50. Obeticholic acid - OCALIVA (CAP) - PSUSA/00010555/202405

Applicant: Advanz Pharma Limited

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.51. Octreotide[13] - MYCAPSSA (CAP) - PSUSA/00011036/202406

Applicant: Amryt Pharmaceuticals DAC

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.52. Onasemnogene abeparvovec - ZOLGENSMA (CAP) - PSUSA/00010848/202405

Applicant: Novartis Europharm Limited, ATMP

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.53. Ozanimod - ZEPOSIA (CAP) - PSUSA/00010852/202405

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[13] For centrally authorised products only

6.1.54. Pandemic influenza vaccine (H5N1) (live attenuated, nasal) - PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) - PSUSA/00010501/202405

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.55. Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) - ADJUPANRIX (CAP) - PSUSA/00002281/202405

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.56. Pegzilarginase - LOARGYS (CAP) - PSUSA/00000222/202406

Applicant: Immedica Pharma AB

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.57. Pentosan polysulfate sodium[14] - ELMIRON (CAP) - PSUSA/00010614/202406

Applicant: bene-Arzneimittel GmbH

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.58. Pertuzumab - PERJETA (CAP) - PSUSA/00010125/202406

Applicant: Roche Registration GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.59. Pertuzumab, trastuzumab - PHESGO (CAP) - PSUSA/00010906/202406

Applicant: Roche Registration GmbH

[14] For centrally authorised product

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.60. Piflufolastat (^{18}F) - PYLCLARI (CAP) - PSUSA/00000097/202405

Applicant: Curium Pet France

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.61. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - PREVENAR 20 (CAP) - PSUSA/00010981/202406

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.62. Polatuzumab vedotin - POLIVY (CAP) - PSUSA/00010817/202406

Applicant: Roche Registration GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.63. Quizartinib - VANFLYTA (CAP) - PSUSA/00000176/202406

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: John Joseph Borg

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.64. Radium-223 dichloride - XOFIGO (CAP) - PSUSA/00010132/202405

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.65. Relugolix, estradiol, norethisterone acetate - RYEQO (CAP) - PSUSA/00010942/202405

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.66. Respiratory syncytial virus vaccine (bivalent, recombinant) - ABRYSVO (CAP) - PSUSA/00000102/202405

Applicant: Pfizer Europe Ma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.67. Rilpivirine[15] - EDURANT (CAP) - PSUSA/00009282/202405

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.68. Ritlecitinib - LITFULO (CAP) - PSUSA/00000133/202406

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.69. Roxadustat - EVRENZO (CAP) - PSUSA/00010955/202406

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Anna Mareková

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.70. Rozanolixizumab - RYSTIGGO (CAP) - PSUSA/00000216/202406

Applicant: UCB Pharma

[15] For oral use only

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.71. Coronavirus (COVID-19) vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - PSUSA/00010972/202406

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.72. Satralizumab[16] - ENSPRYNG (CAP) - PSUSA/00010944/202405

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.73. Semaglutide - OZEMPIC (CAP); RYBELSUS (CAP); WEGOVY (CAP) - PSUSA/00010671/202405

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.74. Setmelanotide - IMCIVREE (CAP) - PSUSA/00010941/202405

Applicant: Rhythm Pharmaceuticals Netherlands B.V.,

PRAC Rapporteur: Anna Mareková

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.75. Sildenafil[17] - REVATIO (CAP) - PSUSA/00002700/202405

Applicant: Upjohn EESV

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

[16] For centrally authorised products only
[17] Indicated for the treatment of pulmonary hypertension

Action: For adoption of recommendation to CHMP

6.1.76. Sonidegib - ODOMZO (CAP) - PSUSA/00010408/202406

Applicant: Sun Pharmaceutical Industries Europe B.V.

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.77. Sotorasib - LUMYKRAS (CAP) - PSUSA/00010970/202405

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.78. Tabelecleucel - EBVALLO (CAP) - PSUSA/00011028/202406

Applicant: Pierre Fabre Medicament, ATMP

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CAT and CHMP

6.1.79. Tasimelteon - HETLIOZ (CAP) - PSUSA/00010394/202407

Applicant: Vanda Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.80. Tezepelumab - TEZSPIRE (CAP) - PSUSA/00011015/202406

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.81. Tislelizumab - TEVIMBRA (CAP) - PSUSA/00000136/202406

Applicant: Beigene Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.82. Tolvaptan[18] - JINARC (CAP) - PSUSA/00010395/202405

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.83. Tolvaptan[19] - SAMSCA (CAP) - PSUSA/00002994/202405

Applicant: Otsuka Pharmaceutical Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.84. Tralokinumab - ADTRALZA (CAP) - PSUSA/00010937/202406

Applicant: LEO Pharma A/S

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.85. Trametinib - MEKINIST (CAP); SPEXOTRAS (CAP) - PSUSA/00010262/202405

Applicant: Novartis Europharm Limited

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.86. Trastuzumab deruxtecan - ENHERTU (CAP) - PSUSA/00010894/202406

Applicant: Daiichi Sankyo Europe GmbH

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

[18] Indicated for adults with autosomal dominant polycystic kidney disease (ADPKD)
[19] Indicated for adults with hyponatraemia secondary to syndrome of inappropriate antidiuretic hormone secretion (SIADH)

6.1.87. Turoctocog alfa pegol - ESPEROCT (CAP) - PSUSA/00010782/202406

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.88. Ublituximab - BRIUMVI (CAP) - PSUSA/00000045/202406

