02 June 2025
EMA/PRAC/168514/2025
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 02-05 June 2025

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

02 June 2025, 13:00 – 19:30, room 1C

03 June 2025, 08:30 – 19:30, room 1C

04 June 2025, 08:30 – 19:30, room 1C

05 June 2025, 08:30 – 16:00, room 1C

Organisational, regulatory and methodological matters (ORGAM)

23 June 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 02-05 June 2025. See June month 2025 PRAC minutes (to be published post July 2025 PRAC).

1.2. Agenda of the meeting on 02-05 June 2025

Action: For adoption

1.3. Minutes of the previous meeting on 05-08 May 2025

Action: For adoption

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

2.1. Newly triggered procedures

None

2.2. Ongoing procedures

None

2.3. Procedures for finalisation

None

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

3.1. Newly triggered procedures

None

3.2. Ongoing procedures

None

3.3. Procedures for finalisation

None

3.4. Re-examination procedures[1]

None

3.5. Others

None

4. Signals assessment and prioritisation[2]

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

4.1.1. Epcoritamab – TEPKINLY (CAP)

Applicant: AbbVie Deutschland GmbH & Co. KG

PRAC Rapporteur: Monica Martinez Redondo

Scope: Signal of hypogammaglobulinaemia

Action: For adoption

EPITT 20174 – New signal

Lead Member State(s): ES

4.1.2. Varicella vaccine (live) (NAP)

Applicant: various

PRAC Rapporteur: To be appointed

Scope: Signal of new aspect of the known risk of encephalitis

Action: For adoption

EPITT 20180 – New signal

Lead Member State(s): BE

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

4.2. Signals follow-up and prioritisation

4.2.1. Axicabtagene ciloleucel - YESCARTA (CAP) - EMEA/H/C/004480/SDA/017; Brexucabtagene autoleucel - TECARTUS (CAP) - EMEA/H/C/005102/SDA/014; Ciltacabtagene autoleucel – CARVYKTI (CAP) - EMEA/H/C/005095/SDA/020; Idecabtagene vicleucel - ABECMA (CAP) - EMEA/H/C/004662/SDA/023; Lisocabtagene maraleucel - BREYANZI (CAP) - EMEA/H/C/004731/SDA/024; Tisagenlecleucel - KYMRIAH (CAP) - EMEA/H/C/004090/SDA/025;

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

PRAC Rapporteur: Jo Robays

Scope: Signal of immune-mediated enterocolitis / immune effector cell-associated enteritis with CAR T-cell products

Action: For adoption

EPITT 20133 – Follow-up to January 2025

Lead Member State(s): BE

4.2.2. Brodalumab - KYNTHEUM (CAP) - EMEA/H/C/003959/SDA/006

Applicant: LEO Pharma A/S

PRAC Rapporteur: Monica Martinez Redondo

Scope: Signal of pyoderma gangrenosum

Action: For adoption

EPITT 20162 – Follow-up to April 2025

4.2.3. Enzalutamide - XTANDI (CAP) - EMEA/H/C/002639/SDA/016; ENZALUTAMIDE VIATRIS (CAP), NAP; Digoxin (NAP)

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

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Signal of laboratory test interference leading to falsely elevated digoxin plasma levels with enzalutamide

Action: For adoption

EPITT 20134 – Follow-up to January 2025

4.2.4. Omalizumab – XOLAIR (CAP) - EMEA/H/C/000606/SDA/076; OMLYCLO (CAP)

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

PRAC Rapporteur: Mari Thorn

Scope: Signal of hearing losses

Action: For adoption

EPITT 20128 – Follow-up to January 2025

4.2.5. Vortioxetine - BRINTELLIX (CAP) - EMEA/H/C/002717/SDA/010

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Jo Robays

Scope: Signal of hallucinations, not related to serotoninergic syndrome

Action: For adoption

EPITT 20152 – Follow-up to February 2025

4.3. Variation procedure(s) resulting from signal evaluation

4.3.1. Telmisartan / hydrochlorothiazide – TOLUCOMBI (CAP); NAP – EMA/VR/0000242380

Applicant(s): KRKA tovarna zdravil d.d. Novo mesto, various
PRAC Rapporteur: Amelia Cupelli

Scope: C.I.z: Update section 4.4 and 4.8 of the SmPC to added new safety information regarding intestinal angioedema. The package leaflet was update accordingly.

C.I.2.a: Update of sections 4.2, 4.3 (anuria), 4.4 (hyponatremia), 4.5 (iodinated contrast products), 4.6 (fertility), 4.7 (syncope, vertigo), 4.8 (combined table of ADR) and 5.2 (renal impairment) of the SmPC in order to align with reference labels for both active substances. The Package Leaflet is updated accordingly.

In addition, the MAH has taken to opportunity to update the annexes in line with QRD version 10.4 and to update the list of local representatives

Action: For adoption

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Belumosudil (CAP MAA) - EMEA/H/C/006421, Orphan

Applicant: Sanofi Winthrop Industrie

Scope (pre D-180 phase): Treatment of chronic graft-versus host disease (cGVHD) after failure of at least two prior lines of systemic therapy

Action: For adoption

5.1.2. Denosumab (CAP MAA) - EMEA/H/C/006490

Scope (pre D-180 phase): Treatment of osteoporosis and bone loss in postmenopausal women and in men

Action: For adoption

5.1.3. Denosumab (CAP MAA) - EMEA/H/C/006722

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

Action: For adoption

5.1.4. Denosumab (CAP MAA) - EMEA/H/C/006734

Scope: Treatment of osteoporosis and bone loss

Action: For adoption

5.1.5. Denosumab (CAP MAA) - EMEA/H/C/006238

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

Action: For adoption

5.1.6. Denosumab (CAP MAA) - EMEA/H/C/006552

Scope (pre D-180 phase): Prevention of skeletal related events in adults and treatment of adults and skeletally mature adolescents with giant cell tumour of bone

Action: For adoption

5.1.7. Golimumab (CAP MAA) - EMEA/H/C/006560

Scope (pre D-180 phase): Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis and ulcerative colitis

Action: For adoption

5.1.8. Hydrocortisone (CAP MAA) - EMEA/H/C/005201, PUMA[3]

Scope (pre D-180 phase): Prevention of bronchopulmonary dysplasia in preterm infants born less than 28 weeks of gestation

Action: For adoption

5.1.9. Mozafancogene autotemcel (CAP MAA) - EMEA/H/C/005537, PRIME, Orphan

Applicant: Rocket Pharmaceuticals B.V., ATMP

[3] Paediatric-use marketing authorisation(s)

Scope (pre D-180 phase): Treatment of paediatric patients with Fanconi Anaemia Type A

Action: For adoption

5.1.10. Nipocalimab (CAP MAA) - EMEA/H/C/006379

Scope (pre D-180 phase): Treatment of generalised myasthenia gravis

Action: For adoption

5.1.11. Pegfilgrastim (CAP MAA) - EMEA/H/C/006739

Scope: Treatment of neutropenia

Action: For adoption

5.1.12. Plozasiran (CAP MAA) - EMEA/H/C/006579, Orphan

Applicant: Arrowhead Pharmaceuticals Ireland Limited

Scope (pre D-120 phase, accelerated assessment): Treatment of familial chylomicronaemia syndrome (FCS)

Action: For adoption

5.2. Medicines in the post-authorisation phase – PRAC-led procedures

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

Applicant: Fresenius Kabi Deutschland GmbH

PRAC Rapporteur: Karin Bolin

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

Action: For adoption

5.2.2. Alemtuzumab – LEMTRADA (CAP) – EMA/VR/0000259153

Applicant: Sanofi Belgium

PRAC Rapporteur: Karin Erneholm

Scope: Submission of an updated RMP version 13.0 following the completion of the two non-interventional PASS category 1 Drug Utilization Study (dut0008) and Mortality study (csa0002). The risks table was updated with new DLP 12 September 2024 without new safety concerns

Action: For adoption

5.2.3. Apixaban – ELIQUIS (CAP) – EMA/VR/0000262422

Applicant: Bristol-Myers Squibb Pfizer EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Submission of an updated RMP version 22.0 and updated Annex II of the PI in order to discontinue the apixaban Prescriber Guide (PG) and Patient Alert Card (PAC) as an additional risk minimization measure (aRMM) for healthcare professionals (HCPs) and patients. Accordingly, information about PG and PAC is removed from Annexes III of the PI

Action: For adoption

5.2.4. Covid-19 mRNA vaccine – COMIRNATY (CAP) – EMA/VR/0000262269

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

C.I.11.b: Submission of an updated RMP version 14.1 in order to revise key objectives, design and study population of study C4591048 according to protocol amendment 6.

