21 July 2025
EMA/CHMP/211682/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 21-24 July 2025
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

21 July 2025, 09:30 – 19:30, virtual meeting/room 1C

22 July 2025, 08:30 – 19:30, virtual meeting/room 1C

23 July 2025, 08:30 – 19:30, virtual meeting/room 1C

24 July 2025, 08:30 – 15:00, virtual meeting/room 1C

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 vary during the course of the review. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CHMP 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).

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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 CHMP plenary session to be held 21-24 July 2025. See July 2025 CHMP minutes (to be published post August 2025 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 21-24 July 2025

1.3. Adoption of the minutes

CHMP minutes for the 22-25 April 2025 and the 19-22 May 2025 meetings.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 14 July 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Pridopidine - Orphan - EMEA/H/C/006261

Prilenia Therapeutics B.V.; treatment of Huntington's disease

Scope: Oral explanation

Action: Oral explanation to be held on 22 July 2025 at 11:00

List of Outstanding Issues adopted on 22.05.2025. List of Questions adopted on 12.12.2024.

2.2. Re-examination procedure oral explanations

2.2.1. Kisunla - Donanemab - EMEA/H/C/006024

Eli Lilly Nederland B.V.; to slow disease progression in adult patients with Alzheimer’s disease (AD).

Scope: Oral explanation

Action: Oral explanation to be held on 21 July 2025 at 14:00

New active substance (Article 8(3) of Directive No 2001/83/EC)

Opinion adopted on 27.03.2025. List of Outstanding Issues adopted on 12.12.2024, 25.04.2024. List of Questions adopted on 14.12.2023.

See 3.5

2.2.2. Aplidin - plitidepsin - Orphan - EMEA/H/C/004354

Pharma Mar, S.A.; treatment of multiple myeloma

Scope: Oral explanation

Action: Oral explanation to be held on 23 July 2025 at 11:00

New active substance (Article 8(3) of Directive No 2001/83/EC)

See 3.5

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Lifileucel - ATMP - EMEA/H/C/004741

treatment of unresectable or metastatic melanoma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 16.05.2025. List of Questions adopted on 06.12.2024.

3.1.2. L-Acetylleucine - Orphan - EMEA/H/C/006327

Intrabio Ireland Limited; chronic treatment of Niemann-Pick Type C (NPC) in adults and children from birth

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025, 27.02.2025. List of Questions adopted on 17.10.2024.

3.1.3. Denosumab - EMEA/H/C/006434

treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

3.1.4. Denosumab - EMEA/H/C/006435

prevention of skeletal related events in adults with advanced malignancies involving bone

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

3.1.5. Sebetralstat - Orphan - EMEA/H/C/006211

Kalvista Pharmaceuticals (Ireland) Limited; treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.05.2025. List of Questions adopted on 12.12.2024.

3.1.6. Delandistrogene moxeparvovec - Orphan - ATMP - EMEA/H/C/005293

Roche Registration GmbH; treatment of ambulatory patients aged 3 to 7 years old with Duchenne muscular dystrophy

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 16.04.2025. List of Questions adopted on 11.10.2024.

3.1.7. Aflibercept - EMEA/H/C/006282

treatment of age-related macular degeneration (AMD) and visual impairment

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025. List of Questions adopted on 14.11.2024.

3.1.8. Autologous cartilage-derived articular chondrocytes, in-vitro expanded - ATMP - EMEA/H/C/004594

repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 13.06.2025, 21.03.2025. List of Questions adopted on 19.04.2024.

3.1.9. Lenacapavir - EMEA/H/C/006658

Accelerated assessment

pre-exposure prophylaxis to prevent HIV-1

Scope: Opinion

Action: For adoption

List of Questions adopted on 20.05.2025.

3.1.10. Lenacapavir - Article 58 - EMEA/H/W/006659

Accelerated assessment

pre-exposure prophylaxis to prevent HIV-1

Scope: Opinion

Action: For adoption

3.1.11. Macitentan - EMEA/H/C/006524

treatment of pulmonary arterial hypertension (PAH)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025. List of Questions adopted on 19.09.2024.

3.1.12. Macitentan - EMEA/H/C/006523

treatment of pulmonary arterial hypertension (PAH)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025. List of Questions adopted on 19.09.2024.

3.1.13. Vimseltinib - Orphan - EMEA/H/C/006363

Deciphera Pharmaceuticals (Netherlands) B.V.; Treatment of adult patients with tenosynovial giant cell tumour (TGCT) who are not amenable to surgery

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025. List of Questions adopted on 14.11.2024.

3.1.14. Olezarsen - Orphan - EMEA/H/C/006477

Ionis Ireland Limited; treatment of familial chylomicronemia syndrome

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.05.2025. List of Questions adopted on 12.12.2024.