Applicant: Neuraxpharm Pharmaceuticals S.L.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.89. Vadadustat - VAFSEO (CAP) - PSUSA/00011050/202406

Applicant: Medice Arzneimittel Pütter GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.90. Vedolizumab - ENTYVIO (CAP) - PSUSA/00010186/202405

Applicant: Takeda Pharma A/S

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.1.91. Vutrisiran - AMVUTTRA (CAP) - PSUSA/00011021/202406

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Liana Martirosyan

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. 5-aminolevulinic acid[20] - AMELUZ (CAP); NAP - PSUSA/00010006/202406

Applicant(s): Biofrontera Bioscience GmbH (Ameluz), various

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.2. Brinzolamide, timolol - AZARGA (CAP); NAP - PSUSA/00000433/202404

Applicant(s): Novartis Europharm Limited (Azarga), various

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.3. Capecitabine - CAPECITABINE ACCORD (CAP); CAPECITABINE MEDAC (CAP); ECANSYA (CAP); XELODA (CAP); NAP - PSUSA/00000531/202404

Applicant(s): Accord Healthcare S.L.U. (Capecitabine Accord), medac Gesellschaft fur klinische Spezialpraparate mbH (Capecitabine medac), KRKA, d.d., Novo mesto (Ecansya), CHEPLAPHARM Arzneimittel GmbH (Xeloda), various

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.4. Linagliptin, metformin hydrochloride - JENTADUETO (CAP); linagliptin - TRAJENTA (CAP); NAP - PSUSA/00010427/202405

Applicant(s): Boehringer Ingelheim International GmbH (Jentadueto, Trajenta), various

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.5. Measles, mumps, rubella vaccines (live, attenuated) - M-M-RVAXPRO (CAP); NAP - PSUSA/00001937/202405

Applicant(s): Merck Sharp & Dohme B.V. (M-M-RvaxPro), various

PRAC Rapporteur: Gabriele Maurer

[20] For treatment of keratosis only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.6. Naloxone[21] - NYXOID (CAP); NAP - PSUSA/00010657/202405

Applicant(s): Mundipharma Corporation (Ireland) Limited (Nyxoid), various

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.7. Olopatadine - OPATANOL (CAP); NAP - PSUSA/00002211/202404

Applicant: Novartis Europharm Limited, various

PRAC Rapporteur: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.8. Treprostinil - TREPULMIX (CAP); NAP - PSUSA/00003013/202405

Applicant: SciPharm Sarl, various

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CHMP

6.2.9. Ulipristal[22] - ELLAONE (CAP); NAP - PSUSA/00003074/202405

Applicant(s): Laboratoire HRA Pharma (ellaOne), various

PRAC Rapporteur: Bianca Mulder

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. Acemetacin (NAP) - PSUSA/00000026/202405

Applicant(s): various

PRAC Lead: Melinda Palfi

[21] For use in non-medical settings
[22] For female emergency contraception only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.2. Aciclovir (NAP) - PSUSA/00000048/202406

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.3. Alginic acid, aluminium oxide hydrated, sodium hydrogen carbonate (NAP); alginic acid, aluminium hydroxide, calcium carbonate, sodium carbonate (NAP) - PSUSA/00000123/202406

Applicant(s): various

PRAC Lead: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.4. Biclotymol (NAP) - PSUSA/00000408/202405

Applicant(s): various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.5. Bismuth subcitrate potassium, metronidazole, tetracycline (NAP) - PSUSA/00010199/202405

Applicant(s): various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.6. Buspirone (NAP) - PSUSA/00000463/202404

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.7. Cefuroxime sodium[23] (NAP) - PSUSA/00010206/202405

Applicant(s): various

PRAC Lead: Maia Uusküla

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.8. Cidofovir (NAP) - PSUSA/00010558/202406

Applicant(s): various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.9. Daunorubicin (NAP) - PSUSA/00000936/202406

Applicant(s): various

PRAC Lead: Sonja Hrabcik

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.10. Deoxycholic acid (NAP) - PSUSA/00010525/202404

Applicant(s): various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.11. Dienogest, estradiol[24] (NAP) - PSUSA/00010443/202406

Applicant(s): various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.12. Enalapril maleate, lercanidipine (NAP) - PSUSA/00001215/202406

Applicant(s): various

PRAC Lead: Carla Torre

[23] For intracameral use only
[24] Hormone replacement therapy (HRT) indication(s) only

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.13. Ferucarbotran (NAP) - PSUSA/00001382/202406

Applicant(s): various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.14. Flunarizine (NAP) - PSUSA/00001416/202405

Applicant(s): various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.15. Human hemin (NAP) - PSUSA/00001629/202405

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.16. Hydrochlorothiazide, zofenopril (NAP) - PSUSA/00003148/202405

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.17. Indocyanine green (NAP) - PSUSA/00001737/202405

Applicant(s): various

PRAC Lead: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.18. Iobitridol (NAP) - PSUSA/00001761/202404

Applicant(s): various

PRAC Lead: Eamon O'Murchu

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.19. Iodine (^{131}i) iobenguane (NAP) - PSUSA/00001764/202405

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.20. Isoniazid, rifampicin (NAP) - PSUSA/00001792/202405

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.21. Loperamide (NAP); loperamide, simeticone (NAP) - PSUSA/00010665/202405

Applicant(s): various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.22. Loteprednol (NAP) - PSUSA/00001913/202405

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.23. Metyrapone (NAP) - PSUSA/00002046/202406

Applicant(s): various

PRAC Lead: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.24. Olodaterol, tiotropium (NAP) - PSUSA/00010489/202405