C.I.11.b: Submission of an updated RMP version 14.1 in order to propose the removal of the missing information 'Use in pregnancy and while breast feeding' from the list of the safety concerns with consequential removal of study C4591022 (US Pregnancy Postmarketing Requirement) study). In addition, the MAH took the opportunity to implement minor administrative changes to the RMP

Action: For adoption

5.2.5. Covid-19 vaccine (recombinant, adjuvanted) – NUVAXOVID (CAP) – EMA/VR/0000257347

Applicant: Novavax CZ a.s.

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of an updated RMP version 7.1 in order to align with the latest information in the SmPC, recently completed clinical study reports, and PSUR

Action: For adoption

5.2.6. 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

5.2.7. Linagliptin – TRAJENTA (CAP); JENTADUETO (CAP); GLYXAMBI (CAP) – EMA/VR/0000248932

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Submission of an updated RMP version 15.0 for Trajenta and Jentadueto and updated RMP version 12.0 for Glyxambi in order to review the list of safety concerns in line with GVP Module V, Rev 2

Action: For adoption

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

5.3.1. Afamelanotide – SCENESSE (CAP) – EMA/VR/0000247271

Applicant: Clinuvel Europe Limited

PRAC Rapporteur: Martin Huber

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

Action: For adoption

5.3.2. Aflibercept – AHZANTIVE (CAP); BAIAMA (CAP) – EMA/VR/0000255900

Applicant: Formycon AG

PRAC Rapporteur: Zoubida Amimour

Scope: Quality

Action: For adoption

5.3.3. Aflibercept – YESAFILI (CAP) – EMA/VR/0000245097

Applicant: Biosimilar Collaborations Ireland Limited

PRAC Rapporteur: Zoubida Amimour

Scope: Quality

Action: For adoption

5.3.4. Atezolizumab – TECENTRIQ (CAP) – EMA/VR/0000262253

Applicant: Roche Registration GmbH

PRAC Rapporteur: Carla Torre

Scope: Update of section 4.4 of the SmPC in order to amend an existing warning on infusion-related reactions with anaphylaxis based on Drug safety report No. 1135433; the Package Leaflet is updated accordingly. The RMP version 32.0 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

Action: For adoption

5.3.5. Andexanet alfa - ONDEXXYA (CAP) - EMEA/H/C/004108/II/0044

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3

Action: For adoption

5.3.6. Avelumab – BAVENCIO (CAP) – EMA/VR/0000261861

Applicant: Merck Europe B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add 'Gastritis' to the list of adverse drug reactions (ADRs) with frequency 'Not known' based on postmarketing data and literature. The Package Leaflet is updated accordingly. The RMP version 9.1 has also been submitted

Action: For adoption

5.3.7. Burosumab – CRYSVITA (CAP) – EMA/VR/0000261369

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: A grouped application consisting of:

C.I.4: Update of sections 4.4, 4.5, and 4.8 of the SmPC in order to update safety information about Severe Hypercalcaemia in patients with Tertiary Hyperparathyroidism based on data from clinical trials and post-authorisation data sources; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted. In addition, the MAH took the opportunity (1) to improve the existing guidance in section 4.2 based on the accumulated

clinical experience, (2) to introduce editorial changes to the PI, (3) to bring the PI in line with the latest QRD template, current guidelines, and Paul-Ehrlich-Institut (PEI) requests.

C.I.4: Update of section 4.8 of the SmPC in order to add urticaria to the list of adverse drug reactions (ADRs) with frequency common based on data from clinical trials and post-authorisation data sources; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted

Action: For adoption

5.3.8. 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

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

5.3.10. Darunavir / cobicistat / emtricitabine / tenofovir alafenamide – SYMTUZA (CAP) – EMA/X/0000248421

Applicant: Janssen Cilag International

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension application to add a new strength of 675 mg/150 mg/ 20mg/ 10 mg film-coated tablets grouped with an extension of indication (C.I.6) to include treatment of human

[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)

immunodeficiency virus type 1 (HIV 1) infection in paediatric patients (aged 6 years and older with body weight at least 25 kg) for SYMTUZA, based on the 24-week interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicentere, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1, 6.3, 6.4, 6.5 and 8 of the SmPC are updated. The Annex II, Labelling and Package Leaflet are updated accordingly. Version 9.1 of the RMP has also been submitted. Furthermore, the MAH took the opportunity to bring the product information (PI) in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet

Action: For adoption

5.3.11. Defatted powder of Arachis hypogaea l., semen (peanuts) – PALFORZIA (CAP) – EMA/VR/0000256580

Applicant: Stallergenes

PRAC Rapporteur: Terhi Lehtinen

Scope: Update of section 4.8 of the SmPC in order update the description of Eosinophilic esophagitis cases occurring in Palforzia clinical trials following CHMP request in EMEA/H/C/004917/P46/011 concerning report from study ARC008. The RMP version 1.3 has also been submitted. In addition, the MAH took the opportunity to bring minor updates to the SmPC following the Paul-Ehrlich-Institut (PEI) linguistic review

Action: For adoption

5.3.12. Dupilumab – DUPIXENT (CAP) – EMA/VR/0000257461

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents 12 years and older, whose disease is inadequately controlled by H1 antihistamines and who are naive to anti-IgE therapy for chronic spontaneous urticaria (CSU) for Dupixent, based on final results from 2 studies: EFC16461 (CUPID) study A and study C; both of them were phase 3, randomised, double-blind, placebo-controlled, multi-center, parallel-group study of dupilumab in patients with CSU who remain symptomatic despite the use of H1 antihistamine treatment in patients naïve to omalizumab. 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 13.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI

Action: For adoption

5.3.13. Epinephrine – EURNEFFY (CAP) – EMA/X/0000248440

Applicant: Alk-Abello A/S

PRAC Rapporteur: Terhi Lehtinen

Scope: Extension application to introduce a new strength (1 mg nasal spray, solution). The new strength is indicated for children with a body weight of 15 kg to less than 30 kg

Action: For adoption

5.3.14. Finerenone – KERENDIA (CAP) – EMA/X/0000248026

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Extension application to introduce a new strength 40 mg for film-coated tablets, packed in blisters of 14 tablets, 28 tablets, 98 tablets and 100 x 1 tablets (unit dose) grouped with a type II variations C.I.6: Extension of indication to include the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in adults for KERENDIA, based on final results from the phase 3 study FINEARTS-HF (20103); this is a randomized, double-blind, placebo-controlled phase 3 study evaluating the efficacy and safety of finerenone on morbidity and mortality in participants with symptomatic heart failure with left ventricular ejection fraction (LVEF) ≥40%.; Type II variation C.I.13: Submission of the final report from non-clinical study T105281-7, R-14405 - Juvenile toxicology study in rats

As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.1, 6.6 and 8 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and administrative changes to the PI and to bring it in line with the latest QRD template version 10.4

Action: For adoption

5.3.15. Guselkumab – TREMFYA (CAP) – EMA/X/0000248626

Applicant: Janssen Cilag International

PRAC Rapporteur: Gabriele Maurer

Scope: Extension application to add a new strength of 45 mg (100 mg/ml) in a pre-filled syringe (glass) in pre-filled pen (VarioJect) grouped with an extension of indication (C.I.6.a) to include treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years who are candidates for systemic therapy based on results from study CNTO1959PSO3011. This is a Phase 3, Multicenter, Randomized, Placebo- and Active Comparator-Controlled Study Evaluating the Efficacy, Safety, and Pharmacokinetics of Subcutaneously Administered Guselkumab for the Treatment of Chronic Plaque Psoriasis in Pediatric Participants (≥6 To <18 Years of Age). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 10.3 of the RMP has also been submitted

Action: For adoption

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

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Sonja Radowan

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

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

Applicant: Janssen-Cilag International N.V.

