08 June 2026
EMA/PRAC/115322/2026
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 08-11 June 2026

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

08 June 2026, 09:30 – 19:30, room via teleconference

09 June 2026, 08:30 – 19:30, room via teleconference

10 June 2026, 08:30 – 19:30, room via teleconference

11 June 2026, 08:30 – 16:00, room via teleconference

Organisational, regulatory and methodological matters (ORGAM)

25 June 2026 via teleconference

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 08-11 June 2026. See June 2026 PRAC minutes (to be published post July 2026 PRAC meeting).

1.2. Agenda of the meeting on 08-11 June 2026

Action: For adoption

1.3. Minutes of the previous meeting on 04-07 May 2026

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 procedure

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. Abemaciclib – VERZENIOS (CAP); palbociclib – IBRANCE (CAP); ribociclib – KISQALI (CAP)

Applicant: Eli Lilly Nederland B.V. (Verzenios), Novartis Europharm Limited (Kisqali), Pfizer Europe MA EEIG (Ibrance)

PRAC Rapporteur: To be appointed

Scope: Signal of progressive multifocal leukoencephalopathy (PML)

Action: For adoption of PRAC recommendation

EPITT 20271 – New signal

Lead Member State(s): DK, PT

4.1.2. Atezolizumab – TECENTRIQ (CAP); avelumab – BAVENCIO (CAP); cemiplimab - LIBTAYO (CAP); dostarlimab – JEMPERLI (CAP); durvalumab – IMFINZI (CAP); ipilimumab – YERVOY (CAP); nivolumab – OPDIVO (CAP); nivolumab / relatlimab – OPDUALAG (CAP); pembrolizumab – KEYTRUDA (CAP); retifanlimab – ZYNYZ (CAP); serplulimab - HETRONIFLY (CAP); sugemalimab – CEJEMLY (CAP); tislelizumab – TEVIMBRA (CAP); toripalimab – LOQTORZI (CAP); tremelimumab – IMJUDO (CAP)

Applicants: Accord Healthcare S.L.U. (Hetronifly), AstraZeneca AB (Imfinzi, Imjudo), Beone Medicines Ireland Limited (Tevimbra); Bristol-Myers Squibb Pharma (Opdivo), Bristol-Myers Squibb Pharma EEIG (Opdualag, Yervoy), Cstone Pharmaceuticals Ireland Limited (Cejemly), Incyte Biosciences Distribution B.V. (Zynyz), Merck Europe B.V. (Bavencio), Merck Sharp & Dohme B.V. (Keytruda), Glaxosmithkline Trading Services Limited (Jemperli), Regeneron Ireland U.C. (Libtayo), Roche Registration GmbH (Tecentriq),

[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

Topalliance Biosciences Europe Limited (Loqtorzi)

PRAC Rapporteur: To be appointed

Scope: Signal of acquired haemophilia

Action: For adoption of PRAC recommendation

EPITT 20279 – New signal

Lead Member States: DE, DK, HR, NL, NO, PT, AT

4.1.3. Belzutifan – WELIREG (CAP)

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Dennis Lex

Scope: Signal of retinal oedema

Action: For adoption of PRAC recommendation

EPITT 20278 – New signal

Lead Member State(s): DE

4.1.4. Cefpodoxime (NAP)

Applicant: various

PRAC Rapporteur: To be appointed

Scope: Signal of drug interaction between cefpodoxime and proton pump inhibitor (PPIs) resulting in a potentially reduced efficacy of cefpodoxime

Action: For adoption of PRAC recommendation

EPITT 20280

4.1.5. Lithium (NAP)

Applicants: various

PRAC Rapporteur: To be appointed

Scope: Signal of drug interaction between lithium and GLP-1 agonists leading to increased lithium levels

Action: For adoption of PRAC recommendation

EPITT 20275 – New signal

Lead Member State: DE

4.1.6. Luspatercept - REBLOZYL (CAP)

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Jo Robays

Scope: Signal of ventilation perfusion mismatch

Action: For adoption of PRAC recommendation

EPITT 20281 – New signal

Lead Member State: BE

4.1.7. Osimertinib - TAGRISSO (CAP)

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Signal of pulmonary alveolar haemorrhage

Action: For adoption of PRAC recommendation

EPITT 20284 – New signal

Lead Member State: NL

4.2. Signals follow-up and prioritisation

4.2.1. Darolutamide - NUBEQA (CAP) - EMEA/H/C/004790/SDA/005

Applicant: Bayer AG

PRAC Rapporteur: Jan Neuhauser

Scope: Signal of angioedema

Action: For adoption of PRAC recommendation

EPITT 20237 – Follow-up to January 2026

4.2.2. Gemcitabine (NAP)

Applicant(s): various

PRAC Lead: Jenny Jönsson

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

Action: For adoption

EPITT 20256 – New signal

4.2.3. Valproate (NAP) and related substances[3]

Applicant(s): various

PRAC Lead: Liana Martirosyan

Scope: Signal of neurodevelopmental disorders with paternal exposure

[3] Valproic acid, sodium valproate, valproate semisodium, valpromide,

Action: For adoption

EPITT 20191 – Follow-up to December 2025

4.2.4. Vortioxetine - BRINTELLIX (CAP) - EMEA/H/C/002717/SDA/011

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Jo Robays

Scope: Signal of acute pancreatitis

Action: For adoption

EPITT 20234 – Follow-up to January 2026

4.2.5. X-ray contrast agents: Iobitridol (NAP); Iodixanol (NAP); Iohexol (NAP); Iomeprol (NAP); Iopamidol (NAP); Iopromide (NAP); Ioversol (NAP); Ioxitalamic acid (NAP)

Applicants: various

PRAC Lead: Pernille Harg

Scope: Signal of fixed drug eruption

Action: For adoption

EPITT 20229 - Follow-up to January 2026

4.2.6. Zolbetuximab - VYLOY (CAP) - EMEA/H/C/005868/SDA/002

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Signal of protein-losing gastroenteropathy

Action: For adoption

EPITT 20236 – Follow-up to January 2026

4.3. Variation procedure(s) resulting from signal evaluation

None

5. Risk management plans (RMPs)

5.1. Medicines in the pre-authorisation phase

5.1.1. Glepaglutide - (CAP MAA) - EMEA/H/C/005855

Scope (pre D-180 phase): Treatment of adults with short bowel syndrome

Action: For adoption

5.1.2. Omalizumab (CAP MAA) - EMEA/H/C/006756

Scope (pre D-180 phase): Treatment of asthma, chronic rhinosinusitis with nasal polyps (CRSwNP) and chronic spontaneous urticaria (CSU)

Action: For adoption

5.1.3. Pegfilgrastim (CAP MAA) - EMEA/H/C/006085

Scope (pre D-180 phase): Reduction of neutropoenia in adults

Action: For adoption

5.1.4. RABIES VIRUS (INACTIVATED) STRAIN WISTAR (PM/WI 38-1503-3M) (CAP MAA) - EMEA/H/C/006602

Scope (pre D-180 phase): Pre-exposure and post-exposure prophylaxis against rabies in all age groups

Action: For adoption

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

5.2.1. Bosentan – STAYVEER (CAP); TRACLEER (CAP) – EMA/VR/0000316336

Applicant: Janssen Cilag International

PRAC Rapporteur: Zoubida Amimour

Scope: Submission of an updated RMP version 12 for TRACLEER and STAYVEER to remove the Liver Safety Update Report (LSUR) as a routine pharmacovigilance activity for the important identified risk of hepatotoxicity. The Annex II is updated accordingly. In addition, the MAH is updating the list of safety concerns in line with requests from the PRAC in their assessment report for procedure PSUSA/00000425/202411.

Action: For adoption

5.2.2. Emtricitabine / Tenofovir disoproxil - EMTRICITABINE/TENOFOVIR DISOPROXIL ZENTIVA (CAP); NAP – EMA/VR/0000335678

Applicants: Zentiva k.s., various

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: To update the RMP in line with the reference medicinal product:

To remove missing Information Safety in pregnancy and lactation. To add Annex 4: Specific Adverse Reaction Follow-up Questionnaire for Lack of efficacy in pre-exposure prophylaxis. And to remove Follow-up form for renal toxicity, Follow-up form for renal tubulopathy, Follow-up form for bone events, Pregnancy report form (to report pregnancy before outcome is known) and Pregnancy outcome report (to be used when pregnancy outcome is known).

Action: For adoption

5.2.3. Infliximab – REMICADE (CAP) – EMA/VR/0000338953

Applicant: Janssen Cilag International

PRAC Rapporteur: Karin Bolin

Scope: Submission of an updated RMP version 23.1 in order to reduce the planned duration of follow up in the DEVELOP registry from 20 years to 10 years for all patients currently active in the registry, which is listed as a category 3 study in the RMP, as well as to introduce additional changes to the RMP.