Applicant(s): various

PRAC Lead: Bianca Mulder

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.25. Oxycodone hydrochloride, paracetamol (NAP) - PSUSA/00002256/202407

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.26. Phenylpropanolamine (NAP) - PSUSA/00010483/202406

Applicant(s): various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.27. Praziquantel (NAP) - PSUSA/00002503/202404

Applicant(s): various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.28. Ranitidine (NAP) - PSUSA/00002610/202405

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.29. Tafluprost (NAP) - PSUSA/00002843/202404

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.30. Terlipressin (NAP) - PSUSA/00002905/202404

Applicant(s): various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.31. Tolperisone (NAP) - PSUSA/00002991/202406

Applicant(s): various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure

Action: For adoption of recommendation to CMDh

6.3.32. Yohimbine (NAP) - PSUSA/00003136/202405

Applicant(s): various

PRAC Lead: Jan Neuhauser

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. Ivacaftor, tezacaftor, elexacaftor - KAFTRIO (CAP) - EMEA/H/C/005269/II/0052/G, Orphan

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Martin Huber

Scope: Grouped application comprising two type II variations as follows:
Type II (C.I.3.b) – Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on rash and to add hypersensitivity to the list of adverse drug reactions (ADRs) with frequency "not known" following the outcome of procedure PSUSA/00010868/202310. The Package Leaflet is updated accordingly.
Type II (C.I.z) – Submission of post-marketing breast-feeding case reports

Action: For adoption of PRAC Assessment Report

6.5.2. Ivacaftor, tezacaftor, elexacaftor - KAFTRIO (CAP) - EMEA/H/C/005269/II/0055, Orphan

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Martin Huber

Scope: Update of section 4.6 of the SmPC in order to amend the existing wording on exposure during pregnancy following PSUR procedure (EMEA/H/C/PSUSA/00010868/202310)

Action: For adoption of PRAC Assessment Report

6.5.3. 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

6.6. Expedited summary safety reviews[25]

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[26]

7.1.1. Axicabtagene ciloleucel – YESCARTA (CAP) - EMEA/H/C/PSA/S/0118

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Substantial amendment to a protocol for a long-term, non-interventional study of recipients of Yescarta for treatment of relapsed or refractory Diffuse Large B-cell Lymphoma and Primary Mediastinal B-cell Lymphoma

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

7.1.2. Ciltacabtagene autoleucel – CARVYKTI (CAP) - EMEA/H/C/PSA/S/0116

Applicant: Janssen-Cilag International NV, ATMP

[25] 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

[26] In accordance with Article 107n of Directive 2001/83/EC

PRAC Rapporteur: Jo Robays

Scope: Substantial amendment to a PASS Study 68284528MMY4004 Protocol submission: An Observational Post-authorization Safety Study to Evaluate the Safety of Multiple Myeloma Patients Treated with Ciltacabtagene Autoleucel

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

7.1.3. Dinutuximab beta – QARZIBA (CAP) - EMEA/H/C/PSA/S/0117

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Substantial amendment to a patient registry of patients with high-risk neuroblastoma being treated with the monoclonal antibody dinutuximab beta to assess:

• Pain severity and use of analgesics during treatment

• Incidence of neurotoxicity, visual impairment, capillary leak syndrome, cardiovascular events and hypersensitivity reactions.

• Long term safety

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

7.1.4. Pegzilarginase – LOARGYS (CAP) - EMEA/H/C/PSP/S/0105.2

Applicant: Immedica Pharma AB

PRAC Rapporteur: Martin Huber

Scope: MAH's response to PSP/0105.1 [A European, non-interventional, multicentre, registry-based post-authorisation safety study to evaluate the long-term safety of Loargys treatment in arginase 1 deficiency patients in standard clinical care] as per the request for supplementary information (RSI) adopted in September 2024

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

7.1.5. Tofersen – QALSODY (CAP) - EMEA/H/C/PSP/S/0109

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: An observational registry-based study utilising data from two disease registry networks pecision ALS and ALS/MND NHC to evaluate the long-term safety of tofersen in people with SOD1-ALS

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

7.1.6. Topiramate (NAP) - EMEA/H/N/PSP/J/0106.1

Applicant: Janssen (on behalf of a consortium)

PRAC Rapporteur: Karin Bolin

Scope: MAH's response to PSP/0106 [DUS to evaluate the effectiveness of the implemented risk minimisation measures, particularly focusing on preventing pregnancies and further characterising the prescribing patterns for topiramate in the target populations for pregnancy prevention] as per the request for supplementary information (RSI) adopted in July 2024

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

7.1.7. Topiramate (NAP) - EMEA/H/N/PSP/J/0107.1

Applicant: Janssen (on behalf of a consortium)

PRAC Rapporteur: Karin Bolin

Scope: MAH's response to PSP/0107 [PASS survey among healthcare professionals and patients to assess their knowledge and behaviour regarding the risks of topiramate use during pregnancy, the measures implemented to prevent pregnancy, and the receipt/use of educational materials as part of the pregnancy prevention program] as per the request for supplementary information (RSI) adopted in July 2024

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

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

7.2.1. Anifrolumab - SAPHNELO (CAP) - EMEA/H/C/004975/MEA 001.4

Applicant: AstraZeneca AB

PRAC Rapporteur: Liana Martirosyan

Scope: From Initial MAA:
Revised Protocol for PASS No. D3461R00028 (non-imposed)
Title: A multiple database study of the use (and safety) of anifrolumab in women with SLE during pregnancy