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Extension of indication to include IMBRUVICA in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone (R-CHOP) for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are eligible for autologous stem cell transplantation (ASCT), based on results from study MCL3003. This is a randomised, 3-arm, parallel-group, open-label, international, multicenter Phase 3 study. The purpose of Study MCL3003 is to compare 3 alternating courses of R CHOP/R-DHAP followed by ASCT (control Arm A), versus the combination with ibrutinib in induction and maintenance (experimental Arm A+I), or the experimental arm without ASCT (experimental Arm I) in participants with previously untreated MCL who are eligible for ASCT. Consequently, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Version 23.1 of the RMP has also been submitted

Action: For adoption

5.3.18. Inebilizumab - UPLIZNA (CAP) - EMEA/H/C/005818/II/0012

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Extension of indication to include treatment of adult patients with Immunoglobulin G4-Related Disease (IgG4-RD) for UPLIZNA, based on primary analysis results from study MITIGATE (VIB0551.P3.S2) for all subjects from the completed 52-week randomised-controlled period. This is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adult subjects with IgG4-RD. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 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 editorial changes to the PI and to bring it 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

5.3.19. Lutetium (^{177}Lu) oxodotreotide - LUTATHERA (CAP) - EMEA/H/C/004123/II/0058, Orphan

Applicant: Advanced Accelerator Applications

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include the treatment of unresectable or metastatic, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adolescents aged 12 years and older for LUTATHERA based on primary analysis results from study CAAA601A32201 (also referred to as NETTER-P) as well as results from modelling and simulation analysis of PK and dosimetry data of Lutathera in adolescents. NETTER-P study is a Phase II, multicenter open-label study which evaluated the safety and dosimetry of Lutathera in adolescent patients with somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) and pheochromocytoma and paragangliomas (PPGLs). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 11 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted

Action: For adoption

5.3.20. 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

5.3.21. Ponesimod - PONVORY (CAP) - EMEA/H/C/005163/II/0018/G

Applicant: Laboratoires Juvise Pharmaceuticals

PRAC Rapporteur: Karin Erneholm

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

C.I.13: Submission of the final report from study AC-058B202; this is a Multicenter, Randomized, Double-blind, Parallel-group Extension to Study AC-058B201 to Investigate the Long-term Safety, Tolerability, and Efficacy of 10, 20, and 40 mg/day Ponesimod, an Oral S1P1 Receptor Agonist, in Patients with Relapsing-remitting Multiple Sclerosis.

C.I.13: Submission of the final report from study AC-058B303 (OPTIMUM-LT); this is a Multicenter, Non-Comparative Extension to Study AC-058B301, to Investigate the Long-Term Safety, Tolerability, and Control of Disease of Ponesimod 20 mg in Subjects with Relapsing Multiple Sclerosis.

The RMP version 4.1 has also been submitted

Action: For adoption

5.3.22. Pyronaridine / Artesunate - PYRAMAX (Art 58[5]) - EMEA/H/W/002319/II/0036

Applicant: Shin Poong Pharmaceutical Co., Ltd.

PRAC Rapporteur: Zoubida Amimour

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

5.3.23. Spesolimab - SPEVIGO (CAP) - EMEA/H/C/005874/X/0011

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Zoubida Amimour

Scope: Extension application to add a new strength of 300 mg (150 mg/ml) for solution for injection in a pre-filled syringe.
The RMP (version 3.0) is updated in accordance.
In addition, the applicant has updated SmPC (Annex I) and Package Leaflet (Annex IIIB) for both 450 mg concentrate for solution for infusion and 150 mg and 300 mg solution for injection in line with the new excipient guideline

Action: For adoption

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

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

[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)

5.3.25. Inebilizumab – UPLIZNA (CAP) – EMA/VR/0000257358

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: A grouped application consisting of:

C.I.6 (Extension of indication): Extension of indication to include add-on to standard therapy for the treatment of adult patients with generalised myasthenia gravis (gMG) for Uplizna, based on primary analysis results from Study MINT (VIB0551.P3.S1); this is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adults subjects with myasthenia gravis. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1, 5.2, and 7 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

A.6: Update of the ATC code of inebilizumab to L04AG10 in line with the 2024 ATC INDEX

Action: For adoption

5.3.26. Mepolizumab – NUCALA (CAP) – EMA/VR/0000257645

Applicant: GlaxoSmithKline Trading Services Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication for NUCALA to include treatment of Chronic Obstructive Pulmonary Disease (COPD) based on final results from study 208657 (MATINEE). This is a randomized, double-blind, parallel-group, placebo-controlled study of mepolizumab 100 mg SC as add-on treatment in participants with COPD experiencing frequent exacerbations and characterized by eosinophil levels. 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 14.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI

Action: For adoption

5.3.27. Mirikizumab – OMVOH (CAP) – EMA/VR/0000264533

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Grouped application of a Type II and a Type IB Variation, as follows:

Type II (C.I.4): Update of section 4.2 of the SmPC in order to modify administration instructions to include an alternative option for the maintenance dose administration for the treatment of ulcerative colitis (UC) changing from two injections of Omvoh 100 mg to a single injection of Omvoh 200 mg, based on results from study I6T-MC-AMCB; this is a

bioequivalence study of subcutaneous injections of citrate-free mirikizumab solution using a 1-ml autoinjector and an investigational 2-ml autoinjector in healthy participants. The RMP version 2.1 has also been submitted.

The Labelling and Package Leaflet have been updated accordingly

Action: For adoption

5.3.28. Pembrolizumab – KEYTRUDA (CAP) – EMA/X/0000248795

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension application to introduce a new pharmaceutical form (solution for injection) associated with two new strengths (790 mg and 395 mg) and new route of administration (subcutaneous use).

The RMP (version 49.1) is updated in accordance

Action: For adoption

5.3.29. Ponatinib – ICLUSIG (CAP) – EMA/VR/0000261199

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Update of sections 4.2, 4.4, 4.8, and 5.1 of the SmPC based on final results from study OPTIC (AP24534-14-203) listed as a category 3 study in the Annex II; this is a Randomised, Open-label, Phase 2 Trial of Ponatinib in Patients with Resistant Chronic Phase Myeloid Leukaemia to Characterize the Efficacy and Safety of a Range of Doses. The Package Leaflet is updated accordingly. The RMP version 23.1 has also been submitted. In addition, the MAH took the opportunity to update Annex II

Action: For adoption

5.3.30. Semaglutide – RYBELSUS (CAP) – EMA/VR/0000244874

Applicant: Novo Nordisk A/S
PRAC Rapporteur: Mari Thorn

Scope: A grouped application consisting of:

C.I.4: Update of sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC in order to update clinical efficacy and safety information based on the final results from study EX9924-4473 (SOUL); this is a phase 3b study comparing oral semaglutide versus placebo and added to standard of care in patients with type 2 diabetes at high risk of cardiovascular events; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI.

C.I.4: Update of sections 4.2, and 5.1 of the SmPC in order to introduce chronic kidney disease outcomes based on final results from study NN9535-4321 (FLOW); this is a phase 3b study evaluating the effect of semaglutide versus placebo on the progression of renal

impairment in subjects with type 2 diabetes and chronic kidney disease; the Package Leaflet is updated accordingly.

Action: For adoption

5.3.31. Tafasitamab – MINJUVI (CAP) – EMA/VR/0000255975

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include in combination with lenalidomide and rituximab treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least one line of systemic therapy for MINJUVI, based on interim results from study INCMOR 0208-301 (inMIND); this is a phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of tafasitamab plus lenalidomide and rituximab vs lenalidomide and rituximab in patients with relapsed/refractory (R/R) follicular lymphoma grade 1 to 3a or R/R marginal zone lymphoma. 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 introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection

Action: For adoption

5.3.32. Talquetamab – TALVEY (CAP) – EMA/VR/0000258454

Applicant: Janssen Cilag International

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add a new warning on Ataxia/Balance disorder based on post-marketing data. The Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted

Action: For adoption

6. Periodic safety update reports (PSURs)

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

6.1.1. Abaloparatide – ELADYNOS (CAP) – EMA/PSUR/0000248500

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00011029/202410)

Action: For adoption

6.1.2. Acalabrutinib – CALQUENCE (CAP) – EMA/PSUR/0000248483

Applicant: AstraZeneca AB

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00010887/202410)

Action: For adoption

6.1.3. Aminosalicylic acid – GRANUPAS (CAP) – EMA/PSUR/0000248493

Applicant: Eurocept International B.V.

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010171/202410)

Action: For adoption

6.1.4. Amivantamab – RYBREVANT (CAP) – EMA/PSUR/0000248975

Applicant: Janssen Cilag International

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010977/202411)

Action: For adoption

6.1.5. Andexanet alfa – ONDEXXYA (CAP) – EMA/PSUR/0000248508

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010764/202410)

Action: For adoption

6.1.6. Bazedoxifene – CONBRIZA (CAP) – EMA/PSUR/0000248443

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000302/202410)

Action: For adoption

6.1.7. Bupivacaine – EXPAREL LIPOSOMAL (CAP) – EMA/PSUR/0000248494

Applicant: Pacira Ireland Limited

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00010889/202410)

Action: For adoption

6.1.8. Capivasertib – TRUQAP (CAP) – EMA/PSUR/0000248507

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011061/202411)

Action: For adoption

6.1.9. Cariprazine – REAGILA (CAP) – EMA/PSUR/0000248475

Applicant: Gedeon Richter Plc.