Action: For adoption

5.2.4. Lecanemab – LEQEMBI (CAP) – EMA/VR/0000302769

Applicant: Eisai GmbH

PRAC Rapporteur: Eva Jirsová

Scope: Submission of an updated RMP version 1.1 in order to propose an update to PASS study deadlines. In addition, the MAH has taken the opportunity to update Annex II accordingly.

Action: For adoption

5.2.5. Loncastuximab tesirine – ZYNLONTA (CAP) – EMA/VR/0000337919

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Eva Jirsová

Scope: Submission of an updated RMP version 3.1 in order to remove the Category 3 study ADCT-402-107 (LOTIS-10). This is a phase 1b, open-label, non-randomized, dose-escalation hepatic impairment (HI) study to determine the recommended dosing regimen of loncastuximab tesirine in patients with moderate and severe HI, with assessment of safety and pharmacokinetics.

Action: For adoption

5.2.6. Teriflunomide - TERIFLUNOMIDE VIATRIS (CAP), NAP – EMA/VR/0000320266

Applicants: Viatris Limited, various

PRAC Rapporteur: Dennis Lex

Scope: C.I.11.z - to propose an updated RMP to align it with the one from reference product Aubagio® (teriflunomide) RMP version 9.1, dated 28-Mar-2024 (MAH Sanofi), published by EMA on 12 June 2024.

Action: For adoption

5.2.7. Tenofovir disoproxil - TENOFOVIR DISOPROXIL ZENTIVA (CAP), NAP – EMA/VR/0000342258

Applicants: Zentiva k.s., various

PRAC Rapporteur: Zoubida Amimour

Scope: Type IB, C.9.b – to provide an updated RMP update following adoption of the same changes for the reference product VIREAD RMP during procedure EMAVR0000280825.

Important Identified risks: Renal Toxicity; Bone events due to proximal renal tubulopathy / loss of bone mineral density and Missing Information: Safety in pregnancy and lactation; Safety in patients with renal impairment were removed. All Specific adverse reaction follow-up questionnaires were removed.

Action: For adoption

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

5.3.1. Atogepant – AQUIPTA (CAP) – EMA/VR/0000334780

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilviniene

Scope: Update of section 5.1 of the SmPC in order to update long term safety, tolerability and efficacy information based on final results from study 3101-312-002 listed as a category 3 study in the RMP; this is a phase 3, multicenter, open-label, 156-week extension study to evaluate the long-term safety and tolerability of oral atogepant for the prevention of migraine in participants with chronic or episodic migraine. The RMP version 2.3 has also been submitted.

Action: For adoption

5.3.2. Concizumab – ALHEMO (CAP) – EMA/VR/0000335954

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include routine prophylaxis of bleeding in paediatric patients below 12 years of age with haemophilia A or B with or without inhibitors for ALHEMO, based on the results from the phase 3 study NN7415-4616; this is an open-label study investigating efficacy, safety and pharmacokinetics of concizumab prophylaxis in children below 12 years with haemophilia A or B with or without inhibitors. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor edits to the PI.

Action: For adoption

5.3.3. COVID-19 vaccine (recombinant, adjuvanted) – BIMERVAX (CAP) – EMA/VR/0000316063

Applicant: Hipra Human Health S.L.

PRAC Rapporteur: Zane Neikena

Scope: Update of section 4.5 of the SmPC in order to add coadministration information with seasonal influenza vaccines based on final results from study HIPRA-HH-11. HIPRA-HH-11 was a Phase II randomized, double-blind, multi-centre trial to evaluate the safety and immunogenicity of BIMERVAX when coadministered with seasonal surface antigen, inactivated adjuvanted influenza vaccine (SIIV) in adults older than 65 years of age fully vaccinated against COVID-19. The Package Leaflet is updated accordingly. The RMP version 3.0 is also submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.

Action: For adoption

5.3.4. Daratumumab – DARZALEX (CAP) – EMA/VR/0000334930

Applicant: Janssen Cilag International

PRAC Rapporteur: Carla Torre

Scope: Update of section 4.8 of the SmPC in order to add ''Hypotension and Weight decreased'' to the list of adverse drug reactions (ADRs) with frequency ''Common'' and to update the description of the Summary of the safety profile to remove influenza of the serious adverse reactions based on final results from study AMY2009 listed as a category 3 study in the RMP; this is phase 2, a multicenter, prospective study of daratumumab-based therapy in newly diagnosed patients with Amyloid light-chain (AL) amyloidosis and with pre-existing Mayo Cardiac Stage II and IIIa cardiac involvement, to further characterize cardiac adverse effects in terms of incidence, severity, clinical presentation, management, and outcome, and to identify potential mitigation strategies. The package leaflet is updated accordingly. The RMP version 13.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.5. Dengue tetravalent vaccine (live, attenuated) – DENGUE TETRAVALENT VACCINE (LIVE, ATTENUATED) TAKEDA (Art 58); QDENGA (CAP) – EMA/VR/0000323434

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update safety and efficacy information regarding the administration of a booster dose based on the final results of Part 5 from study DEN-301, listed as a category 3 study in the RMP; this is a Phase III, double-blind, randomized, placebo-controlled trial to investigate the efficacy, safety and immunogenicity of a Tetravalent Dengue Vaccine (TDV) administered subcutaneously in healthy children aged 4–16 years old, investigating a TDV booster dose in the booster phase (Parts 4 and 5) of the trial. The RMP version 3.3 has also been submitted. In addition, the

MAH took the opportunity to introduce minor formatting changes to the PI and to update the list of local representatives in the Package Leaflet for Qdenga.

Action: For adoption

5.3.6. Dinutuximab beta – QARZIBA (CAP) – EMA/VR/0000316241

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: A grouped application, comprised of the following variations:

C.I.4: Update of sections 4.8 and 5.1 of the SmPC to introduce changes based on the final results from study APN311-304; this is a Phase II, interventional, single-arm, open-label study evaluating the anti-tumor activity and safety of dinutuximab beta (ch14.18/CHO) continuous infusion in pediatric patients with primary refractory or relapsed neuroblastoma. The Package Leaflet has been updated accordingly.

C.I.4: Update of sections 4.8 and 5.1 of the SmPC to introduce changes based on the final results from study APN311-202 V1/V2; this is a Phase I/II, interventional, multi-center, open-label study evaluating the tolerability, immunomodulatory efficacy, and anti-tumor activity of dinutuximab beta (ch14.18/CHO) administered as prolonged continuous infusion in combination with subcutaneous aldesleukin (IL-2) in pediatric patients with primary refractory or relapsed neuroblastoma. The Package Leaflet has been updated accordingly.

C.I.13: Submission of final results from study APN 311-201. This is a Phase II feasibility study using ch14.18/CHO antibody and subcutaneous interleukin 2 after haploidentical stem cell transplantation in children with relapsed neuroblastoma.

The RMP version 10.1 has also been submitted. In addition, the MAH took the opportunity to introduce changes to the PI for completion and to update excipient wording for polysorbates.

Action: For adoption

5.3.7. Enfortumab vedotin – PADCEV (CAP) – EMA/VR/0000336191

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include Padcev, in combination with pembrolizumab, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment, is indicated for the treatment of adults with muscle invasive bladder cancer (MIBC) who are eligible for cisplatin-containing chemotherapy, based on the results from Interim Analysis 1 of the pivotal Study KN-B15 (EV-304); this is a phase 3, randomized, open-label study to evaluate perioperative enfortumab vedotin plus pembrolizumab (MK-3475) versus neoadjuvant gemcitabine and cisplatin in cisplatin-eligible participants with Muscle-Invasive Bladder Cancer. As consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC have been updated; the Package Leaflet is updated accordingly. Version 6.1 of the RMP is submitted, to reflect the updated data. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.8. Ertugliflozin – STEGLATRO (CAP) – EMA/VR/0000335920

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of new paediatric population aged 10 years and older for STEGLATRO, based on final results from paediatric study study MK-8835-P059/B1521066 (P059). This is a randomised, double-blind, placebo-controlled trial to evaluate the safety and efficacy of two doses of ertugliflozin in paediatric patients from 10 years to less than 18 years of age with type 2 diabetes mellitus and inadequate glycaemic control on metformin therapy, ± insulin. 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 2.5 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to implement minor editorial/formatting corrections.

Action: For adoption

5.3.9. Florbetapir (^{18}F) – AMYVID (CAP) – EMA/VR/0000333287

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Dennis Lex

Scope: Update of section 4.8 of the SmPC in order to revise the frequency category of ADRs and include additional adverse reaction terms related to injection site reactions based on a pooled safety analysis incorporating cumulative florbetapir (^{18}F) exposure data from 26 979 subjects from 48 clinical trials; the Package Leaflet is updated accordingly. The RMP version 6.1 has also been submitted. In addition, the MAH took the opportunity update Annex II.D of the SmPC to align with proposed RMP changes.