Action: For adoption of advice to CHMP

7.2.2. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/MEA 002.5

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: ***Revised Protocol / PS0038***- Version 3.0, amendment #3
Bimekizumab real-world outcomes study:
The goal of this study is to evaluate any potential increase in the risk of safety outcomes of interest in bimekizumab exposed PSO patients compared to PSO patients exposed to other biologics (eg, anti TNF, anti-IL-23, but not anti IL 17).
The PAM is not fulfilled. The MAH is requested to submit a revised protocol by 05 Nov 2024

[27] 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

taking into account the comments raised in section 5 of the report

Action: For adoption of advice to CHMP

7.2.3. Capivasertib - TRUQAP (CAP) - EMEA/H/C/006017/MEA 001.1

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Hrabcik

Scope: From initial MAA
Protocol / Study D3612R00020 (CAPIseid)
A database study of the safety and effectiveness of TRUQAP (capivasertib) + fulvestrant in patients with advanced breast cancer and type 1 or type 2 diabetes. (NINI; RMP)

Action: For adoption of advice to CHMP

7.2.4. Ciltacabtagene autoleucel - CARVYKTI (CAP) - EMEA/H/C/005095/MEA 007.3

Applicant: Janssen-Cilag International NV

PRAC Rapporteur: Jo Robays

Scope: ***Protocol amendment / PASS study PCSONCA0014***(v. 1)
Post-authorization Safety Study Survey to Evaluate the Effectiveness of the Ciltacabtagene Autoleucel HCP Educational Program and the Product Handling Training

Action: For adoption of advice to CHMP

7.2.5. Deucravacitinib - SOTYKTU (CAP) - EMEA/H/C/005755/MEA 001.3

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: MAH Response to MEA 001.2 [Revised Protocol No. IM011194] as adopted in September 2024:
Long-term, observational cohort study of adults with plaque psoriasis, who are new users of deucravacitinib, non-TNFi (tumor necrosis factor inhibitor) biologics, TNFi biologics, or non-biologic systemic therapy in the real-world clinical setting (IM011194). To evaluate the long-term safety of deucravacitinib in patients with psoriasis in the real-world setting

Action: For adoption of advice to CHMP

7.2.6. Dulaglutide - TRULICITY (CAP) - EMEA/H/C/002825/MEA 006.7

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: MAH's response to MEA 006.6 [***REVISED PROTOCOL / H9X-MC-B013***] RSI as adopted in September 2024.

Action: For adoption of advice to CHMP

7.2.7. Enfortumab vedotin - PADCEV (CAP) - EMEA/H/C/005392/MEA 003.2

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: ***Updated Study Protocol / Study no.: 7465-PV-0002*** version 3.0
To evaluate patients understanding and awareness of the content of the patient card related to risks of skin reactions and patients behaviours to minimise the risks

Action: For adoption of advice to CHMP

7.2.8. Hydroxycarbamide - XROMI (CAP) - EMEA/H/C/004837/MEA 006.1

Applicant: Nova Laboratories Ireland Limited

PRAC Rapporteur: Jo Robays

Scope: MAH Response to MEA 006 [Study No. NOVVD-001]as adopted in September 2024

Action: For adoption of advice to CHMP

7.2.9. Netarsudil - RHOKIINSA (CAP) - EMEA/H/C/004583/MEA 001.5

Applicant: Santen Oy

PRAC Rapporteur: Maria del Pilar Rayon

Scope: ***Updated Protocol / Study AR-13324-OBS02***
Non-interventional, observational post-authorisation safety study (PASS) cohort study to investigate the long-term safety of netarsudil beyond 12 months treatment

Action: For adoption of advice to CHMP

7.2.10. Pegcetacoplan - ASPAVELI (CAP) - EMEA/H/C/005553/MEA 002.2

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: ***Updated PASS Protocol / Study Sobi.PEGCET-301***
MAH's response to include the appropriate reference group, once the use of internal reference group from the IPIG registry has been further explored and agreed with the IPIG registry holder

Action: For adoption of advice to CHMP

7.2.11. Risankizumab - SKYRIZI (CAP) - EMEA/H/C/004759/MEA 009.3

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: ***Protocol Amendment / PASS study P23-653 v2.0***
Pregnancy Exposures and Outcomes in Women with Inflammatory Bowel Disease Treated with Risankizumab.

Action: For adoption of advice to CHMP

7.2.12. Risankizumab - SKYRIZI (CAP) - EMEA/H/C/004759/MEA 010.4

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: ***Protocol Amendment / PASS study P23-654*** v3.0
Comparative Cohort Study of Long-term Safety Outcomes of Risankizumab Compared to Biologic Treatments for Ulcerative Colitis and Crohn's Disease in a Real-world Setting in Sweden and Denmark.

Action: For adoption of advice to CHMP

7.2.13. Spesolimab - SPEVIGO (CAP) - EMEA/H/C/005874/MEA 003.2

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Tiphaine Vaillant

Scope: ***Updated PASS Protocol / Study no.: 1368-0128*** (version 2.0)
A 5-year active surveillance, post-authorisation safety study to characterise the safety of spesolimab for flare treatment in patients with GPP. Objectives: To evaluate the risks serious or opportunistic infections, systemic hypersensitivity reaction, malignancy, and peripheral neuropathy in adult patients (aged ≥18 years) experiencing a GPP flare who are treated with spesolimab or other treatments in the routine clinical care setting.
PROTOCOL

Action: For adoption of advice to CHMP

7.2.14. Tirzepatide - MOUNJARO (CAP) - EMEA/H/C/005620/MEA 002.3

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: ***Revised Protocol*** and MAH's responses to MEA 002.2 [I8B-MC-B011] RSI as adopted in June 2024