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010623/202410)

Action: For adoption

6.1.10. Cefiderocol – FETCROJA (CAP) – EMA/PSUR/0000248460

Applicant: Shionogi B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010849/202411)

Action: For adoption

6.1.11. Ceftaroline fosamil – ZINFORO (CAP) – EMA/PSUR/0000248505

Applicant: Pfizer Ireland Pharmaceuticals Unlimited Company

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00010013/202410)

Action: For adoption

6.1.12. Chikungunya vaccine (live) – IXCHIQ (CAP) – EMA/PSUR/0000248502

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011058/202411)

Action: For adoption

6.1.13. Conestat alfa – RUCONEST (CAP) – EMA/PSUR/0000248470

Applicant: Pharming Group N.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000873/202410)

Action: For adoption

6.1.14. Darifenacin – EMSELEX (CAP) – EMA/PSUR/0000248469

Applicant: pharmaand GmbH

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00000933/202410)

Action: For adoption

6.1.15. Delamanid – DELTYBA (CAP) – EMA/PSUR/0000248476

Applicant: Otsuka Novel Products GmbH

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00010213/202410)

Action: For adoption

6.1.16. Dinutuximab beta – QARZIBA (CAP) – EMA/PSUR/0000248495

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010597/202411)

Action: For adoption

6.1.17. Efbemalenograstim alfa – RYZNEUTA (CAP) – EMA/PSUR/0000248467

Applicant: Evive Biotechnology Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000286/202411)

Action: For adoption

6.1.18. Elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide – GENVOYA (CAP) – EMA/PSUR/0000248490

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010449/202411)

Action: For adoption

6.1.19. Emicizumab – HEMLIBRA (CAP) – EMA/PSUR/0000248515

Applicant: Roche Registration GmbH

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010668/202411)

Action: For adoption

6.1.20. Etranacogene dezaparvovec – HEMGENIX (CAP) – EMA/PSUR/0000248978

Applicant: CSL Behring GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011037/202411)

Action: For adoption

6.1.21. Exagamglogene autotemcel – CASGEVY (CAP) – EMA/PSUR/0000248449

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000244/202411)

Action: For adoption

6.1.22. Fezolinetant – VEOZA (CAP) – EMA/PSUR/0000248472

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00000231/202411)

Action: For adoption

6.1.23. Flutemetamol (18f) – VIZAMYL (CAP) – EMA/PSUR/0000248481

Applicant: GE Healthcare AS

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010293/202410)

Action: For adoption

6.1.24. Follitropin alfa – GONAL-F (CAP); OVALEAP (CAP); BEMFOLA (CAP) – EMA/PSUR/0000248456

Applicant: Merck Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00001463/202410)

Action: For adoption

6.1.25. Follitropin alfa / lutropin alfa – PERGOVERIS (CAP) – EMA/PSUR/0000248455

Applicant: Merck Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001464/202410)

Action: For adoption

6.1.26. Fosnetupitant / netupitant / palonosetron – AKYNZEO (CAP) – EMA/PSUR/0000248514

Applicant: Helsinn Birex Pharmaceuticals Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00010393/202410)

Action: For adoption

6.1.27. Glasdegib – DAURISMO (CAP) – EMA/PSUR/0000248492

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010859/202411)

Action: For adoption

6.1.28. Hepatitis b surface antigen – HEPLISAV B (CAP) – EMA/PSUR/0000248489

Applicant: Dynavax GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010919/202411)

Action: For adoption

6.1.29. Idarucizumab – PRAXBIND (CAP) – EMA/PSUR/0000248479

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010435/202410)

Action: For adoption

6.1.30. Insulin detemir – LEVEMIR (CAP) – EMA/PSUR/0000248485

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001750/202410)

Action: For adoption

6.1.31. Insulin icodec – AWIQLI (CAP) – EMA/PSUR/0000248499

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011053/202411)

Action: For adoption

6.1.32. Ivosidenib – TIBSOVO (CAP) – EMA/PSUR/0000248512

Applicant: Les Laboratoires Servier

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011048/202411)

Action: For adoption

6.1.33. Latanoprost – CATIOLANZE (CAP) – EMA/PSUR/0000248447

Applicant: Santen Oy

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00000202/202411)

Action: For adoption

6.1.34. Lebrikizumab – EBGLYSS (CAP) – EMA/PSUR/0000248530

Applicant: Almirall S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000175/202411)

Action: For adoption

6.1.35. Ledipasvir / sofosbuvir – HARVONI (CAP) – EMA/PSUR/0000248480

Applicant: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010306/202410)

Action: For adoption

6.1.36. Letermovir – PREVYMIS (CAP) – EMA/PSUR/0000248461

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010660/202411)

Action: For adoption

6.1.37. Linzagolix choline – YSELTY (CAP) – EMA/PSUR/0000248513

Applicant: Theramex Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010998/202411)

Action: For adoption

6.1.38. Lonafarnib – ZOKINVY (CAP) – EMA/PSUR/0000248976

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011005/202411)

Action: For adoption

6.1.39. Lumasiran – OXLUMO (CAP) – EMA/PSUR/0000248463

Applicant: Alnylam Netherlands B.V.

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00010884/202411)

Action: For adoption

6.1.40. Mavacamten – CAMZYOS (CAP) – EMA/PSUR/0000248442

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00000074/202410)

Action: For adoption

6.1.41. Meningococcal group b vaccine (recombinant, adsorbed) – TRUMENBA (CAP) – EMA/PSUR/0000248484

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010607/202410)

Action: For adoption

6.1.42. Micafungin – MYCAMINE (CAP) – EMA/PSUR/0000248462

Applicant: Sandoz Pharmaceuticals d.d.

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00002051/202410)

Action: For adoption

6.1.43. Midostaurin – RYDAPT (CAP) – EMA/PSUR/0000248529

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Carla Torre

Scope: Evaluation of a PSUSA procedure (PSUSA/00010638/202410)

Action: For adoption

6.1.44. Miglustat – ZAVESCA (CAP) – EMA/PSUR/0000248450

Applicant: Janssen Cilag International

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00002062/202410)

Action: For adoption

6.1.45. Nirsevimab – BEYFORTUS (CAP) – EMA/PSUR/0000248497

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00011026/202410)

Action: For adoption

6.1.46. Palopegteriparatide – YORVIPATH (CAP) – EMA/PSUR/0000248444

Applicant: Ascendis Pharma Bone Diseases A/S

PRAC Rapporteur: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure (PSUSA/00000173/202411)

Action: For adoption

6.1.47. Pandemic influenza vaccine (h5n1) (live attenuated, nasal) – PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) – EMA/PSUR/0000248977

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010501/202411)

Action: For adoption

6.1.48. Pazopanib – VOTRIENT (CAP) – EMA/PSUR/0000248488

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00002321/202410)

Action: For adoption

6.1.49. Pegcetacoplan – ASPAVELI (CAP) – EMA/PSUR/0000248510

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010974/202411)

Action: For adoption

6.1.50. Pegunigalsidase alfa – ELFABRIO (CAP) – EMA/PSUR/0000248528

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011049/202411)

Action: For adoption

6.1.51. Radamts13 – ADZYNMA (CAP) – EMA/PSUR/0000248509

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00011077/202411)

Action: For adoption

6.1.52. Recombinant respiratory syncytial virus pre-fusion f protein, adjuvanted with as01e – AREXVY (CAP) – EMA/PSUR/0000248473

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00000031/202411)

Action: For adoption

6.1.53. Rurioctocog alfa pegol – ADYNOVI (CAP) – EMA/PSUR/0000248511

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010663/202411)

Action: For adoption

6.1.54. Selpercatinib – RETSEVMO (CAP) – EMA/PSUR/0000248503

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010917/202411)

Action: For adoption

6.1.55. Sirolimus – HYFTOR (CAP) – EMA/PSUR/0000248441

Applicant: Plusultra Pharma GmbH

PRAC Rapporteur: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00000025/202411)

Action: For adoption

6.1.56. Somatrogon – NGENLA (CAP) – EMA/PSUR/0000248527

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010982/202410)

Action: For adoption

6.1.57. Tirzepatide – MOUNJARO (CAP) – EMA/PSUR/0000248506

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011019/202411)