Action: For adoption

5.3.10. Gemtuzumab ozogamicin – MYLOTARG (CAP) – EMA/VR/0000304835

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include, in combination with mitoxantrone and cytarabine (AraC), the treatment of paediatric patients aged 1 year to less than 18 years with newly diagnosed CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL) for MYLOTARG, based on results from study MyeChild 01 (WI203680). This is a Phase 3, randomised, open-label, multicenter study incorporating an embedded dose finding study in children with newly diagnosed AML/high risk MDS /isolated myeloid sarcoma (de novo or secondary). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.11. Guanfacine – INTUNIV (CAP) – EMA/VR/0000334464

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Update of section 5.1 of the SmPC in order to update long term efficacy and safety information based on final results from study SPD503-401 listed as a specific obligation in Annex II; this is an interventional, a phase 4, long-term safety and efficacy study comprising a randomized, double-blind, parallel-group, placebo-controlled, active-comparator phase followed by an open-label phase conducted in children and adolescents aged 6 to 17 years with ADHD to assess long term safety of guanfacine; the Package Leaflet and Annex II of the PI are updated accordingly. The RMP version 5.0 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI.

Action: For adoption

5.3.12. Ivacaftor / Tezacaftor / Elexacaftor – KAFTRIO (CAP) – EMA/VR/0000320413

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Dennis Lex

Scope: Submission of Part A (week 96) clinical study report for study VX21-445-125 (study 125). This is a Phase 3, open-label study to evaluate the long-term safety, tolerability, efficacy, and pharmacodynamics of elexacaftor/tezacaftor/ivacaftor (ELX/TEZ/IVA) in cystic fibrosis (CF) subjects ≥6 years of age who have qualifying non-F508del ELX/TEZ/IVA-responsive CFTR mutations. RMP version 10.3 has also been submitted.

Action: For adoption

5.3.13. Meningococcal Group A, C, W and Y conjugate vaccine – MENQUADFI (CAP) – EMA/VR/0000281377

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Jean-Michel Dogné

Scope: Extension of indication for MENQUADFI to include the active immunisation of patients from 6 weeks of age based on final results from study MET58 and additional supportive clinical studies. Study MET58 is a Phase 3, immunogenicity and Safety Study of an Investigational Quadrivalent Meningococcal Conjugate Vaccine when Administered Concomitantly with Routine Pediatric Vaccines in Healthy Infants and Toddlers in Europe. As a consequence, sections 4.1, 4.2, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. An updated Risk Management Plan (RMP) version 4.0 is also included.

Action: For adoption

5.3.14. Methylphenidate hydrochloride – TUZULBY (CAP) – EMA/X/0000327555

Applicant: Neuraxpharm Pharmaceuticals S.L.

PRAC Rapporteur: Dennis Lex

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (5 mg/ml powder for prolonged-release oral suspension).

The RMP version 1.1 is updated in accordance.

Action: For adoption

5.3.15. Mirabegron – BETMIGA (CAP) – EMA/VR/0000327362

Applicant: Astellas Pharma Europe B.V.

PRAC Rapporteur: Maria del Pilar Rayon

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

Type IB (C.7.a): To delete the Betmiga 8 mg/ml granules for prolonged-release oral suspension from the Betmiga marketing authorisation (EU/1/12/809/019, EU/1/12/809/020)

Type II (C.6.a): To modify the approved therapeutic indication for neurogenic detrusor overactivity (NDO) to patients less than 18 years of age, weighing 35 kg or more. The updated indication aligns the weight criteria for children with the remaining tablet posology. Consequently, sections 4.1, 4.2 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. The RMP version 9.3 has been submitted. In addition, the MAH took the opportunity to introduce additional changes to the PI.

Action: For adoption

5.3.16. Nivolumab / Relatlimab – OPDUALAG (CAP) – EMA/VR/0000339077

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to revise the wording regarding Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis; and to add ''Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis'' to the list of adverse drug reactions (ADRs) with frequency ''Uncommon'' based on postmarketing data and literature; the Package Leaflet is updated accordingly. The RMP version 6.0 has also been submitted.

Action: For adoption

5.3.17. Ocrelizumab – OCREVUS (CAP) – EMA/VR/0000309389

Applicant: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include treatment of paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (RRMS) for OCREVUS, based on primary analysis results from the pivotal phase III study (WN42086/Operetta 2) and primary and updated results from a supportive phase II study (WA39085/Operetta 1). Operetta 1 is an open-label, parallel-group, dose-finding Phase II study to determine the dosing regimen of ocrelizumab to be further investigated in Operetta 2, and Operetta 2 is a Phase III, randomized, double-blind, double-dummy, parallel-group, multicenter, non-inferiority study

to evaluate the efficacy and safety of intravenous ocrelizumab in comparison with fingolimod. As a consequence, sections 2, 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 15.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce updates to other sections of the SmPC and PL as per previous procedures linguistic review comments (sodium, pH and osmolality), updates to comply with the Excipient Guideline (polysorbates), changes to the list of local representatives in the Package Leaflet, as well as editorial and clarification changes to the PI.

Action: For adoption

5.3.18. Ocrelizumab – OCREVUS (CAP) – EMA/VR/0000313041

Applicant: Roche Registration GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Liver Injury' and to add it to the list of adverse drug reactions (ADRs) with frequency 'rare', based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to submit a DHPC Letter and to introduce minor changes to the PI, including the Labelling section.

Action: For adoption

5.3.19. Olezarsen – TRYNGOLZA (CAP) – EMA/VR/0000336189

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of adult patients with severe hypertriglyceridemia for Tryngolza, based on final results from phase 3 studies ISIS 678354-CS5 (CORE), ISIS 678354-CS6 (CORE2) and ISIS 678354-CS9; and open-label extension study ISIS 678354-CS15. 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 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.3.20. Omaveloxolone – SKYCLARYS (CAP) – EMA/VR/0000296476

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Update of section 5.3 of the SmPC in order to update preclinical information based on results from study RTA-P-21070: this is a 104-week once daily oral gavage toxicity and toxicokinetic study with RTA 408 in rats. The RMP version 2.0 has also been submitted.

Action: For adoption

5.3.21. Palbociclib – IBRANCE (CAP) – EMA/VR/0000316536

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include, in combination with anti-HER2 and endocrine therapies, the maintenance treatment of adult patients with HR-positive, HER2-positive locally advanced or metastatic breast cancer (MBC) following induction treatment for IBRANCE, based on the interim results from the open-label Phase 3 study PATINA (AFT-38/WI215662). This is a randomized, open-label Phase 3 study evaluating the efficacy and safety of IBRANCE (palbociclib) in combination with anti-HER2 therapy and endocrine therapy compared to anti-HER2 therapy and endocrine therapy alone as a first-line maintenance therapy (following induction chemotherapy treatment) for patients with HR positive, HER2-positive MBC. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. RMP version 1.10 has also been submitted.

Action: For adoption

5.3.22. Pembrolizumab – KEYTRUDA (CAP) – EMA/VR/0000336194

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include KEYTRUDA, in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment, is indicated for the treatment of adults with muscle invasive bladder cancer (MIBC) who are eligible for cisplatin containing chemotherapy, based on the results from Interim Analysis 1 of the pivotal Study KN-B15 (EV-304); this is a phase 3, randomized, open-label study to evaluate perioperative enfortumab vedotin plus pembrolizumab (MK-3475) versus neoadjuvant gemcitabine and cisplatin in cisplatin-eligible participants with Muscle-Invasive Bladder Cancer. As consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC have been updated; the Package Leaflet is updated accordingly. Version 54.1 of the RMP is submitted, to reflect the updated data.

Action: For adoption

5.3.23. Pirtobrutinib – JAYPIRCA (CAP) – EMA/VR/0000316267

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of adult patients with chronic lymphocytic leukaemia (CLL) for JAYPIRCA, based on interim results from studies LOXO-BTK-20023 (BRUIN-CLL-313) and LOXO-BTK-20030 (BRUIN-CLL-314). Study 20023 is a phase 3 open-label, randomized study of pirtobrutinib (LOXO-305) versus bendamustine plus rituximab in untreated patients with CLL/SLL. Study 20030 is a phase 3 open-label, randomized study of pirtobrutinib (LOXO-305) versus ibrutinib in patients with CLL/SLL. As a consequence, sections 4.1, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted.

Action: For adoption

5.3.24. Respiratory syncytial virus mRNA vaccine (nucleoside modified) – mRESVIA (CAP) – EMA/VR/0000320244

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update clinical efficacy and safety information on the use of mRESVIA in immunocompromised individuals 18 years of age and older, based on interim results from study mRNA-1345-P303 Part B; this is a Phase 3 study to evaluate the immunogenicity and safety of mRNA-1345, an mRNA vaccine targeting respiratory syncytial virus, in high-risk adults. The updated RMP version 6.0 has also been submitted.

Action: For adoption

5.3.25. Rimegepant – VYDURA (CAP) – EMA/VR/0000339929

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Karin Erneholm

Scope: Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to introduce an every day (QD) posology regimen for prophylaxis of migraine and to amend an existing warning on medication overuse headache (MOH), as well as to update clinical safety and efficacy information based on results from studies C4951010 and C4951011. Study C4951010 is a phase 4 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of rimegepant in episodic migraine prevention with multiple dosing regimens, while study C4951011 is a phase 4, open-label study to evaluate the safety and tolerability of daily dosing of rimegepant in episodic migraine prevention. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted.