Action: For adoption of advice to CHMP

7.2.15. Tirzepatide - MOUNJARO (CAP) - EMEA/H/C/005620/MEA 005.3

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: ***Revised Protocol*** and MAH's responses to MEA 005.2 [(IBF-MC-B014 (formerly IBF-MC-B013)] RSI adopted in June 2024

Action: For adoption of advice to CHMP

7.2.16. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/MEA 047.5

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: ***MAH's responses and Updated Study Protocol – SWIBREG*** (Version 6.0) Amendment 2
An Observational Post-authorization Safety Study to Describe The Safety of Ustekinumab and Other Biologic Treatments in a Cohort of Patients With Ulcerative Colitis or Crohn's Disease Using Compulsory Swedish Nationwide Healthcare Registers and the Independent Swedish National Quality Register for Inflammatory Bowel Disease.

Action: For adoption of advice to CHMP

7.3. Results of PASS imposed in the marketing authorisation(s)[28]

7.3.1. 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 CHMP (or request for supplementary information (RSI)

7.3.2. Lenalidomide – REVLIMID (CAP) - EMEA/H/C/PSR/S/0049

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Final study report for a post-authorisation, non-interventional, retrospective, drug-utilisation study to describe the pattern of use of lenalidomide in patients with myelodysplastic syndromes (MDS)

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

7.4. Results of PASS non-imposed in the marketing authorisation(s)[29]

7.4.1. Ertugliflozin - STEGLATRO (CAP) - EMEA/H/C/004315/MEA 002.6

Applicant: Merck Sharp & Dohme B.V.

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

PRAC Rapporteur: Bianca Mulder

Scope: Linked to WS/2794:
Post-authorisation safety study to assess the risk of diabetic ketoacidosis (DKA) among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents
FINAL STUDY REPORT / Study number: MK8835-062

Action: For adoption of advice to CHMP

7.4.2. Ertugliflozin, metformin hydrochloride - SEGLUROMET (CAP) - EMEA/H/C/004314/MEA 002.6

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Linked to WS/2794:

Post-authorisation safety study to assess the risk of diabetic ketoacidosis (DKA) among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents

FINAL STUDY REPORT / Study number: MK8835-062

Action: For adoption of advice to CHMP

7.4.3. Ertugliflozin, metformin hydrochloride - SEGLUROMET (CAP) - EMEA/H/C/004314/WS2794/0026; Ertugliflozin - STEGLATRO (CAP) - EMEA/H/C/004315/WS2794/0025; Ertugliflozin, sitagliptin - STEGLUJAN (CAP) - EMEA/H/C/004313/WS2794/0029

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Submission of the final report from study 8835-062 listed as a category 3 study in the RMP for Steglatro, Steglujan and Segluromet. This is a non-interventional post-authorization safety study (PASS) to assess the risk of diabetic ketoacidosis (DKA) among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents. The RMP version 2.3 have also been submitted

Action: For adoption of advice to CHMP

7.4.4. Ertugliflozin, sitagliptin - STEGLUJAN (CAP) - EMEA/H/C/004313/MEA 002.6

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Linked to WS/2794:

Post-authorisation safety study to assess the risk of diabetic ketoacidosis (DKA) among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents.

FINAL STUDY REPORT / Study number: MK8835-062

Action: For adoption of advice to CHMP

7.4.5. 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 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 advice to CHMP

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

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Tiphaine Vaillant

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

Action: For adoption of advice to CHMP

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

7.5.1. Bimekizumab - BIMZELX (CAP) - EMEA/H/C/005316/MEA 007

Applicant: UCB Pharma S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: From RMP:
Interim Study Report / Study AS0014
Title: A multicenter, open-label extension study to assess the long-term safety, tolerability, and efficacy of bimekizumab in the treatment of study participants with active axial spondyloarthritis, ankylosing spondylitis, and nonradiographic axial spondyloarthritis.

Action: For adoption of advice to CHMP

7.5.2. Cladribine - MAVENCLAD (CAP) - EMEA/H/C/004230/MEA 002.5

Applicant: Merck Europe B.V.

PRAC Rapporteur: Carla Torre

Scope: From Initial MAA:
Study MS 700568-0002:
Long-term PASS (categ. 3 study) - prospective, observational cohort study evaluating the safety profile, in terms of incidence of adverse events of special interest, in patients with highly active relapsing multiple sclerosis (RMS) newly started on oral cladribine.
Second Interim Study Report, Study MS 700568-0002

Action: For adoption of advice to CHMP

7.5.3. Coronavirus (COVID-19) vaccine (recombinant, adjuvanted) - NUVAXOVID (CAP) - EMEA/H/C/005808/MEA 006.4

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: From Initial MAA:
Study 2019nCoV-404:
US Post-authorisation safety study to evaluate the pooled of risk of selected AESI within specified time periods after vaccination with Nuvaxovid using a claim and/or EHR database.
Second Interim Report, Study 2019nCoV-404

Action: For adoption of advice to CHMP

7.5.4. Damoctocog alfa pegol - JIVI (CAP) - EMEA/H/C/004054/ANX 001.4

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: ***THIRD INTERIM REPORT***
Study number 20904 (HA-SAFE)
'Observational study evaluating long-term safety of real-world treatment with damoctocog alfa pegol in previously treated patients with hemophilia A' (HA-SAFE). The HA-SAFE study is a post-authorisation measure defined in Annex II.D of the Jivi EU PI.The study protocol was agreed with EMA/PRAC in Nov 2019 (outcome letter); the date of FPFV was 14 May 2021 (impacted by the Covid-19 pandemic). As Annex to the first interim report also the statistical analysis plan is submitted