Action: For adoption

6.1.58. Tixagevimab / cilgavimab – EVUSHELD (CAP) – EMA/PSUR/0000248482

Applicant: AstraZeneca AB

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010992/202411)

Action: For adoption

6.1.59. Tofacitinib – XELJANZ (CAP) – EMA/PSUR/0000248531

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010588/202411)

Action: For adoption

6.1.60. Vamorolone – AGAMREE (CAP) – EMA/PSUR/0000248446

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00000223/202410)

Action: For adoption

6.1.61. Volanesorsen – WAYLIVRA (CAP) – EMA/PSUR/0000248465

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00010762/202411)

Action: For adoption

6.1.62. Zanubrutinib – BRUKINSA (CAP) – EMA/PSUR/0000248496

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010960/202411)

Action: For adoption

6.2. PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) and nationally authorised products (NAPs)

6.2.1. Levodopa / carbidopa / entacapone – CORBILTA (CAP); LEVODOPA/CARBIDOPA/ENTACAPONE ORION (CAP); STALEVO (CAP); NAP – EMA/PSUR/0000248477

Applicant(s): Orion Corporation, various

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000547/202410)

Action: For adoption

6.2.2. Sevelamer – RENAGEL (CAP); RENVELA (CAP); SEVELAMER CARBONATE WINTHROP (CAP); NAP – EMA/PSUR/0000248474

Applicant(s): Sanofi Winthrop Industrie, various

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00002697/202410)

Action: For adoption

6.2.3. Stiripentol – DIACOMIT (CAP); NAP – EMA/PSUR/0000248464

Applicant(s): Biocodex, various

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00002789/202411)

Action: For adoption

6.2.4. Thalidomide – THALIDOMIDE BMS (CAP); THALIDOMIDE LIPOMED (CAP); NAP – EMA/PSUR/0000248471

Applicant(s): Bristol-Myers Squibb Pharma EEIG; Lipomed GmbH, various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00002919/202410)

Action: For adoption

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

6.3.1. Acitretin (NAP) - EMA/PSUR/0000248445

Applicant(s): various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000051/202410)

Action: For adoption

6.3.2. Ascorbic acid / magnesium aspartate / leucine L / lysine L / phenylalanine L / valine L (NAP) - EMA/PSUR/0000248498

Applicant(s): various

PRAC Lead: Guðrún Stefánsdóttir

Scope: Evaluation of a PSUSA procedure (PSUSA/00010988/202410)

Action: For adoption

6.3.3. Azelastine / fluticasone (NAP) - EMA/PSUR/0000248486

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010067/202410)

Action: For adoption

6.3.4. Benzydamine (NAP) - EMA/PSUR/0000248448

Applicant(s): various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000375/202410)

Action: For adoption

6.3.5. Clindamycin (NAP) - EMA/PSUR/0000248466

Applicant(s): various

PRAC Lead: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000795/202410)

Action: For adoption

6.3.6. Colecalciferol, colecalciferol / calcium, ergocalciferol, ergocalciferol / calcium (NAP) - EMA/PSUR/0000248516

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010386/202410)

Action: For adoption

6.3.7. Corticorelin (NAP) - EMA/PSUR/0000248451

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000876/202410)

Action: For adoption

6.3.8. Dexketoprofen (NAP) - EMA/PSUR/0000248453

Applicant(s): various

PRAC Lead: Monica Martinez Redondo

Scope: Evaluation of a PSUSA procedure (PSUSA/00000997/202410)

Action: For adoption

6.3.9. Drospirenone (NAP) - EMA/PSUR/0000248478

Applicant(s): various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00010853/202411)

Action: For adoption

6.3.10. Fluticasone / salmeterol[6] (NAP) - EMA/PSUR/0000248452

Applicant(s): various

PRAC Lead: Mari Thorn

Scope: Evaluation of a PSUSA procedure (PSUSA/00001455/202410)

Action: For adoption

[6] For nationally authorised products only

6.3.11. Isoniazid (NAP) - EMA/PSUR/0000248454

Applicant(s): various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00001789/202411)

Action: For adoption

6.3.12. Letrozole (NAP) - EMA/PSUR/0000248457

Applicant(s): various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00001842/202410)

Action: For adoption

6.3.13. Meningococcal group c polysaccharide conjugate vaccine (NAP) - EMA/PSUR/0000248458

Applicant(s): various

PRAC Lead: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00001971/202410)

Action: For adoption

6.3.14. Methylphenidate hydrochloride (NAP) - EMA/PSUR/0000248487

Applicant(s): various

PRAC Lead: Martin Huber

Scope: Evaluation of a PSUSA procedure (PSUSA/00002024/202410)

Action: For adoption

6.3.15. Miconazole, hydrocortisone / miconazole nitrate, miconazole nitrate / zinc oxide (NAP) - EMA/PSUR/0000248459

Applicant(s): various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00002052/202410)

Action: For adoption

6.3.16. Milrinone (NAP) - EMA/PSUR/0000248468

Applicant(s): various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00002064/202410)

Action: For adoption

6.3.17. Timolol[7] (NAP) - EMA/PSUR/0000249788

Applicant(s): various

PRAC Lead: Jana Lukacisinova

Scope: Evaluation of a PSUSA procedure (PSUSA/00010432/202410)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Azacitidine – ONUREG (CAP) – EMA/PAM/0000262249

Applicant(s): various

PRAC Rapporteur: Bianca Mulder

Scope: Clinical safety review: provision of a thorough causality assessment of all cumulative cases of differentiation syndrome and provision of a review of any cases of pericardial effusion and pericarditis with oral azacitidine for azacitidine oral and discuss the need for an update of the product information (LEG from EMEA/H/C/PSUSA/00010935/202405)

Action: For adoption

6.4.2. Ixekizumab – TALTZ (CAP) – EMA/PAM/0000262763

Applicant: Eli Lilly and Co (Ireland) Limited

PRAC Rapporteur: Gabriele Maurer

Scope: PAM/0000262763 - Response to the PRAC request for a LEG on Taltz for a cumulative review on major adverse cardiovascular events (MACE) using data from clinical trials, post-marketing sources and literature adopted on 31 October 2024 following an assessment of EMEA/H/C/PSUSA/00010493/202403 (ixekizumab PSUR 11 -covering period 23 March 2021 to 22 March 2024) and to be submitted within 6 months

Action: For adoption

6.4.3. Semaglutide – OZEMPIC (CAP) – EMA/PAM/0000262468

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

[7] For systemic use only

Scope: Clinical Safety Review: To assess the potential association between semaglutide exposure and non-arteritic anterior ischemic optic neuropathy (NAION)

Action: For adoption

6.4.4. Semaglutide – RYBELSUS (CAP) – EMA/PAM/0000262449

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Clinical Safety Review: To assess the potential association between semaglutide exposure and non-arteritic anterior ischemic optic neuropathy (NAION)

Action: For adoption

6.4.5. Semaglutide – WEGOVY (CAP) – EMA/PAM/0000262475

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Mari Thorn

Scope: Clinical Safety Review: To assess the potential association between semaglutide exposure and non-arteritic anterior ischemic optic neuropathy (NAION)

Action: For adoption

6.5. Variation procedure(s) resulting from PSUSA evaluation

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

Applicant: Kyowa Kirin Holdings B.V.

PRAC Rapporteur: Gabriele Maurer

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

Action: For adoption

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

Applicant: Celltrion Healthcare Hungary Kft.