Action: For adoption

5.3.26. Ruxolitinib – OPZELURA (CAP) – EMA/VR/0000313318

Applicant: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of moderate atopic dermatitis in adult patients who are inadequately controlled with, have a contraindication to, or are intolerant to topical corticosteroids and topical calcineurin inhibitors for OPZELURA, based on the results of the pivotal Phase III study INCB 18424-326 and the two supportive Phase III studies INCB 18424-303 and INCB 18424-304. INCB 18424-326 is a Phase 3b, double-blind, multicenter, randomized, vehicle-controlled, efficacy, and safety study of ruxolitinib cream in adults with moderate atopic dermatitis. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.0 of the RMP has also been submitted.

Action: For adoption

5.3.27. Sotorasib – LUMYKRAS (CAP) – EMA/VR/0000339051

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: To update Annex II and the RMP to request an 18-month extension of the due dates for the Specific Obligation (SOB) SOB2 related to the Phase 3 Study 20190341.

Action: For adoption

5.3.28. Teclistamab – TECVAYLI (CAP) – EMA/VR/0000336274

Applicant: Janssen Cilag International

PRAC Rapporteur: Veronika Macurova

Scope: Extension of indication to include treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy, for TECVAYLI as monotherapy, based on interim analysis data from the pivotal study 64007957MMY3006 (MajesTEC-9). This is a Phase 3 randomized study comparing teclistamab monotherapy versus pomalidomide, bortezomib, dexamethasone (PVd) or carfilzomib, dexamethasone (Kd) in participants with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy, including an anti-CD38 monoclonal antibody and lenalidomide. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Labelling and Package Leaflet are updated accordingly. The RMP version 6.2 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.3.29. Tezepelumab – TEZSPIRE (CAP) – EMA/VR/0000321455

Applicant: AstraZeneca AB

PRAC Rapporteur: Eva Jirsová

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

C.I.13: Submission of the report from study D5180C00024 (SUNRISE) listed as a category 3 study in the RMP. This is a randomised, double-blind, parallel-group, placebo-controlled 28-week phase 3 efficacy and safety study of tezepelumab in reducing oral corticosteroid use in adults with oral corticosteroid dependent asthma. The RMP version 7 has also been updated accordingly.

C.I.11: Submission of an updated RMP version 7 in order to add study D5241C00006 (EMBARK) and study D5241C00007 (JOURNEY) as additional pharmacovigilance activities to further characterize the important potential risks: "Serious infections" and "Malignancies".

Action: For adoption

5.3.30. Tucatinib – TUYSA (CAP) – EMA/VR/0000337235

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Extension of indication to include in combination with trastuzumab and pertuzumab for the maintenance treatment of adult patients with unresectable locally advanced or metastatic HER2-positive breast cancer based on final results from Study H2C05. This is a Phase 3, global,randomized, double-blind, placebo-controlled study of tucatinib vs placebo in combination with trastuzumab and pertuzumab as maintenance therapy in participants with advanced HER2+ breast cancer who had last received trastuzumab, pertuzumab, and a taxane with no evidence of progression. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

6. Periodic safety update reports (PSURs)

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

6.1.1. Acalabrutinib – CALQUENCE (CAP) – EMA/PSUR/0000327904

Applicant: AstraZeneca AB

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00010887/202510)

Action: For adoption

6.1.2. Acoramidis – BEYONTTRA (CAP) – EMA/PSUR/0000327953

Applicant: Bayer AG

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00011106/202511)

Action: For adoption

6.1.3. Andexanet alfa – ONDEXXYA (CAP) – EMA/PSUR/0000327908

Applicant: AstraZeneca AB

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010764/202510)

Action: For adoption

6.1.4. Avacopan – TAVNEOS (CAP) – EMA/PSUR/0000327958

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010967/202509)

Action: For adoption

6.1.5. Axicabtagene ciloleucel – YESCARTA (CAP) – EMA/PSUR/0000327951

Applicant: Kite Pharma EU B.V., ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00010703/202510)

Action: For adoption

6.1.6. Aztreonam / Avibactam – EMBLAVEO (CAP) – EMA/PSUR/0000327924

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure (PSUSA/00011055/202510)

Action: For adoption

6.1.7. Belantamab mafodotin – BLENREP (CAP) – EMA/PSUR/0000327952

Applicant: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00010869/202510)

Action: For adoption

6.1.8. Beremagene geperpavec – VYJUVEK (CAP) – EMA/PSUR/0000327959

Applicant: Krystal Biotech Netherlands B.V., ATMP

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011131/202511)

Action: For adoption

6.1.9. Bevacizumab gamma – LYTENAVA (CAP) – EMA/PSUR/0000327928

Applicant: Outlook Therapeutics NL B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00011065/202511)

Action: For adoption

6.1.10. Bezlotoxumab – ZINPLAVA (CAP) – EMA/PSUR/0000327891

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00010576/202510)

Action: For adoption

6.1.11. Bupivacaine – EXPAREL LIPOSOMAL (CAP) – EMA/PSUR/0000327916

Applicant: Pacira Ireland Limited

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00010889/202510)

Action: For adoption

6.1.12. Capivasertib – TRUQAP (CAP) – EMA/PSUR/0000327927

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011061/202511)

Action: For adoption

6.1.13. Ceritinib – ZYKADIA (CAP) – EMA/PSUR/0000327894

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00010372/202510)

Action: For adoption

6.1.14. Chikungunya vaccine (live) – IXCHIQ (CAP) – EMA/PSUR/0000327923

Applicant: Valneva Austria GmbH

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011058/202511)

Action: For adoption

6.1.15. Conestat alfa – RUCONEST (CAP) – EMA/PSUR/0000327863

Applicant: Pharming Group N.V.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000873/202510)

Action: For adoption

6.1.16. COVID-19 mRNA vaccine – KOSTAIVE (CAP) – EMA/PSUR/0000327932

Applicant: Seqirus Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011115/202511)

Action: For adoption

6.1.17. Delamanid – DELTYBA (CAP) – EMA/PSUR/0000327880

Applicant: Otsuka Novel Products GmbH

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUSA/00010213/202510)

Action: For adoption

6.1.18. Dinutuximab beta – QARZIBA (CAP) – EMA/PSUR/0000327902

Applicant: Recordati Netherlands B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010597/202511)

Action: For adoption

6.1.19. Dopamine hydrochloride – NEOATRICON (CAP) – EMA/PSUR/0000327930

Applicant: BrePco Biopharma Limited

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00011066/202511)

Action: For adoption

6.1.20. Eculizumab – BEKEMV (CAP); EPYSQLI (CAP); SOLIRIS (CAP) – EMA/PSUR/0000327869

Applicant: Alexion Europe

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00001198/202510)

Action: For adoption

6.1.21. Etranacogene dezaparvovec – HEMGENIX (CAP) – EMA/PSUR/0000327921

Applicant: CSL Behring GmbH, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011037/202511)

Action: For adoption

6.1.22. Exagamglogene autotemcel – CASGEVY (CAP) – EMA/PSUR/0000327950

Applicant: Vertex Pharmaceuticals (Ireland) Limited, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00000244/202511)

Action: For adoption

6.1.23. Hydrocortisone – EFMODY (CAP); PLENADREN (CAP) – EMA/PSUR/0000327910

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00009176/202511)

Action: For adoption

6.1.24. Insulin degludec / Liraglutide – XULTOPHY (CAP) – EMA/PSUR/0000327890

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010272/202509)

Action: For adoption

6.1.25. Irinotecan hydrochloride trihydrate – ONIVYDE PEGYLATED LIPOSOMAL (CAP) – EMA/PSUR/0000327915

Applicant: Les Laboratoires Servier

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010534/202510)

Action: For adoption

6.1.26. Ivacaftor / Tezacaftor / Elexacaftor – KAFTRIO (CAP) – EMA/PSUR/0000327903

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010868/202510)

Action: For adoption

6.1.27. Larotrectinib – VITRAKVI (CAP) – EMA/PSUR/0000327912

Applicant: Bayer AG

PRAC Rapporteur: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00010799/202511)

Action: For adoption

6.1.28. Latanoprost – CATIOLANZE (CAP) – EMA/PSUR/0000327866

Applicant: Santen Oy

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00000202/202511)

Action: For adoption

6.1.29. Lazertinib – LAZCLUZE (CAP) – EMA/PSUR/0000327949

Applicant: Janssen Cilag International

PRAC Rapporteur: Petar Mas

Scope: Evaluation of a PSUSA procedure (PSUSA/00011110/202511)

Action: For adoption

6.1.30. Linvoseltamab – LYNOZYFIC (CAP) – EMA/PSUR/0000327948

Applicant: Regeneron Ireland Designated Activity Company

PRAC Rapporteur: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00011130/202510)