Action: For adoption of advice to CHMP

7.5.5. Difelikefalin - KAPRUVIA (CAP) - EMEA/H/C/005612/MEA 002.2

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: From initial MAA RMP Category 3
Study CR845- 310301

A Multicenter, Randomized, Double-blind, Placebo-controlled 12-Week Study to Evaluate the Safety and Efficacy of Oral Difelikefalin in Advanced Chronic Kidney Disease Subjects With Moderate-to-Severe Pruritus and Not on Dialysis With an up to 52-Week Long-term Extension
INTERIM REPORT

Action: For adoption of advice to CHMP

7.5.6. Difelikefalin - KAPRUVIA (CAP) - EMEA/H/C/005612/MEA 003.2

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: From initial MAA RMP Category 3
Study CR845- 310302
A Multicenter, Randomized, Double-blind, Placebo-controlled 12-Week Study to Evaluate the Safety and Efficacy of Oral Difelikefalin in Advanced Chronic Kidney Disease Subjects With Moderate-to-Severe Pruritus and Not on Dialysis With an up to 52-Week Long-term Extension
INTERIM REPORT

Action: For adoption of advice to CHMP

7.5.7. Difelikefalin - KAPRUVIA (CAP) - EMEA/H/C/005612/MEA 004.2

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Mari Thorn

Scope: From initial MAA RMP Category 3
Study CR845- 310501
A Two-part, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy and Safety of Oral Difelikefalin as Adjunct Therapy to a Topical Corticosteroid for Moderate-to-Severe Pruritus in Adult Subjects With Atopic Dermatitis
INTERIM REPORT

Action: For adoption of advice to CHMP

7.5.8. Diroximel fumarate - VUMERITY (CAP) - EMEA/H/C/005437/MEA 002.4

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Martin Huber

Scope: MAH Response to MEA 002.3 [***Annual Progress Report / Study 272MS403***] as adopted in July 2024. In addition, a proposal is made to terminate Study 272MS403.
Title: An observational study utilising data from big MS data registries to evaluate the long-term safety of Vumerity and Tecfidera.

Action: For adoption of advice to CHMP

7.5.9. Drospirenone, estetrol - DROVELIS (CAP) - EMEA/H/C/005336/MEA 001.5

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Martin Huber

Scope: MAH Response to MEA 001.4 [PASS No. INAS-NEES] RSI as adopted in September 2024

Action: For adoption of advice to CHMP

7.5.10. Drospirenone, estetrol - LYDISILKA (CAP) - EMEA/H/C/005382/MEA 001.5

Applicant: Estetra SRL

PRAC Rapporteur: Martin Huber

Scope: MAH Response to MEA 001.4 [PASS No. INAS-NEES] RSI as adopted in September 2024

Action: For adoption of advice to CHMP

7.5.11. Elasomeran - SPIKEVAX (CAP) - EMEA/H/C/005791/MEA 066.4

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Study mRNA-1273-P911 Long-term outcomes of myocarditis following administration of Spikevax (COVID-19 vaccine mRNA).
Third Interim Report, study P911 and updated Protocols and SAP for study mRNA-1273-P911

Action: For adoption of advice to CHMP

7.5.12. Etanercept - NEPEXTO (CAP) - EMEA/H/C/004711/MEA 001.2

Applicant: Biosimilar Collaborations Ireland Limited

PRAC Rapporteur: Monica Martinez Redondo

Scope: The MAH is asked to provide subsequent biannual interim reports until final study reports are available.

*** First Biannual Interim Report***

Action: For adoption of advice to CHMP

7.5.13. Galcanezumab - EMGALITY (CAP) - EMEA/H/C/004648/MEA 002.2

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: ***Fourth annual progress report / Study I5Q-MC-B003***
Observational Cohort Study of Exposure to Galcanezumab during Pregnancy. From 28

September 2018 through 31 March 2024.

Action: For adoption of advice to CHMP

7.5.14. Galcanezumab - EMGALITY (CAP) - EMEA/H/C/004648/MEA 003.3

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: ***Annual progress report / Study I5Q-MC-B002***
A retrospective cohort study to assess drug utilisation and long-term safety of galcanezumab in European patients in the course of routine clinical care

Action: For adoption of advice to CHMP

7.5.15. Galcanezumab - EMGALITY (CAP) - EMEA/H/C/004648/MEA 004.2

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: ***Third Annual Progress Report / Study I5Q-MC-B001***
A Cohort Study to Assess Drug Utilisation and Long-Term Safety of Galcanezumab in US Patients in the Course of Routine Clinical Care.
Galcanezumab US Drug Utilization and Safety Outcomes Study (Planned).
- To describe, in real-world clinical practice, the utilization of galcanezumab in the US, and the incidence of important safety outcomes such as serious hypersensitivity and long-term safety including serious cardiovascular events, and malignancies. Another objective is to understand the risk of specified safety events in patients receiving galcanezumab relative to adult patients who initiated treatment with another prophylactic migraine medication

Action: For adoption of advice to CHMP

7.5.16. Ketoconazole - KETOCONAZOLE HRA (CAP) - EMEA/H/C/003906/ANX 002.12

Applicant: HRA Pharma Rare Diseases

PRAC Rapporteur: Petar Mas

Scope: ***Seventh Annual Interim Report***
PASS EUPAS21731
Prospective, multi-country, observational registry to collect clinical information on patients with endogenous Cushing's syndrome exposed to Ketoconazole (using the existing European Registry on Cushing's Syndrome (ERCUSYN)), to assess drug utilization pattern and to document the safety (e.g. hepatotoxicity, QT prolongation) and effectiveness of Ketoconazole