PRAC Rapporteur: Karin Erneholm

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

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

Action: For adoption

6.6. Expedited summary safety reviews[8]

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[9]

7.1.1. Blinatumomab – BLINCYTO (CAP) – EMA/PASS/0000263976

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Jana Lukacisinova

Scope: PASS amendment [107o]: Substantial amendment to an observational PASS of long-term safety in paediatric patients with B-precursor acute lymphoblastic leukaemia (ALL) who have been treated with either blinatumomab or chemotherapy, followed by transplantation

Action: For adoption

7.1.2. Ciltacabtagene autoleucel – CARVYKTI (CAP) – EMA/PASS/0000264227

Applicant: Janssen Cilag International

PRAC Rapporteur: Jo Robays

Scope: PASS amendment [107o]: Substantial amendment to Study 68284528MMY4004: An Observational Post-authorization Safety Study to Evaluate the Safety of Multiple Myeloma Patients Treated with Ciltacabtagene Autoleucel [MAH's response to EMEA/H/C/PSA/S/0116]

Action: For adoption

7.1.3. Odevixibat – KAYFANDA (CAP) – EMA/PASS/0000262884

Applicant: Ipsen Pharma

PRAC Rapporteur: Adam Przybylkowski

Scope: PASS protocol [107n]: Prospective non-interventional study evaluating the long-term safety of odevixibat in patients with Alagille Syndrome (ALGS)

Action: For adoption

[8] 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
[9] In accordance with Article 107n of Directive 2001/83/EC

7.1.4. Pitolisant – WAKIX (CAP) – EMA/PASS/0000264232

Applicant: Bioprojet Pharma

PRAC Rapporteur: Terhi Lehtinen

Scope: PASS amendment [107o]: Substantial amendment to a 5-year multi-center, observational PASS to document the utilisation of Wakix in the treatment of narcolepsy with or without cataplexy and to collect information on its long-term safety when used in routine medical practice

Action: For adoption

7.1.5. Tofersen – QALSODY (CAP) – EMA/PASS/0000264233

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: PASS protocol [107n]: An observational registry-based study utilising data from two disease registry networks precision amyotrophic lateral sclerosis (ALS) and ALS/ motor neuron disease (MND) NHC to evaluate the long-term safety of tofersen in people with SOD1-ALS [MAH's response to EMEA/H/C/PSP/S/0109]

Action: For adoption

7.1.6. Volanesorsen – WAYLIVRA (CAP) – EMA/PASS/0000262889

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Martin Huber

Scope: PASS amendment [107o]: Substantial amendment to a PASS to characterise the safety and effectiveness of WAYLIVRA in patients with Familial Chylomicronaemia Syndrome (FCS) under real-world conditions

Action: For adoption

7.1.7. Voretigene neparvovec – LUXTURNA (CAP) – EMA/PASS/0000263977

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Gabriele Maurer

Scope: PASS amendment [107o]: Substantial amendment to a post-authorization observational study to collect long-term safety information (i.e., for 5 years after treatment) associated with voretigene neparvovec (vector and/or transgene), its subretinal injection procedure, the concomitant use of corticosteroids, or a combination of these procedures and products [MAH's response to EMEA/H/C/PSA/S/0114.1]

Action: For adoption

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[10]

7.2.1. Fremanezumab – AJOVY (CAP) – EMA/PAM/0000262615

Applicant: TEVA GmbH

PRAC Rapporteur: Terhi Lehtinen

Scope: Revised protocol for Study TV48125-MH-50038 "Assessment of Pregnancy Outcomes in Patients Treated with AJOVY (fremanezumab) in the Pregnancy Database Study (Non-Interventional Phase IV Study)"

Action: For adoption

7.2.2. Herpes zoster vaccine (recombinant, adjuvanted) – SHINGRIX (CAP) – EMA/PAM/0000262632

Applicant: GlaxoSmithKline Biologicals

PRAC Rapporteur: Sonja Radowan

Scope: From Initial MAA: previously MEA 009

Study EPI-ZOSTER-030 VS (Targeted Safety Study):

Non-interventional (observational) prospective cohort study to evaluate the safety of Shingrix in older adults (≥ 50 YOA) in the US.

protocol amendment for Study No. EPI-ZOSTER-030**

Action: For adoption

7.2.3. Interferon beta-1a – AVONEX (CAP) – EMA/PAM/0000262800

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Joint PASS see EMA/PAM/0000262645 (Betaferon) Revised protocol PASS INFORM 2600153: Observational Study regarding Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden

Action: For adoption

7.2.4. Interferon beta-1a – REBIF (CAP) – EMA/PAM/0000264549

Applicant: Merck Europe B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Joint PASS see EMA/PAM/0000262645 (Betaferon) Revised protocol PASS INFORM 2600153: Observational Study regarding Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden

[10] 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

Action: For adoption

7.2.5. Interferon beta-1b – BETAFERON (CAP) – EMA/PAM/0000262645

Applicant: Bayer AG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Joint PASS see EMA/PAM/0000262645 (Betaferon) Revised protocol PASS INFORM 2600153: Observational Study regarding Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden

Action: For adoption

7.2.6. Maribavir – LIVTENCITY (CAP) – EMA/PAM/0000262637

Applicant: Takeda Pharmaceuticals International AG

PRAC Rapporteur: Adam Przybylkowski

Scope: Submission of an amendment to the protocol version 1.0 for the Retrospective Chart Review Study (TAK-620-4007, a category 3Retrospective chart review study) as initially endorsed on September 14, 2023.

Action: For adoption

7.2.7. Peginterferon beta-1a – PLEGRIDY (CAP) – EMA/PAM/0000263236

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Joint PASS see EMA/PAM/0000262645 (Betaferon) Revised protocol PASS INFORM 2600153: Observational Study regarding Interferon-Beta Exposure in the 2nd and 3rd Trimester of Pregnancy - a Register-Based Drug Utilisation Study in Finland and Sweden

Action: For adoption

7.2.8. Romosozumab – EVENITY (CAP) – EMA/PAM/0000264559

Applicant: UCB Pharma

PRAC Rapporteur: Tiphaine Vaillant

Scope: Protocol amendment for PASS No. OP0006: European non-interventional post-authorisation safety study (PASS) related to serious infections risk for romosozumab by the EU-ADR Alliance to evaluate potential differences in terms of serious infection between romosozumab and currently available therapies used in comparable patients in real-world conditions

Action: For adoption

7.2.9. Romosozumab – EVENITY (CAP) – EMA/PAM/0000264555

Applicant: UCB Pharma

PRAC Rapporteur: Tiphaine Vaillant

Scope: Protocol amendment for PASS No. OP0004: European non-interventional post-authorisation safety study (PASS) related to serious cardiovascular adverse events of myocardial infarction and stroke for romosozumab by the EU-ADR Alliance to evaluate potential differences in terms of serious cardiovascular adverse events between romosozumab and currently available therapies used in comparable patients in real-world conditions

Action: For adoption

7.2.10. Rozanolixizumab – RYSTIGGO (CAP) – EMA/PAM/0000262838

Applicant: UCB Pharma

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Revised protocol for PASS No. MG0027 Real-world observational secondary data study: A Multi-National Cohort Study to evaluate the safety of rozanolixizumab in generalized myasthenia gravis patients

Action: For adoption

7.2.11. Setmelanotide – IMCIVREE (CAP) – EMA/PAM/0000262795

Applicant: Rhythm Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Anna Mareková

Scope: Protocol Amendment for the registry of patients with Biallelic Pro Opiomelanocortin (POMC), Proprotein Convertase Subtilisin/Kexin Type 1 (PCSK1), or Leptin Receptor (LEPR) Deficiency Obesity, or Bardet-Biedl Syndrome (BBS), Treated with Setmelanotide (RM-IMC-901) following CHMP recommendation on the extension of indications in paediatric population from 2 to less than 6 years of age (EMEA/H/C/5089/II/18). The registry is included as category 3 study in the RMP

Action: For adoption

7.2.12. Tirzepatide – MOUNJARO (CAP) – EMA/PAM/0000262771

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Protocol amendment for PASS No I8F-MC-B013: A database linkage study to evaluate the important potential risk of medullary thyroid cancer

Action: For adoption

7.2.13. Tisagenlecleucel – KYMRIAH (CAP) – EMA/PAM/0000258545

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of protocol of the MEA Category 3 PASS CCTL019B2402 study entitiled 'A Non-Interventional Study (NIS) PASS to characterize secondary malignancies of T-cell origin following tisagenlecleucel therapy'

Action: For adoption

7.2.14. Tofacitinib – XELJANZ (CAP) – EMA/PAM/0000261850

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the third interim study reports for the four Rheumatoid Arthritis (RA) Registry Post-Authorization Safety Studies (PASSs) in line with protocol milestones for A3921312 (v3.0), A3921314 (v4.0), A3921316 (v3.0) & A3921317 (v5.0) for Xeljanz (tofacitinib).