Action: For adoption

6.1.31. Lonafarnib – ZOKINVY (CAP) – EMA/PSUR/0000327913

Applicant: TMC Pharma (EU) Limited

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011005/202511)

Action: For adoption

6.1.32. Loncastuximab tesirine – ZYNLONTA (CAP) – EMA/PSUR/0000327917

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00011027/202510)

Action: For adoption

6.1.33. Mercaptamine – PROCYSBI (CAP); Mercaptamine bitartrate – CYSTAGON (CAP) – EMA/PSUR/0000327901

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00010573/202510)

Action: For adoption

6.1.34. Mirvetuximab soravtansine – ELAHERE (CAP) – EMA/PSUR/0000327931

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00011097/202511)

Action: For adoption

6.1.35. Nintedanib – OFEV (CAP) – EMA/PSUR/0000327881

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00010319/202510)

Action: For adoption

6.1.36. Nintedanib – VARGATEF (CAP) – EMA/PSUR/0000327882

Applicant: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Georgia Gkegka

Scope: Evaluation of a PSUSA procedure (PSUSA/00010318/202510)

Action: For adoption

6.1.37. Niraparib / Abiraterone acetate – AKEEGA (CAP) – EMA/PSUR/0000327922

Applicant: Janssen Cilag International

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011051/202510)

Action: For adoption

6.1.38. Nirogacestat – OGSIVEO (CAP) – EMA/PSUR/0000327941

Applicant: Merck Europe B.V.

PRAC Rapporteur: Terhi Lehtinen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011163/202511)

Action: For adoption

6.1.39. Obecabtagene autoleucel – AUCATZYL (CAP) – EMA/PSUR/0000327934

Applicant: Autolus GmbH, ATMP

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00011160/202511)

Action: For adoption

6.1.40. Palopegteriparatide – YORVIPATH (CAP) – EMA/PSUR/0000327865

Applicant: Ascendis Pharma Bone Diseases A/S

PRAC Rapporteur: Lina Seibokiene

Scope: Evaluation of a PSUSA procedure (PSUSA/00000173/202511)

Action: For adoption

6.1.41. Pandemic influenza vaccine (H5N1) (live attenuated, nasal) – PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA (CAP) – EMA/PSUR/0000327887

Applicant: AstraZeneca AB

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00010501/202511)

Action: For adoption

6.1.42. Panitumumab – VECTIBIX (CAP) – EMA/PSUR/0000327879

Applicant: Amgen Europe B.V.

PRAC Rapporteur: David Olsen

Scope: Evaluation of a PSUSA procedure (PSUSA/00002283/202509)

Action: For adoption

6.1.43. Parathyroid hormone – NATPAR (CAP) – EMA/PSUR/0000327892

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00010591/202510)

Action: For adoption

6.1.44. Pegcetacoplan – ASPAVELI (CAP) – EMA/PSUR/0000327907

Applicant: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010974/202511)

Action: For adoption

6.1.45. Piperaquine tetraphosphate / Artenimol – EURARTESIM (CAP) – EMA/PSUR/0000327942

Applicant: Alfasigma S.p.A.

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00001069/202510)

Action: For adoption

6.1.46. Prucalopride – RESOLOR (CAP) – EMA/PSUR/0000327877

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00002568/202510)

Action: For adoption

6.1.47. rADAMTS13 – ADZYNMA (CAP) – EMA/PSUR/0000327926

Applicant: Takeda Manufacturing Austria AG

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00011077/202511)

Action: For adoption

6.1.48. Raltegravir – ISENTRESS (CAP) – EMA/PSUR/0000327884

Applicant: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00010373/202509)

Action: For adoption

6.1.49. Ranibizumab – BYOOVIZ (CAP); EPRUVY (CAP); LUCENTIS (CAP); RANIVISIO (CAP); RIMMYRAH (CAP); XIMLUCI (CAP) – EMA/PSUR/0000327906

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00002609/202510)

Action: For adoption

6.1.50. RdESAT-6 / rCFP-10 – SIILTIBCY (CAP) – EMA/PSUR/0000327947

Applicant: Serum Life Science Europe GmbH

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011104/202511)

Action: For adoption

6.1.51. Repotrectinib – AUGTYRO (CAP) – EMA/PSUR/0000327933

Applicant: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00011102/202511)

Action: For adoption

6.1.52. Selpercatinib – RETSEVMO (CAP) – EMA/PSUR/0000327889

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010917/202511)

Action: For adoption

6.1.53. Setmelanotide – IMCIVREE (CAP) – EMA/PSUR/0000327886

Applicant: Rhythm Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Miroslava Gocova

Scope: Evaluation of a PSUSA procedure (PSUSA/00010941/202511)

Action: For adoption

6.1.54. Sirolimus – HYFTOR (CAP) – EMA/PSUR/0000327938

Applicant: Plusultra Pharma GmbH

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00000025/202511)

Action: For adoption

6.1.55. Sotorasib – LUMYKRAS (CAP) – EMA/PSUR/0000327925

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00010970/202511)

Action: For adoption

6.1.56. Tofersen – QALSODY (CAP) – EMA/PSUR/0000327929

Applicant: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00011064/202510)

Action: For adoption

6.1.57. Vamorolone – AGAMREE (CAP) – EMA/PSUR/0000327937

Applicant: Santhera Pharmaceuticals (Deutschland) GmbH

PRAC Rapporteur: Rhea Fitzgerald

Scope: Evaluation of a PSUSA procedure (PSUSA/00000223/202510)

Action: For adoption

6.1.58. Vandetanib – CAPRELSA (CAP) – EMA/PSUR/0000327919

Applicant: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00009327/202510)

Action: For adoption

6.1.59. Volanesorsen – WAYLIVRA (CAP) – EMA/PSUR/0000327897

Applicant: Akcea Therapeutics Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00010762/202511)

Action: For adoption

6.1.60. Zanidatamab – ZIIHERA (CAP) – EMA/PSUR/0000327940

Applicant: Jazz Pharmaceuticals Ireland Limited

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00011147/202511)

Action: For adoption

6.1.61. Zanubrutinib – BRUKINSA (CAP) – EMA/PSUR/0000327900

Applicant: Beone Medicines Ireland Limited

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010960/202511)

Action: For adoption

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

6.2.1. Deferasirox - DEFERASIROX ACCORD (CAP); DEFERASIROX MYLAN (CAP); EXJADE (CAP), NAP – EMA/PSUR/0000327939

Applicants: Accord Healthcare S.L.U. (Deferasirox Accord), Mylan Pharmaceuticals Limited (Deferasirox Mylan), Novartis Europharm Limited (Exjade), various

PRAC Rapporteur: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00000939/202510)

Action: For adoption

6.2.2. Methotrexate - JYLAMVO (CAP); NORDIMET (CAP), NAP – EMA/PSUR/0000327873

Applicants: Nordic Group B.V. (Nordimet), Oresund Pharma ApS (Jylamvo), various

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00002014/202510)

Action: For adoption

6.2.3. Stiripentol - DIACOMIT (CAP), NAP – EMA/PSUR/0000327885

Applicants: Biocodex (Diacomit), various

PRAC Rapporteur: Maia Uusküla

Scope: Evaluation of a PSUSA procedure (PSUSA/00002789/202511)

Action: For adoption

6.2.4. Tadalafil - ADCIRCA (CAP); CIALIS (CAP); TADALAFIL LILLY (CAP), NAP – EMA/PSUR/0000327895

Applicants: Eli Lilly Nederland B.V. (Adcirca, Cialis, Tadalafil Lilly), various

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Evaluation of a PSUSA procedure (PSUSA/00002841/202510)

Action: For adoption

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

6.3.1. A-tocopheril, a-tocopherol, vitamin E – EMA/PSUR/0000327898

Applicants: various

PRAC Lead: Roxana Stefania Udrescu

Scope: Evaluation of a PSUSA procedure (PSUSA/00003186/202511)

Action: For adoption

6.3.2. A-tocopherol / ergocalciferol / phytomenadion / retinol palmitate – EMA/PSUR/0000327883

Applicants: various

PRAC Lead: Miroslava Gocova

Scope: Evaluation of a PSUSA procedure (PSUSA/00002633/202511)

Action: For adoption

6.3.3. Acetylsalicylic acid / chlorphenamine / phenylephrine – EMA/PSUR/0000327862

Applicants: various

PRAC Lead: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000694/202511)

Action: For adoption

6.3.4. Aluminium chloride hexahydrate – EMA/PSUR/0000327918

Applicants: various

PRAC Lead: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00009050/202511)

Action: For adoption

6.3.5. Aminosalicylic acid – EMA/PSUR/0000327860

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00000165/202510)

Action: For adoption

6.3.6. Amlodipine / atorvastatin / perindopril, amlodipine / atorvastatin / rampiril – EMA/PSUR/0000327896

Applicants: various

PRAC Lead: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00010431/202510)