Action: For adoption of advice to CHMP

7.5.17. Odevixibat - BYLVAY (CAP) - EMEA/H/C/004691/MEA 003.4

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: Prospective Registry-Based Study of the Long-Term Safety of Odevixibat in Subjects with Progressive Familial Intrahepatic Cholestasis (PFIC). (First Annual Report Version 1.0) ***FIRST INTERIM REPORT / Study Number: A4250-019***

Action: For adoption of advice to CHMP

7.5.18. Patisiran - ONPATTRO (CAP) - EMEA/H/C/004699/MEA 003.7

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: ***Fourth Interim study report*** / Study no.: ALN-TTR02-010
Description: Patisiran-LNP Pregnancy Surveillance Program.
To collect primary data on pregnant women from the US, the United Kingdom (UK), France, Spain, Italy, Portugal and Germany, and other potential countries, who have been exposed to patisiran during the exposure window, defined as 12 weeks prior to their last menstrual period (LMP), or at any time during pregnancy. Establish a worldwide Pregnancy Surveillance Program (PSP) to collect and analyze information pertaining to pregnancy complications and birth outcomes in women exposed to patisiran during pregnancy. The collection and analysis of data should continue for a minimum of 10 years.

Action: For adoption of advice to CHMP

7.5.19. Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - MOSQUIRIX (Art 58[30]) - EMEA/H/W/002300/MEA 015.2

Applicant: GlaxoSmithkline Biologicals SA

PRAC Rapporteur: Jean-Michel Dogné

Scope: MAH's responses to questions related to MEA 015.1 [Statistical Analysis Plan (SAP) and Interim Report / Study EPI-MAL-010] as adopted in April 2024.
A phase IV, longitudinal, cross-sectional, retrospective, ancillary epidemiology study of the EPI-MAL-005 study to evaluate the genetic diversity in the Plasmodium falciparum parasite circumsporozoite sequences before and after the implementation of the RTS,S/AS01E vaccine in malaria-positive subjects ranging from 6 months to less than 5 years of age

Action: For adoption of advice to CHMP

7.5.20. Reslizumab - CINQAERO (CAP) - EMEA/H/C/003912/MEA 005.9

Applicant: Teva B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: MAH's response to MEA 005.8 [Study number C38072-AS-50027] RSI as adopted in September 2024.
Assessment of Potential Risk of Malignancy in Patients with Severe Asthma Treated with Reslizumab: A cohort Study using Secondary Administrative Healthcare Data

[30] 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)

Action: For adoption of advice to CHMP

7.5.21. Risdiplam - EVRYSDI (CAP) - EMEA/H/C/005145/MEA 007.5

Applicant: Roche Registration GmbH

PRAC Rapporteur: Jan Neuhauser

Scope: From Initial MAA:
Study BN42833 (Risdiplam Pregnancy Surveillance Study):
A Phase IV, non-interventional surveillance study.
Third Interim Progress Report

Action: For adoption of advice to CHMP

7.5.22. Rivaroxaban - XARELTO (CAP) - EMEA/H/C/000944/MEA 049.5

Applicant: Bayer AG

PRAC Rapporteur: Mari Thorn

Scope: Xarelto Paediatric VTE PASS Drug Utilization Study: An observational, longitudinal, multi-source drug utilization safety study to evaluate the drug use patterns and safety of rivaroxaban oral suspension in children under two years with venous thromboembolism (XAPAEDUS)".
Second Progress Report

Action: For adoption of advice to CHMP

7.5.23. Tofacitinib - XELJANZ (CAP) - EMEA/H/C/004214/MEA 024.2

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: An Active Surveillance, Post-Authorization Study to Characterize the Safety of Tofacitinib in Patients with Moderately to Severely Active Ulcerative Colitis in the Real-World Setting Using Data from a US Administrative Healthcare Claims Database.
Second Interim Study Result; Updated Protocol with responses / PASS Study A3921347

Action: For adoption of advice to CHMP

7.5.24. Upadacitinib - RINVOQ (CAP) - EMEA/H/C/004760/MEA 016.3

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: ***First Annual Progress Report / PASS study P24-344***
Title:Drug Utilization Study for Evaluation of the Effectiveness of Additional Risk Minimisation Measures for Upadacitinib in the Treatment of Ulcerative Colitis in Sweden and Denmark

Action: For adoption of advice to CHMP

7.5.25. Ustekinumab - STELARA (CAP) - EMEA/H/C/000958/MEA 048.5

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Rhea Fitzgerald

Scope: ***SECOND PROGRESS REPORT and SAP*** including a response document and updated study protocol to address the limitations as identified in the Assessment Report for MEA 048.4.
An observational post-authorisation safety study (PASS) to describe the safety of ustekinumab and other ulcerative colitis treatments in a cohort of patients with ulcerative colitis using SNDS PCSIMM002659

Action: For adoption of advice to CHMP

7.6. Others

7.6.1. Alemtuzumab - LEMTRADA (CAP) - EMEA/H/C/003718/MEA 007.18

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: ***Feasibility assessment / Study (PASS) OBS13434***
Submission a feasibility assessment of study A prospective, multicenter, observational, post-authorization safety study(PASS) to evaluate the long-term safety profile of LEMTRADA (alemtuzumab) treatment in patients with relapsing forms of multiple sclerosis (RMS)