3.1.15. Ustekinumab - EMEA/H/C/006794

treatment of Crohn’s Disease, treatment of Plaque psoriasis, Psoriatic arthritis (PsA)

Scope: Opinion

Action: For adoption

3.1.16. Vorasidenib - Orphan - EMEA/H/C/006284

Les Laboratoires Servier; treatment of predominantly non-enhancing astrocytoma or oligodendroglioma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.01.2025, 19.09.2024, 25.07.2024. List of Questions adopted on 23.04.2024.

3.1.17. Zuranolone - EMEA/H/C/006488

treatment of postpartum depression (PPD) in adults

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.05.2025. List of Questions adopted on 12.12.2024.

3.2. Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable)

3.2.1. Clesrovimab - EMEA/H/C/006497

prevention of infections with respiratory syncytial virus (RSV) and lower respiratory tract disease (LRTD)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.03.2025.

3.2.2. Denosumab - EMEA/H/C/006239

prevention of skeletal related events in adults with advanced malignancies involving bone

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.03.2025.

3.2.3. Enzalutamide - EMEA/H/C/006612

treatment of prostate cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2025.

3.2.4. Insulin icodec / Semaglutide - EMEA/H/C/006279

treatment of adults with type 2 diabetes mellitus insufficiently controlled on basal insulin or glucagon-like peptide 1 (GLP-1) receptor agonists

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2025.

3.2.5. Elinzanetant - EMEA/H/C/006298

for the treatment of moderate to severe vasomotor symptoms (VMS)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2025.

3.2.6. ACELLULAR PERTUSSIS VACCINE - EMEA/H/C/006304

indicated as active booster immunization against *pertussis* of persons aged 11 years onwards and passive protection against *pertussis* in early infancy following maternal immunization during pregnancy

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

3.2.7. Rivaroxaban - EMEA/H/C/006643

prevention of atherothrombotic events

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2025.

3.2.8. Teduglutide - EMEA/H/C/006564

treatment of Short Bowel Syndrome

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2025.

3.2.9. Rilzabrutinib - Orphan - EMEA/H/C/006425

Sanofi B.V.; for the treatment of persistent or chronic immune thrombocytopenia (ITP)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2025.

3.3. Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable)

3.3.1. Copper (64Cu) oxodotreotide - Orphan - EMEA/H/C/006608

Cis Bio International; positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine neoplasms (NENs).

Scope: List of questions

Action: For adoption

3.3.2. Liraglutide - EMEA/H/C/006620

treatment of diabetes and weight management

Scope: List of questions

Action: For adoption

3.3.3. Furosemide - PUMA - EMEA/H/C/006617

treatment of all conditions requiring diuresis due to mechanical obstruction or venous insufficiency.

Scope: List of questions

Action: For adoption

3.3.4. Brensocatib - PRIME - EMEA/H/C/005820

Accelerated assessment

treatment of non-cystic fibrosis bronchiectasis

Scope: List of questions

Action: For adoption

3.3.5. Apitegromab - PRIME - Orphan - EMEA/H/C/005909

Scholar Rock Netherlands B.V.; treatment of 5q spinal muscular atrophy (SMA)

Scope: List of questions

Action: For adoption

3.3.6. Semaglutide - EMEA/H/C/006426

treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis with liver fibrosis

Scope: List of questions

Action: For adoption

3.3.7. Liraglutide - EMEA/H/C/006615

treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

Scope: List of questions

Action: For adoption

3.3.8. Tovorafenib - Orphan - EMEA/H/C/006140

Ipsen Pharma; treatment of paediatric low-grade glioma (LGG)

Scope: List of questions

Action: For adoption

3.3.9. Paltusotine - Orphan - EMEA/H/C/006636

Voisin Consulting Life Sciences; maintenance treatment in adult patients with acromegaly

Scope: List of questions

Action: For adoption

3.3.10. Pertuzumab - EMEA/H/C/006583

treatment of breast cancer

Scope: List of questions

Action: For adoption

3.3.11. Remibrutinib - EMEA/H/C/006313

treatment of chronic spontaneous urticaria in patients with inadequate response to H1 antihistamine

Scope: List of questions

Action: For adoption

3.3.12. INFLUENZA VACCINE - EMEA/H/C/006674

immunisation for the prevention of influenza disease

Scope: List of questions

Action: For adoption

3.3.13. Autologous melanoma-derived tumour infiltrating lymphocytes, ex vivo-expanded - ATMP - EMEA/H/C/006563

treatment of melanoma

Scope: List of questions

Action: For adoption

3.3.14. Tocilizumab - EMEA/H/C/006416

treatment of rheumatoid arthritis and other immunological conditions

Scope: List of questions

Action: For adoption

3.4. Update on on-going initial applications for Centralised procedure

3.4.1. Belumosudil - Orphan - EMEA/H/C/006421

Sanofi Winthrop Industrie; treatment of chronic graft-versus host disease (cGVHD) after failure of at least two prior lines of systemic therapy.