Action: For adoption

6.3.7. Artemether / lumefantrin (apart from the dispersible tablet) – EMA/PSUR/0000327946

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00000236/202510)

Action: For adoption

6.3.8. Ascorbic acid / caffeine / paracetamol / phenylephrine hydrochloride / terpine – EMA/PSUR/0000327878

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00002305/202511)

Action: For adoption

6.3.9. Bisoprolol – EMA/PSUR/0000327936

Applicants: various

PRAC Lead: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00000419/202509)

Action: For adoption

6.3.10. Bisoprolol / perindopril – EMA/PSUR/0000327893

Applicants: various

PRAC Lead: Jana Pecherova

Scope: Evaluation of a PSUSA procedure (PSUSA/00010462/202510)

Action: For adoption

6.3.11. Bromhexine – EMA/PSUR/0000327935

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000437/202509)

Action: For adoption

6.3.12. Carbidopa / levodopa – EMA/PSUR/0000327864

Applicants: various

PRAC Lead: Barbara Kovacic Bytyqi

Scope: Evaluation of a PSUSA procedure (PSUSA/00000548/202510)

Action: For adoption

6.3.13. Cinnarizine / dimenhydrinate – EMA/PSUR/0000327867

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00000767/202511)

Action: For adoption

6.3.14. Clenbuterol – EMA/PSUR/0000327861

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00000794/202509)

Action: For adoption

6.3.15. Cyanocobalamin / folic acid, cyanocobalamin / folic acid / potassium iodide – EMA/PSUR/0000327944

Applicants: various

PRAC Lead: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00000892/202511)

Action: For adoption

6.3.16. Desogestrel / ethinylestradiol – EMA/PSUR/0000327943

Applicants: various

PRAC Lead: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00000967/202509)

Action: For adoption

6.3.17. Dinoprostone – EMA/PSUR/0000327945

Applicants: various

PRAC Lead: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00001104/202509)

Action: For adoption

6.3.18. Felbamate – EMA/PSUR/0000327920

Applicants: various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00010155/202509)

Action: For adoption

6.3.19. Human coagulation factor VII – EMA/PSUR/0000327871

Applicants: various

PRAC Lead: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00001619/202510)

Action: For adoption

6.3.20. Isoflurane – EMA/PSUR/0000327868

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00001786/202510)

Action: For adoption

6.3.21. Minoxidil (non topical formulations) – EMA/PSUR/0000327876

Applicants: various

PRAC Lead: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00002066/202510)

Action: For adoption

6.3.22. Perindopril – EMA/PSUR/0000327874

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00002354/202510)

Action: For adoption

6.3.23. Pipamperone – EMA/PSUR/0000327872

Applicants: various

PRAC Lead: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00002420/202510)

Action: For adoption

6.3.24. Prothipendyl – EMA/PSUR/0000327875

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00002564/202510)

Action: For adoption

6.3.25. Ramipril / bisoprolol – EMA/PSUR/0000327914

Applicants: various

PRAC Lead: Jana Pecherova

Scope: Evaluation of a PSUSA procedure (PSUSA/00011041/202510)

Action: For adoption

6.3.26. Salmeterol – EMA/PSUR/0000327888

Applicants: various

PRAC Lead: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00002681/202510)

Action: For adoption

6.3.27. Sulbutiamine – EMA/PSUR/0000327905

Applicants: various

PRAC Lead: Tiphaine Vaillant

Scope: Evaluation of a PSUSA procedure (PSUSA/00002801/202511)

Action: For adoption

6.3.28. Terbinafine – EMA/PSUR/0000327909

Applicants: various

PRAC Lead: Jana Pecherova

Scope: Evaluation of a PSUSA procedure (PSUSA/00002896/202509)

Action: For adoption

6.3.29. Valsartan / rosuvastatin – EMA/PSUR/0000327899

Applicants: various

PRAC Lead: Polona Golmajer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010735/202510)

Action: For adoption

6.4. Follow-up to PSUR/PSUSA procedures

6.4.1. Semaglutide – RYBELSUS (CAP) – EMA/PAM/0000337900

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Karin Bolin

Scope: Safety review. To assess the potential association between semaglutide exposure and cardioembolic stroke as part of a post-authorisation measure (LEG). - EMEA/H/C/PSUSA/00010671/202505. (LEG/01968/1)

Action: For adoption

6.4.2. Semaglutide – WEGOVY (CAP); WEGOVY FLEXTOUCH (CAP) – EMA/PAM/0000337800

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Karin Bolin

Scope: To assess the potential association between semaglutide exposure and cardioembolic stroke as part of a post-authorisation measure (LEG). -EMEA/H/C/PSUSA/00010671/202505

Action: For adoption

6.4.3. Semaglutide – OZEMPIC (CAP) – EMA/PAM/0000338018

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Karin Bolin

Scope: Safety review. To assess the potential association between semaglutide exposure and cardioembolic stroke as part of a post-authorisation measure (LEG). - EMEA/H/C/PSUSA/00010671/202505. (LEG/01969/1)

Action: For adoption

6.4.4. Voretigene neparvovec – LUXTURNA (CAP) – EMA/PAM/0000339319

Applicant: Novartis Europharm Limited, ATMP

PRAC Rapporteur: Dirk Mentzer

Scope: SPKRPE-PASS final clinical study report requested during PSUSA/00010742/202507 by the PRAC

Action: For adoption

6.5. Variation procedure(s) resulting from PSUSA evaluation

6.5.1. Tacrolimus ADVAGRAF (CAP); MODIGRAF (CAP), NAP – EMA/VR/0000319175

Applicants: Astellas Pharma Europe B.V., various

PRAC Rapporteur: Eamon O Murchu

Scope: Update of section 4.8 of the SmPC in order to include the missing frequency estimations to the list of adverse drug reactions (ADRs) following PSUSA/00002839/202403 procedure. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the PI.

Action: For adoption

6.6. Expedited summary safety reviews[4]

None

7. Post-authorisation safety studies (PASS)

7.1. Protocols of PASS imposed in the marketing authorisation(s)[5]

7.1.1. Donanemab – KISUNLA (CAP) – EMA/PASS/0000339404

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: PASS protocol [107n]: A registry-based observational study to characterise ARIA within a cohort of donanemab-treated patients in the EU (Protocol I5T-MC-B015)

Action: For adoption

7.1.2. Donanemab – KISUNLA (CAP) – EMA/PASS/0000339391

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: PASS protocol [107n]: Secondary database study to characterise safety, drug utilisation and effectiveness of risk minimisation activities in donanemab treated patients in the EU (Protocol I5T-MC-B017)

Action: For adoption

7.1.3. Mirdametinib – EZMEKLY (CAP) – EMA/PASS/0000340654

Applicant: Merck Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: PASS protocol [107n]: Non-interventional PASS to confirm the long-term safety of mirdametnib, in the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric and adult patients with neurofibromatosis type 1 (NF1) aged 2 years and above.

Action: For adoption

7.1.4. Topiramate (NAP) – EMA/PASS/0000340662

Applicants: various

[4] 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

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

PRAC Rapporteur: Karin Bolin

Scope: PASS amendment [107o]: Post-Authorization Safety Study to assess the effectiveness of the newly implemented Risk Minimization Measures for Topiramate: HCP and patient knowledge and behavior survey.

Action: For adoption

7.2. Protocols of PASS non-imposed in the marketing authorisation(s)[6]

7.2.1. Ciltacabtagene autoleucel – CARVYKTI (CAP) – EMA/PAM/0000338559

Applicant: Janssen Cilag International, ATMP

PRAC Rapporteur: Jo Robays

Scope: Amendment of the protocol for PASS study PCSONCA0014: Post-authorization Safety Study Survey to Evaluate the Effectiveness of the Ciltacabtagene Autoleucel HCP Educational Program and the Product Handling Training.

Action: For adoption

7.2.2. COVID-19 mRNA vaccine – MNEXSPIKE (CAP) – EMA/PAM/0000339594

Applicant: Moderna Biotech Spain S.L.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Submission of the post-authorisation safety study (PASS) protocol v2.0 for mRNA-1283-P901; this is a PASS in the United States aimed to estimate the incidence and to compare the risks of myocarditis and pericarditis among in people who receive mNEXSPIKE and in those who have not received the prior seasonal formulation of COVID-19 vaccine or the same seasonal formulation previously.

Action: For adoption

7.2.3. Donanemab – KISUNLA (CAP) – EMA/PAM/0000338752

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Cat. 3 study: Healthcare provider survey to assess the effectiveness of the donanemab additional risk minimisation activities in the EU

Action: For adoption

7.2.4. Efgartigimod alfa – VYVGART (CAP) – EMA/PAM/0000343589

Applicant: Argenx

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

PRAC Rapporteur: Rhea Fitzgerald

Scope: Amendment of the protocol (PAS Registration Number EUPAS1000000005) for the pregnancy registry - A worldwide pregnancy safety study to assess maternal, foetal, and infant outcomes following exposure to efgartigimod alfa during pregnancy and/or breastfeeding.