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. Lonafarnib - ZOKINVY (CAP) - EMEA/H/C/005271/S/0012 (without RMP)

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.2. Metreleptin - MYALEPTA (CAP) - EMEA/H/C/004218/S/0039 (without RMP)

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption of advice to CHMP

8.1.3. Odevixibat - BYLVAY (CAP) - EMEA/H/C/004691/S/0023 (without RMP)

Applicant: Ipsen Pharma

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. Andexanet alfa - ONDEXXYA (CAP) - EMEA/H/C/004108/R/0049 (without RMP)

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.2. Delamanid - DELTYBA (CAP) - EMEA/H/C/002552/R/0076 (with RMP)

Applicant: Otsuka Novel Products GmbH

PRAC Rapporteur: Jo Robays

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

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

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.4. Pandemic influenza vaccine (H5N1) (live attenuated, nasal) - PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) - EMEA/H/C/003963/R/0074 (without RMP)

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Hrabcik

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.2.5. Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - INCELLIPAN (CAP) - EMEA/H/C/006051/R/0002 (without RMP)

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

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

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Conditional renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3. Renewals of the marketing authorisation

8.3.1. Avelumab - BAVENCIO (CAP) - EMEA/H/C/004338/R/0050 (with RMP)

Applicant: Merck Europe B.V.

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.2. Caffeine citrate - GENCEBOK (CAP) - EMEA/H/C/005435/R/0012 (without RMP)

Applicant: Gennisium Pharma

PRAC Rapporteur: Sonja Hrabcik

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.3. Ebola vaccine (rDNA, replication-incompetent) - MVABEA (CAP) - EMEA/H/C/005343/R/0023 (without RMP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.4. Ebola vaccine (rDNA, replication-incompetent) - ZABDENO (CAP) - EMEA/H/C/005337/R/0022 (without RMP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Jean-Michel Dogné

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.5. Fingolimod - FINGOLIMOD ACCORD (CAP) - EMEA/H/C/005191/R/0011 (without RMP)

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.6. Glasdegib - DAURISMO (CAP) - EMEA/H/C/004878/R/0015 (without RMP)

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.7. Indacaterol, mometasone - ATECTURA BREEZHALER (CAP) - EMEA/H/C/005067/R/0031 (without RMP)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Jan Neuhauser

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.8. Indacaterol, mometasone - BEMRIST BREEZHALER (CAP) - EMEA/H/C/005516/R/0026 (without RMP)

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Jan Neuhauser

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

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

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.10. Ivacaftor, tezacaftor, elexacaftor - KAFTRIO (CAP) - EMEA/H/C/005269/R/0059 (without RMP)

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.11. Lefamulin - XENLETA (CAP) - EMEA/H/C/005048/R/0010 (without RMP)

Applicant: Nabriva Therapeutics Ireland DAC

PRAC Rapporteur: Eva Jirsová

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.12. Ozanimod - ZEPOSIA (CAP) - EMEA/H/C/004835/R/0028 (without RMP)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.13. Paliperidone - BYANNLI (CAP) - EMEA/H/C/005486/R/0008 (without RMP)

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.14. Teriparatide - LIVOGIVA (CAP) - EMEA/H/C/005087/R/0015 (with RMP)

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

8.3.15. Trastuzumab - ZERCEPAC (CAP) - EMEA/H/C/005209/R/0039 (without RMP)

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Gabriele Maurer

Scope: 5-year renewal of the marketing authorisation

Action: For adoption of advice to CHMP

9. Product related pharmacovigilance inspections

9.1. List of planned pharmacovigilance inspections

None

9.2. Ongoing or concluded pharmacovigilance inspections

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

9.3. Others

None

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

10.1. Safety related variations of the marketing authorisation

None

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

None

10.3. Other requests

None

10.4. Scientific Advice

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

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

11.1. Safety related variations of the marketing authorisation

None

11.2. Other requests

None

12. Organisational, regulatory and methodological matters

12.1. Mandate and organisation of the PRAC

12.1.1. PRAC membership

Action: For information

12.1.2. Vote by proxy

Action: For information

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

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

None

12.4. Cooperation within the EU regulatory network

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

Action: For discussion

12.5. Cooperation with International Regulators

None

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

None

12.7. PRAC work plan

None

12.8. Planning and reporting

12.8.1. Marketing authorisation applications (MAA) forecast for 2024 – planning update dated Q4 2024

Action: For discussion

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. Granularity and Periodicity Advisory Group (GPAG)

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

None

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. EMA's approach to safety communications

Action: For discussion

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

PRAC lead: Ulla Wändel Liminga

Action: For discussion

12.21.3. Implementation of new fee regulation (EU) 2024/568 from 1 January 2025

Action: For information

12.21.4. PRAC Assessors trainings - update

PRAC Lead(s): Liana Martirosyan, Ulla Wändel Liminga

Action: For discussion

12.21.5. Serious cutaneous adverse reactions (SCARs) - PRAC guidance update

PRAC Lead(s): Ulla Wändel Liminga, Zane Neikena

Action: For discussion

13. Any other business

None

14. Explanatory notes

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

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

(Items 2 and 3 of the PRAC agenda)

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

Signals assessment and prioritisation

(Item 4 of the PRAC agenda)

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

Risk Management Plans (RMPs)

(Item 5 of the PRAC agenda)

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

Assessment of Periodic Safety Update Reports (PSURs)

(Item 6 of the PRAC agenda)

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

Post-authorisation Safety Studies (PASS)

(Item 7 of the PRAC agenda)

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

Product related pharmacovigilance inspections

(Item 9 of the PRAC agenda)

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

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