- A3921312: UK, British Society for Rheumatology Biologics Register-Rheumatoid Arthritis (BSRBR-RA)
- A3921314: Sweden (SE), Anti Rheumatic Treatment in Sweden (ARTIS) register.
- A3921316: Spain (ES), Registry of Adverse Events of Biological Therapies and Biosimilars in Rheumatoid Diseases (BIOBADASER)
- A3921317: Germany (DE), Registry Rheumatoide Arthritis: Beobachtung der Biologika-Therapie (RABBIT)

Submission of a revised PASS protocol version 4.0 (A3921312), version 5.0 (A3921314), version 4.0 (A3921316), and version 6.0 (A3921317) for Tofacitinib (Xeljanz). Follow on from MEA 8.7+9.7+10.7+11.8

Action: For adoption

7.2.15. Zilucoplan – ZILBRYSQ (CAP) – EMA/PAM/0000262862

Applicant: UCB Pharma

PRAC Rapporteur: Karin Erneholm

Scope: Revised protocol for PASS MG0026: A Multi-National Cohort Study to Assess the Implementation of the Risk Minimization Measures to Prevent Meningococcal Infection in Patients with Generalized Myasthenia Gravis Initiating Zilucoplan, and Zilucoplan Safety in Real-World Settings

Action: For adoption

7.3. Results of PASS imposed in the marketing authorisation(s)[11]

7.3.1. Blinatumomab – BLINCYTO (CAP) – EMA/PASS/0000262863

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Jana Lukacisinova

Scope: PASS results [107q]: Final study report for an observational study of blinatumomab safety and effectiveness, utilisation, and treatment practices

Action: For adoption

7.3.2. Pomalidomide – IMNOVID (CAP) – EMA/PASS/0000262876

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Monica Martinez Redondo

Scope: PASS results [107q]: Final study report for a non-interventional post authorization registry of patients treated with pomalidomide for relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy

Action: For adoption

7.4. Results of PASS non-imposed in the marketing authorisation(s)[12]

7.4.1. Brexucabtagene autoleucel - TECARTUS (CAP) - EMEA/H/C/005102/II/0051, Orphan

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Submission of the final study report for the non-interventional study KT-EU-472-5966 titled "Quantitative Testing of Health Care Professional Knowledge About Tecartus Risk Minimisation Measures'' listed as a category 3 study in the RMP

Action: For adoption

7.4.2. Covid-19 vaccine (recombinant, adjuvanted) – BIMERVAX (CAP) – EMA/VR/0000262308

Applicant: Hipra Human Health S.L.

PRAC Rapporteur: Zane Neikena

Scope: Submission of an updated RMP version 2.0 in order to remove one category 3 study (C-VIPER PASS), to include changes to the due date for the provision of the final study report

[11] In accordance with Article 107p-q of Directive 2001/83/EC
[12] 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

for two category 3 studies (VAC4EU PASS, VAC4EU PAES) and to add BIMERVAX XBB.1.16 (Omicron XBB.1.16-adapted BIMERVAX)

Action: For adoption

7.4.3. Dabigatran etexilate – PRADAXA (CAP) – EMA/VR/0000256456

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansens

Scope: Submission of the final report from the non-interventional paediatric PASS 1160.307, listed as a category 3 study in the RMP. This is an observational study to evaluate the safety of dabigatran etexilate for the treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from birth to less than 2 years of age in routine clinical practice setting. The RMP version 41.3 has also been submitted.

Action: For adoption

7.4.4. Fingolimod – GILENYA (CAP) – EMA/VR/0000257758

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: A grouped application consisting of:

C.I.4: Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from Gilenya Pregnancy Registry (study CFTY720D2404) listed as a category 3 study in the RMP; this is a non-interventional, prospective, observational study in pregnant multiple sclerosis (MS) patients with confirmed or suspected maternal exposure to fingolimod; the Package Leaflet is updated accordingly. The RMP version 21.0 has also been submitted. In addition, the MAH took the opportunity to bring editorial changes to the PI.

C.I.4: Update of section 4.6 of the SmPC in order to update information on pregnancy based on the fingolimod Pregnancy outcomes Intensive Monitoring (PRIM) program to collect pregnancy outcome data from the Novartis global pharmacovigilance (PV) database; the Package Leaflet is updated accordingly. The RMP version 21.0 has also been submitted

Action: For adoption

7.4.5. Filgrastim – FILGRASTIM HEXAL (CAP); ZARZIO (CAP) – EMA/VR/0000249070

Applicant: Sandoz GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Submission of the final report from study EP06-501 listed as a category 3 study in the RMP. This is a non-interventional, prospective, long-term observational PASS to assess the safety and effectiveness of Zarzio / Filgrastim HEXAL (EP2006) administered to healthy unrelated stem cell donors for peripheral blood progenitor cell mobilization. The RMP version 14.0 has also been submitted

Action: For adoption

7.4.6. Icatibant - FIRAZYR (CAP) - EMEA/H/C/000899/II/0061

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Mari Thorn

Scope: Update of section 4.6 based on final results from the Icatibant Outcome Survey (IOS) registry listed as a category 3 study in the RMP; this is a prospective, observational disease registry. The RMP version 8 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.4

Action: For adoption

7.4.7. Lenalidomide - REVLIMID (CAP) - EMEA/H/C/000717/II/0130

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Tiphaine Vaillant

Scope: Submission of the final report from study CC-5013-MCL-005 listed as a category 3 study in the RMP. This is a non-interventional, post-authorization safety study of patients with relapsed or refractory mantle cell lymphoma to further investigate and characterize the association of lenalidomide with tumor flare reaction and high tumor burden. The RMP version 42.0 has also been submitted

Action: For adoption

7.4.8. Natalizumab – TYSABRI (CAP) – EMA/VR/0000262419

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: A grouped application consisting of:

C.I.4: Update of sections 4.4 and 5.1 of the SmPC in order to update pharmacodynamic information based on final results from study 101MS411, listed as a category 3 study in the RMP; this is an observational study utilising data from the US Tysabri TOUCH programme and select EU multiple sclerosis (MS) registries to estimate the risk of progressive multifocal leukoencephalopathy (PML) and other serious opportunistic infections among patients who were exposed to an MS disease modifying treatment prior to treatment with Tysabri. The RMP version 32.2 has also been submitted.

C.I.4: Update of section 5.1 of the SmPC in order to update pharmacodynamic information based on final results from study IMA 06 02 (TOP) listed as a category 3 study in the RMP. This is an observational study to evaluate the long-term safety and impact on disease activity and progression of Tysabri as a single disease-modifying agent in patients with relapsing-remitting MS (RRMS) in a clinical practice setting

Action: For adoption

7.4.9. Tocilizumab – ROACTEMRA (CAP) – EMA/VR/0000261482

Applicant: Roche Registration GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: Submission of the final report for study ML28664 (RABBIT), listed as a category 3 study in the RMP. This was a non-interventional post-authorisation safety study aimed at collecting and analysing safety data related to the use of tocilizumab in rheumatoid arthritis patients in Germany. The RMP version 30.0 has also been submitted. In addition, the MAH removed the education materials from the RMP and PI as agreed by PRAC during procedure PSUSA/00002980/202204. Furthermore, the MAH took the opportunity to introduce editorial and formatting changes to the PI and to align the wording used for the pre-filled syringe and the pre-filled pen, as well as to update the list of local representatives in the Package Leaflet

Action: For adoption

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

7.5.1. Cabotegravir – VOCABRIA (CAP) – EMA/PAM/0000262608

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: 3rd interim study report from EuroSIDA-hepatotoxicity study (study 215162, cat. 3 study). A Prospective Observational Cohort Study to Monitor for Hepatotoxicity and Regimen Discontinuation due to Liver Related Adverse Events among People with HIV, initiating Cabotegravir + Rilpivirine Regimens

Action: For adoption

7.5.2. Efgartigimod alfa – VYVGART (CAP) – EMA/PAM/0000263274

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: 2nd interim report for PASS category 3 study (ARGX-113-PAC-2206): This is a multi-country, prospective safety study of pregnant women exposed to efgartigimod during pregnancy and/or breastfeeding or any time within 25 days prior to conception in order to assess maternal, fetal, and infant outcomes

Action: For adoption

7.5.3. Filgotinib – JYSELECA (CAP) – EMA/PAM/0000261394

Applicant: Alfasigma S.p.A.