Scope: Update on the procedure

Action: For information

List of Outstanding Issues adopted on 19.06.2025. List of Questions adopted on 30.01.2025.

3.5. Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004

3.5.1. Aplidin - plitidepsin - Orphan - EMEA/H/C/004354

Pharma Mar, S.A.; treatment of multiple myeloma

Scope: Opinion

Restart the 2018 re-examination procedure relating to the initial marketing authorisation application for Aplidin following the adoption of Commission Implementing Decision C(2024) 4469 final of 28 June 2024 which revoked Commission Implementing Decision C(2018) 4831 final of 17 July 2018 refusing marketing authorisation for 'Aplidin – plitidepsin'. That decision was revoked following the judgment of 14 March 2024 in D & A Pharma v Commission and EMA, C 291/22 P.

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

3.5.2. Atropine sulfate FGK - Atropine - PUMA - EMEA/H/C/006385

FGK Representative Service GmbH; treatment of myopia in children aged 3 years and older

Scope: Adoption of timetable, questions to the AHEG

Action: For adoption

Known active substance (Article 8(3) of Directive No 2001/83/EC)

Opinion adopted on 22.05.2025. List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

3.5.3. Austedo - Deutetrabenazine - EMEA/H/C/006371

Teva GmbH; treatment of tardive dyskinesia

Scope: Request for re-examination, appointment of re-examination rapporteurs

Action: For adoption

Opinion adopted on 19.06.2025. List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 25.07.2024.

3.5.4. Kisunla - Donanemab - EMEA/H/C/006024

Eli Lilly Nederland B.V.; to slow disease progression in adult patients with Alzheimer's disease (AD).

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

Third party intervention

Opinion adopted on 27.03.2025. List of Outstanding Issues adopted on 12.12.2024, 25.04.2024. List of Questions adopted on 14.12.2023.

See 2.2

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Bifikafusp alfa / Onfekafusp alfa - EMEA/H/C/005651

neoadjuvant treatment of adult patients with locally advanced fully resectable melanoma

Scope: Withdrawal of initial marketing authorisation application

Action: For information

4. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

4.1. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion

4.1.1. Azacitidine Accord - Azacitidine - EMEA/H/C/005147/X/0021

Accord Healthcare S.L.U.;

Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to introduce a new pharmaceutical form (film-coated tablet) associated with new strengths (200 and 300 mg) and new route of administration (oral use).The RMP (version 2.0) is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 22.05.2025. List of Questions adopted on 12.12.2024.

4.1.2. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/X/0039

Vanda Pharmaceuticals Netherlands B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (4 mg/ml oral solution). The new formulation is indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in paediatric patients 3 to 15 years of age. The RMP (version 5.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 27.02.2025.

4.1.3. Livmarli - Maralixibat - Orphan - EMEA/H/C/005857/X/0015

Mirum Pharmaceuticals International B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to introduce a new pharmaceutical form (tablet) associated with new strengths 10 mg, 15mg, 20 mg and 30 mg. The RMP (version 5.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 27.02.2025.

4.2. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues

4.2.1. Enzalutamide Viatris - Enzalutamide - EMEA/H/C/006299/X/0003

Viatris Limited;

Rapporteur: Tomas Radimersky, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension application to add a new strength of 160 mg for solution for film-coated tablets.
The RMP (version 1.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 27.03.2025.

4.2.2. Pyrukynd - Mitapivat - Orphan - EMEA/H/C/005540/X/0010/G

Agios Netherlands B.V.;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to introduce a new strength (100 mg film-coated tablet) associated with a new orphan indication for the "treatment of adult patients with non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassaemia". The extension application is grouped with a type II quality variation (C.I.4) to update of sections 4.2 and 5.2 of the SmPC in order to update pharmacokinetic information based on final results from study AG348-C-024 listed as a category 3 study in the RMP; this is a Phase 1, Open-label, Single-dose, Pharmacokinetic Study of Mitapivat in Subjects with Moderate Hepatic Impairment Compared to Matched Healthy Control Subjects with Normal Hepatic Function. The RMP (version 1.1) is updated in accordance."

Action: For adoption

List of Questions adopted on 27.03.2025.

4.2.3. Remsima - Infliximab - EMEA/H/C/002576/X/0149

Celltrion Healthcare Hungary Kft.;

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola

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

Action: For adoption

List of Questions adopted on 25.04.2025.

4.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question

4.3.1. Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMA/X/0000258051

Pfizer Europe MA EEIG

Rapporteur: Jayne Crowe

Scope: Extension application to introduce a new pharmaceutical form Powder and solvent for solution for injection in multidose container.