Action: For adoption

7.2.5. Resmetirom – REZDIFFRA (CAP) – EMA/PAM/0000339780

Applicant: Madrigal Pharmaceuticals EU Limited

PRAC Rapporteur: Lina Seibokiene

Scope: Submission of study protocol for a real-world longitudinal data study to address liver and CV related outcomes in resmetirom treated patients, as compared with a real-world control arm

Action: For adoption

7.2.6. Teprotumumab – TEPEZZA (CAP) – EMA/PAM/0000310214

Applicant: Amgen Europe B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Draft protocol for PASS (non-imposed) 20250081: Drug utilization study to evaluate the effectiveness of teprotumumab aRMMs.

Action: For adoption

7.2.7. Tofacitinib – XELJANZ (CAP) – EMA/PAM/0000316639

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of amended protocols for the non-imposed (category 3) Post Authorisation Safety Study (PASS) - version 6.0 (A3921312), and version 6.0 (A3921316) for Tofacitinib (Xeljanz).

- A3921312: UK, British Society for Rheumatology Biologics Register-Rheumatoid Arthritis (BSRBR-RA)
- A3921316: Spain (ES), Registry of Adverse Events of Biological Therapies and Biosimilars in Rheumatoid Diseases (BIOBADASER)

Action: For adoption

7.2.8. Upadacitinib – RINVOQ (CAP) – EMA/PAM/0000339078

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Protocol amendment for study P21-825: a drug utilisation study evaluating the additional risk minimisation measures for upadacitinib in the treatment of atopic dermatitis in Europe

Action: For adoption

7.2.9. Vonicog alfa – VEYVONDI (CAP) – EMA/PAM/0000337712

Applicant: BAXALTA INNOVATIONS GmbH

PRAC Rapporteur: Karin Bolin

Scope: Protocol for Study TAK-577-4009/EUHASS registry - post-authorisation safety study: safety surveillance of Veyvondi using secondary data from the EUHASS registry.

Action: For adoption

7.3. Results of PASS imposed in the marketing authorisation(s)[7]

7.3.1. Belimumab – BENLYSTA (CAP) – EMA/PASS/0000306411

Applicant: Glaxosmithkline (Ireland) Limited

PRAC Rapporteur: Karin Bolin

Scope: PASS results [107q]: A 5-Year prospective observational registry to assess adverse events of interest and effectiveness in adults with active, autoantibody-positive systemic Lupus erythematosus treated with or without BENLYSTA (belimumab)

Action: For adoption

7.4. Results of PASS imposed and non-imposed in the marketing authorisation(s)[8]

7.4.1. COVID-19 mRNA vaccine – COMIRNATY (CAP); COMIRNATY JN.1 (CAP); COMIRNATY KP.2 (CAP); COMIRNATY LP.8.1 (CAP); COMIRNATY OMICRON XBB.1.5 (CAP); COMIRNATY ORIGINAL/OMICRON BA.4-5 (CAP) – EMA/VR/0000334558

Applicant: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final clinical study report for the non-interventional study C4591022, listed as a category 3 study in the RMP. This is a non-interventional post-approval safety study of pregnancy and infant outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.

Action: For adoption

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

7.4.2. Ivacaftor / Tezacaftor / Elexacaftor – KAFTRIO (CAP) – EMA/VR/0000319887

Applicant: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Dennis Lex

Scope: Submission of the final report from the 5-year Post Authorisation Safety Study (PASS) VX20-445-120, listed as a category 3 study in the RMP. This is a longitudinal, registry based study evaluating the real-world effects and utilisation patterns of elexacaftor, tezacaftor, and ivacaftor combination therapy (ELX/TEZ/IVA) in patients with cystic fibrosis (CF). The RMP version 10.2 has also been submitted.

Action: For adoption

7.4.3. Laronidase – ALDURAZYME (CAP) – EMA/VR/0000282056

Applicant: Sanofi B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Submission of the final report from PASS study ALID01803 listed as a category 3 study in the RMP. This is an observational, open-label study of the effects of Aldurazyme (laronidase) treatment on lactation in postpartum women with Mucopolysaccharidosis Type I and their breastfed infants. This study is to determine whether laronidase activity was present in the breast milk of mothers with MPS I disease and whether Aldurazyme affected the growth, development, and immunologic response of breastfed infants. The RMP version 2.0 has also been submitted.

Action: For adoption

7.4.4. Semaglutide – OZEMPIC (CAP); RYBELSUS (CAP) – EMA/VR/0000334523

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Karin Bolin

Scope: Submission of the final report from the non-interventional post-authorisation safety study NN9535-4447, listed as a category 3 study in the RMP for Ozempic and Rybelsus. This is an epidemiological assessment of the risk for pancreatic cancer associated with the use of semaglutide in patients with type 2 diabetes: a cohort study based on Nordic registry data.

Action: For adoption

7.5. Interim results and other post-authorisation measures for imposed and non-imposed studies

7.5.1. Avacopan – TAVNEOS (CAP) – EMA/PAM/0000336195

Applicant: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the first interim report for the required additional pharmacovigilance activity (Category 3), AVACOSTAR (CS-AVA-2022-0016), which is a post-authorisation safety study (PASS) to evaluate incidence of safety events of interest in patients treated with avacopan for ANCA-associated vasculitis (AAV). In the frame of procedure MEA 002 EMEA/H/C/005523, it was agreed in the RMP version 2.1 that interim reports for AVACOSTAR PASS are submitted every 24 months (after first patient first visit).

Action: For adoption

7.5.2. Cabotegravir – VOCABRIA (CAP) – EMA/PAM/0000339050

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Interim study results. 4th interim report. PASS: A real-world five-year Drug Utilisation Study (DUS). This observational cohort study will aim to better understand the patient population receiving cabotegravir long acting injection and/or rilpivirine long acting injection containing regimens in routine clinical practice. The study will assess usage patterns, adherence, and post marketing clinical effectiveness of these regimens and monitor for resistance among virologic failures for whom data on resistance testing are available. (ANX/01282/2)

Action: For adoption

7.5.3. Cabotegravir – VOCABRIA (CAP) – EMA/PAM/0000339531

Applicant: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Interim study results. PASS No. 215162 (EuroSIDA): A prospective observational cohort study to monitor for hepatotoxicity and regimen discontinuation due to liver related adverse events among patients initiating CAB containing antiretroviral regimen. Summary objectives: Monitor for hepatotoxicity; Estimate the number of patients discontinuing CAB based ARV regimen due to adverse events, and adverse events related to hepatic events. (MEA/01256/2)

Action: For adoption

7.5.4. COVID-19 vaccine (recombinant, adjuvanted) – NUVAXOVID (CAP); NUVAXOVID JN.1 (CAP); NUVAXOVID XBB.1.5 (CAP) – EMA/PAM/0000317251

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Dirk Mentzer

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

Action: For adoption

7.5.5. Damoctocog alfa pegol – JIVI (CAP) – EMA/PAM/0000303584

Applicant: Bayer AG

PRAC Rapporteur: Bianca Mulder

Scope: Fourth interim report of study number 20904 (HA-SAFE), 'Observational study evaluating long-term safety of real-world treatment with damoctocog alfa pegol in previously treated patients with hemophilia A'. The HA-SAFE study is a post-authorisation measure defined in Annex II.D of the Jivi EU PI.

Action: For adoption

7.5.6. Efgartigimod alfa – VYVGART (CAP) – EMA/PAM/0000339564

Applicant: Argenx

PRAC Rapporteur: Rhea Fitzgerald

Scope: Third interim report ARGX-113-PAC-2206: A worldwide pregnancy safety study to assess maternal, fetal, and infant outcomes following exposure to Vyvgart (efgartigimod) during pregnancy and/or breastfeeding.

Action: For adoption

7.5.7. Fenfluramine – FINTEPLA (CAP) – EMA/PAM/0000339786

Applicant: UCB Pharma

PRAC Rapporteur: Dennis Lex

Scope: Final study result. P46 RWE1624 is a descriptive, retrospective, non-interventional longitudinal cohort analysis of patients with Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in the United States, utilizing data from the Komodo claims database. (P46/01995/1)

Action: For adoption

7.5.8. Lecanemab – LEQEMBI (CAP) – EMA/PAM/0000339581

Applicant: Eisai GmbH

PRAC Rapporteur: Eva Jirsová

Scope: Cat 3 PASS BAN2401-G000-301 OLE

Evaluate the long-term safety and tolerability of LEC10-BW in subjects with early Alzheimer's disease in the Extension Phase. (MEA/01037/1)

Action: For adoption

7.5.9. Maribavir – LIVTENCITY (CAP) – EMA/PAM/0000334575

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Adam Przybylkowski

Scope: Submission of interim results from study TAK-620-4007, an RMP category 3 retrospective chart review of safety outcomes associated with use of maribavir in patients with post-transplant refractory cytomegalovirus (CMV) infection and comorbid end-stage renal disease (ESRD) or comorbid severe chronic renal disease requiring peritoneal dialysis or haemodialysis.