PRAC Rapporteur: Petar Mas

Scope: Interim study report for GLPG0634-CL-408: Evalutation of the effectiveness of the additional risk minimization measures for filgotinib use in patients with moderate to severe active rheumatoid arthritis within European registries

Action: For adoption

7.5.4. Ketoconazole – KETOCONAZOLE ESTEVE (CAP) – EMA/PAM/0000256150

Applicant: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Petar Mas

Scope: Response to RSI from seventh interim report on PASS study EUPAS21731

Action: For adoption

7.5.5. Ofatumumab – KESIMPTA (CAP) – EMA/PAM/0000261333

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: Interim study results for PASS COMB157G2399 (ALITHIOS): An open-label, single arm, multi-center extension study evaluating long-term safety, tolerability and effectiveness of ofatumumab in subjects with relapsing multiple sclerosis

Action: For adoption

7.5.6. Selexipag – UPTRAVI (CAP) – EMA/PAM/0000263266

Applicant: Janssen Cilag International

PRAC Rapporteur: Zoubida Amimour

Scope: The 8th annual interim report of study AC-065A401 (EXPOSURE) with data cut-off date of 30 November 2024 is submitted as per agreed study milestones

Action: For adoption

7.5.7. Talimogene laherparepvec – IMLYGIC (CAP) – EMA/PAM/0000262826

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: 7th interim report: PASS 20130193: A post-marketing, prospective cohort study of patients treated with talimogene laherparepvec in clinical practice to characterize the risk of herpetic illness among patients, close contacts, and healthcare providers; and long term safety in treated patients

Action: For adoption

7.6. Others

7.6.1. Atogepant – AQUIPTA (CAP) – EMA/PAM/0000256967

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: Second annual progress report dated 31 January 2025 for non-interventional, category 3 PASS P22-419 observational cohort study using administrative healthcare claims data to assess the risk of pregnancy and infant outcomes among pregnant women using atogepant

Action: For adoption

7.6.2. Atogepant – AQUIPTA (CAP) – EMA/PAM/0000256954

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: Second interim annual progress report for non-interventional, category 3 PASS P22-392 observational prospective study

Action: For adoption

7.6.3. Daratumumab – DARZALEX (CAP) – EMA/PAM/0000262246

Applicant: Janssen Cilag International

PRAC Rapporteur: Carla Torre

Scope: Provision of the final Statistical Analysis Plan (SAP) for Study AMY2009: a multicentre, multicohort, open-label, Phase 2 study in participants with newly diagnosed systemic AL amyloidosis. The primary objective of the study is to further characterise cardiac adverse events in patients with newly diagnosed AL amyloidosis treated with subcutaneous daratumumab-based therapy in terms of the incidence, severity, clinical presentation, management, and outcome

Action: For adoption

7.6.4. Mavacamten – CAMZYOS (CAP) – EMA/PAM/0000262744

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Kimmo Jaakkola

Scope: PASS No CV027-1148: First progress report for meta-analysis of Phase 3 placebo controlled, double-blind randomized studies of mavacamten in patients with symptomatic hypertrophic cardiomyopathy (HCM) to evaluate the cardiovascular (CV) safety profile. The major adverse cardiovascular events (MACE) meta-analysis will assess CV safety based on a composite endpoint of time to first occurrence of MACE meta-analysis event. It will include three clinical trials in symptomatic oHCM population (EXPLORER-HCM, VALOR-HCM, China oHCM Phase 3 trial) and one clinical trial in symptomatic nHCM population (ODYSSEY-HCM). The meta-analysis is listed as cat 3 study in the approved RMP (v. 4.1)

Action: For adoption

7.6.5. Risankizumab – SKYRIZI (CAP) – EMA/PAM/0000262752

Applicant(s): Abbvie Deutschland GmbH & Co. KGn
PRAC Rapporteur: Liana Martirosyan

Scope: Study Progress Report PASS Study P16-751: Pregnancy Exposures and Outcomes in Psoriasis Patients Treated with Risankizumab: A Cohort Study Utilising Large Healthcare Databases with Mother-Baby Linkage in the United States

Action: For adoption

7.6.6. Venetoclax – VENCLYXTO (CAP) – EMA/PAM/0000261396

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: Annual update report for study P22-905: A cross-sectional study evaluating the effectiveness of the venetoclax patient card among adult patients in Europe

Action: For adoption

7.6.7. Venetoclax – VENCLYXTO (CAP) – EMA/PAM/0000262601

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Eva Jirsová

Scope: 7th Study Progress Report for Study P16-562: A prospective observational study to assess the long-term safety profile of venetoclax in a Swedish cohort of Chronic Lymphocytic Leukemia (CLL) Patients

Action: For adoption

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. Amifampridine – FIRDAPSE (CAP) – EMA/S/0000257410

Applicant: Serb

PRAC Rapporteur: Karin Bolin

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.2. Clofarabine – EVOLTRA (CAP) – EMA/S/0000257017

Applicant: Sanofi B.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. Velmanase alfa – LAMZEDE (CAP) – EMA/S/0000257415

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.4. Tabelecleucel – EBVALLO (CAP) - EMA/S/0000249324

Applicant: Pierre Fabre Medicament

PRAC Rapporteur: Amelia Cupelli

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

None

8.3. Renewals of the marketing authorisation

8.3.1. Atidarsagene autotemcel – LIBMELDY (CAP) – EMA/R/0000257479

Applicant: Orchard Therapeutics (Netherlands) B.V.

PRAC Rapporteur: Gabriele Maurer

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.2. Cabotegravir – VOCABRIA (CAP) – EMA/R/0000256925

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.3. Fenfluramine – FINTEPLA (CAP) – EMA/R/0000256601

Applicant: UCB Pharma

PRAC Rapporteur: Martin Huber

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.4. Formoterol / glycopyrronium bromide / budesonide – TRIXEO AEROSPHERE (CAP) – EMA/R/0000245136

Applicant: AstraZeneca AB

PRAC Rapporteur: Jan Neuhauser

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Latanoprost / netarsudil – ROCLANDA (CAP) – EMA/R/0000255956

Applicant: Santen Oy

PRAC Rapporteur: Adam Przybylkowski

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. Lenalidomide – LENALIDOMIDE MYLAN (CAP) – EMA/R/0000257483

Applicant: Mylan Pharmaceuticals Limited

PRAC Rapporteur: Tiphaine Vaillant

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.7. Rilpivirine – REKAMBYS (CAP) – EMA/R/0000257069

Applicant: Janssen Cilag International

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.8. Rivaroxaban – RIVAROXABAN ACCORD (CAP) – EMA/R/0000249659

Applicant: Accord Healthcare S.L.U.

PRAC Rapporteur: Mari Thorn

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.9. Susoctocog alfa – OBIZUR (CAP) - EMA/R/0000248614

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Gabriele Maurer

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

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

11.1.1. Buprenorphine (transdermal patches) (NAP) - DE/H/4394/001-003/II/016

Applicant: Glenmark Arzneimittel GmbH

PRAC Lead: Martin Huber

Scope: PRAC consultation on type II variations to update the product information of buprenorphine-containing products (transdermal patches) regarding the risks of persistent post-operative opioid use (PPOU) and opioid-induced ventilatory impairment (OIVI) based on MHRA safety reviews, at the request of Germany

Action: For adoption

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. Scientific Committee Meetings – alternating face-to-face and virtual meetings schedule for 2026

Action: For information

12.1.3. Vote by proxy

Action: For information

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

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

None

12.4. Cooperation within the EU regulatory network

12.4.1. Explanatory note on the withdrawal of the 'Interim guidance of seasonal influenza vaccines enhanced safety surveillance systems'

PRAC leads: Jean Michel Dogné

Action: For adoption

12.4.2. The Incident Management Plan - overview and guidance update

Action: For information

12.5. Cooperation with International Regulators

12.5.1. EMA/FDA Collaboration and the Liaison Program

Action: For information

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

None

12.7. PRAC work plan

None

12.8. Planning and reporting

None

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits - Working Group of Quality Managers (WGQM) - report to PRAC

PRAC lead: Jan Neuhauser; Klaus Stuewe (WGQM Chair)

Action: For discussion

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

Action: For adoption

12.11. Signal management

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

PRAC lead: Martin Huber

Action: For discussion

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.13.2. Necessity and proportionality of keeping personal data included in Individual Case Safety Reports (ICSRs) – European Data Protection Supervisor (EDPS) Audit recommendation

Action: For discussion

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

12.18.3. Webpage dedicated to risk minimisation measures on EMA website - new initiative

Action: For discussion

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

12.21. Others

12.21.1. Association of venous thromboembolism with non-steroidal anti-inflammatory drug use in women 15-49 years using hormonal contraceptives (P3-C3-008) DARWIN EU® - PRAC Sponsor's critical appraisal

PRAC lead: Karin Erneholm

Action: For discussion

12.21.2. Fitness-for-use of Real-world data (RWD) sources on Duchenne Muscular Dystrophy (DMD)

Action: For information

12.21.3. Good Pharmacovigilance Practice (GVP) – mid-year update 2025

PRAC lead: Ulla Wändel Liminga

Action: For discussion

13. Any other business

None

14. Explanatory notes

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

List of acronyms and abbreviations

For a list of acronyms and abbreviations used in the PRAC agenda, see:

List of abbreviations used in EMA human medicines scientific committees and CMDh documents, and in relation to EMA's regulatory activities

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/