Action: For adoption

7.5.10. Mercaptamine – CYSTADROPS (CAP) – EMA/PAM/0000339522

Applicant: Recordati Rare Diseases

PRAC Rapporteur: Maria del Pilar Rayon

Scope: The fourth interim report for category 3 PASS CYT-DS-001; an open-label, longitudinal, post authorization safety study to assess the safety of Cystadrops in paediatric and adult cystinosis patients in long term Use.

Action: For adoption

7.5.11. Ofatumumab – KESIMPTA (CAP) – EMA/PAM/0000308145

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: First Annual Interim Study Report for long-term PASS, study COMB157G2406 entitled Kesimpta long-term retrospective safety study utilizing real-world data from existing multiple sclerosis registries and databases from multiple countries

Action: For adoption

7.5.12. Ofatumumab – KESIMPTA (CAP) – EMA/PAM/0000337728

Applicant: Novartis Europharm Limited

PRAC Rapporteur: Amelia Cupelli

Scope: 5th Interim Report of 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

7.5.13. Rilpivirine – REKAMBYS (CAP) – EMA/PAM/0000338758

Applicant: Janssen Cilag International

PRAC Rapporteur: Liana Martirosyan

Scope: Interim study results. 4th interim report. PASS: A real-world five-year Drug Utilisation Study (DUS). This observational cohort study will aim to better understand the patient population receiving cabotegravir long acting injection and/or rilpivirine long acting

injection containing regimens in routine clinical practice. The study will assess usage patterns, adherence, and post marketing clinical effectiveness of these regimens and monitor for resistance among virologic failures for whom data on resistance testing are available. (ANX/01281/2)

Action: For adoption

7.5.14. Sarilumab – KEVZARA (CAP) – EMA/PAM/0000339607

Applicant: Sanofi Winthrop Industrie

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: SARILC08312 Interim Report#5: Post-authorization Safety study Surveillance Program for Sarilumab using Rheumatoid Arthritis Registries in Germany, Spain, Sweden, and in the United Kingdom (EUPASS35468).

Action: For adoption

7.5.15. Tofacitinib – XELJANZ (CAP) – EMA/PAM/0000334570

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Next interim study report for Study A3921352 is an active surveillance, post-authorization study to characterize the safety of tofacitinib in patients with moderately to severely active ulcerative colitis in the real-world setting using data from the United Registries for Clinical Assessment and Research (UR-CARE) in the European Union (EU), as requested in MEA/01034/1 (EMA/PAM/0000247897).

Action: For adoption

7.5.16. Velaglucerase alfa – VPRIV (CAP) – EMA/PAM/0000339048

Applicant: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Dennis Lex

Scope: Submission of Feasibility Assessment Report for study TAK-669-4018, a Survey among Patients, Caregivers and Home Infusion Nurses based in the European Union to Assess their Awareness and Understanding of the Risk Minimization Measures in the Educational Materials Supporting VPRIV Infusion at Home

Action: For adoption

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/0000337252

Applicant: Serb

PRAC Rapporteur: Karin Bolin

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.2. Clofarabine – EVOLTRA (CAP) – EMA/S/0000335797

Applicant: Sanofi B.V.

PRAC Rapporteur: Tiphaine Vaillant

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.3. Glucarpidase – VORAXAZE (CAP) – EMA/S/0000322329

Applicant: Serb

PRAC Rapporteur: Dennis Lex

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.4. Maralixibat – LIVMARLI (CAP) – EMA/S/0000317715

Applicant: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.1.5. Velmanase alfa – LAMZEDE (CAP) – EMA/S/0000336192

Applicant: Chiesi Farmaceutici S.p.A.

PRAC Rapporteur: Jan Neuhauser

Scope: Annual reassessment of the marketing authorisation

Action: For adoption

8.2. Conditional renewals of the marketing authorisation

8.2.1. Epcoritamab – TEPKINLY (CAP) – EMA/R/0000334812

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.2.2. Pirtobrutinib – JAYPIRCA (CAP) – EMA/R/0000339971

Applicant: Eli Lilly Nederland B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

Action: For adoption

8.3. Renewals of the marketing authorisation

8.3.1. Abrocitinib – CIBINQO (CAP) – EMA/R/0000336009

Applicant: Pfizer Europe MA EEIG

PRAC Rapporteur: Petar Mas

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.2. Anifrolumab – SAPHNELO (CAP) – EMA/R/0000335943

Applicant: AstraZeneca AB

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.3. Artesunate – ARTESUNATE AMIVAS (CAP) – EMA/R/0000333258

Applicant: Amivas Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.4. Eptinezumab – VYEPTI (CAP) – EMA/R/0000336059

Applicant: H. Lundbeck A/S

PRAC Rapporteur: Liana Martirosyan

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.5. Semaglutide – WEGOVY (CAP); WEGOVY FLEXTOUCH (CAP) – EMA/R/0000336288

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

Action: For adoption

8.3.6. Sitagliptin fumarate – SITAGLIPTIN SUN (CAP) – EMA/R/0000335931

Applicant: Sun Pharmaceutical Industries (Europe) B.V.

PRAC Rapporteur: Bianca Mulder

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 Member States, CHMP or the EMA

10.1.1. Levofloxacin (intravenous and oral use) – DE/H/5119/001-003/II/118

Applicant(s): Sanofi-Aventis Deutschland GmbH (Tavanic)

PRAC Lead: Dennis Lex

Scope: PRAC consultation on a type II national variation to update the product information regarding the risk of encephalopathy, at request of Germany.

Action: For adoption

10.1.2. Mycobacterium bovis BCG, Danish strain 1331 – DK/H/3659/001/II/001

Applicant(s): AJ Vaccines A/S

PRAC Lead: Karin Erneholm

Scope: PRAC consultation on a type II national variation to update the product information, to implement additional risk minimisation measures and to disseminate a direct healthcare professional communication (DHPC) regarding the risk of reactivation of latent BCG infection , at request of Denmark.

Action: For adoption

10.1.3. Upadacitinib – RINVOQ (CAP) – EMA/VR/0000312506

Applicant: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include the treatment of severe alopecia areata (AA) in adult and adolescents 12 years and older for RINVOQ, based on interim results from 2 pivotal, Phase 3 studies (M23-716 Study 1 and Study 2); those are randomized, double blind, placebo-controlled, multi-center studies of Upadacitinib evaluating the efficacy and safety of Upadacitinib 15 mg QD and 30 mg QD versus placebo for the treatment of severe AA in subjects who are at least 12 years of age. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Annex II are updated in accordance. Version 18.0 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

11. Scientific advice procedures

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

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. Nominated proxy

Action: For information

12.1.3. Scientific Committee Meetings – alternating face-to-face and virtual meetings schedule for 2027

Action: For adoption

12.2. Coordination with EMA Scientific Committees or CMDh-v

None

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

12.3.1. Healthcare Professionals Working Party (HCPWP) and Patients and Consumers Working Party (PCWP) – 2025-2028

Action: For information

12.3.2. SAWP-PRAC consultation procedure – guidance update

Action: For adoption

12.4. Cooperation within the EU regulatory network

None

12.5. Cooperation with International Regulators

12.5.1. Opening procedures at EMA to non-EU authorities (OPEN) framework – PRAC involvement

Action: For discussion

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

None

12.7. PRAC work plan

None

12.8. Planning and reporting

None

12.9. Pharmacovigilance audits and inspections

12.9.1. Pharmacovigilance systems and their quality systems

None

12.9.2. Pharmacovigilance inspections

None

12.9.3. Pharmacovigilance audits

None

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

12.10.1. Periodic safety update reports

None

12.10.2. PSURs repository

None

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

Action: For adoption

12.11. Signal management

12.11.1. Good Pharmacovigilance Practice (GVP) module IX on signal management – revision 2

PRAC lead: Dennis Lex

Action: For adoption

12.12. Adverse drug reactions reporting and additional reporting

12.12.1. Management and reporting of adverse reactions to medicinal products

None

12.12.2. Additional monitoring

None

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

Action: For adoption

12.13. EudraVigilance database

12.13.1. Activities related to the confirmation of full functionality

None

12.14. Risk management plans and effectiveness of risk minimisations

12.14.1. Risk management systems

None

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

None

12.15. Post-authorisation safety studies (PASS)

12.15.1. Post-authorisation Safety Studies – imposed PASS

None

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

None

12.16. Community procedures

12.16.1. Referral procedures for safety reasons

None

12.17. Renewals, conditional renewals, annual reassessments

None

12.18. Risk communication and transparency

12.18.1. Public participation in pharmacovigilance

None

12.18.2. Safety communication

None

12.19. Continuous pharmacovigilance

12.19.1. Incident management

None

12.20. Impact of pharmacovigilance activities

None

12.21. Others

12.21.1. Benzyl alcohol and benzoic acid used as excipients in medicinal products - revised labelling requirements

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/

Article 58 procedures (Art 58)

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)