Action: For adoption

4.3.2. Akynzeo - Fosnetupitant / Netupitant / Palonosetron - EMA/X/0000258060

Helsinn Birex Pharmaceuticals Limited

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new pharmaceutical form (300 mg / 0.5 ml oral suspension).

Action: For adoption

4.3.3. Camcevi – Leuprorelin - EMA/X/0000258054

Accord Healthcare S.L.U.

Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to add a new strength of 21 mg for Leuproelin prolonged-release suspension for injection pre-filled syringe, for subcutaneous (SC) administration.

Action: For adoption

4.3.4. Jorveza – Budesonide - EMA/X/0000257468

Dr. Falk Pharma GmbH

Rapporteur: Janet Koenig, PRAC Rapporteur: Zane Neikena

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (0.2 mg/ml oral suspension). The new presentation is indicated for paediatric patients 2 to 17 years of age.

Action: For adoption

4.3.5. Lojuxta – Lomitapide - EMA/X/0000258068

Chiesi Farmaceutici S.p.A.

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Bianca Mulder

Scope: Extension application to add a new strength of 2 mg hard capsules.

This application is grouped with

- type II variation (C.I.6.a): an Extension of Indication to include treatment of paediatric patients aged 5 years and older with homozygous familial hypercholesterolaemia (HoFH) for LOJUXTA, based on final results from the pivotal paediatric study APH-19; this is a phase 3, single-arm, open-label, international, multi-centre study to evaluate the efficacy and safety of lomitapide in paediatric patients with homozygous familial hypercholesterolaemia (HOFH) on stable lipid-lowering therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Annex II and Package Leaflet are updated accordingly. The RMP version 7.1 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.

Action: For adoption

4.3.6. Nexviadyme - Avalglucosidase alfa - EMA/X/0000258013

Sanofi B.V.

Rapporteur: Christian Gartner

Scope: Quality

Action: For adoption

4.3.7. Olumiant – Baricitinib - EMA/X/0000257923

Eli Lilly Nederland B.V.

Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to introduce a new pharmaceutical form (oral suspension) associated with a new strength (2 mg/ml).

Action: For adoption

4.3.8. Scemblix – Asciminib - EMA/X/0000256688

Novartis Europharm Limited

Rapporteur: Jante Koenig, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Eva Jirsová

Scope: Extension application to introduce a new strength (100 mg film-coated tablets) grouped with a type II variation (C.I.6.a) to add a new indication (treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) harbouring the T315I mutation), based on final results from study CABL001X2101 and study CABL001A2004. Study CABL001X2101 is a Phase I, multicentre, open-label, dose escalation FIH study to define the MTD/RDEs, to characterize safety and tolerability, and to assess the PK profile and preliminary evidence of efficacy of asciminib given as single agent or in combination with either nilotinib or imatinib or dasatinib in patients with Ph+ CML or Ph+ ALL.

Study CABL001A2004 assessed the real-world effectiveness of asciminib and treatment patterns in patients with Chronic Myeloid Leukaemia with T315I mutation. As a consequence, sections 1, 2, 3, 4, 5, 6 and 8 of the SmPC are updated. The Package Leaflet and Labelling are 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

4.4. Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008

No items

4.5. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

No items

5. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008

5.1. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information

5.1.1. Alhemo – Concizumab - EMA/VR/0000244862

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include treatment of haemophilia A without inhibitors and haemophilia B without inhibitors for ALHEMO based on final results from study NN7415-4307; this is an interventional study to investigate efficacy and safety of concizumab prophylaxis in patients with haemophilia A or B without inhibitors. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.

Action: For adoption

5.1.2. BAQSIMI – Glucagon - EMA/VR/0000244909

Amphastar France Pharmaceuticals

Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Eamon O Murchu

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

Action: For adoption

5.1.3. BESPONSA - Inotuzumab ozogamicin - EMA/VR/0000257310

Pfizer Europe MA EEIG

Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include treatment of paediatric patients 1 year and older with relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukaemia

(ALL) for BESPONSA, based on final results from studies ITCC-059 (WI203581) and INO-Ped-ALL-1 (WI235086).

Study WI203581 is a Phase 1/2, multicentre, European, multi-cohort, open-label study in paediatric patients (≥1 and <18 years of age) with R/R CD22-positive ALL; Study WI235086 is an open-label, Phase 1 study to assess safety and tolerability of InO in Japanese paediatric patients with R/R CD22-positive AL.

As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 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.

Action: For adoption

5.1.4. Breyanzi - Lisocabtagene maraleucel – ATMP – EMA/VR/0000265024

Bristol-Myers Squibb Pharma EEIG

CAT Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini

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

Type II (C.I.6): Extension of indication to include the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor for BREYANZI, based on results from the pivotal Study 017001 MCL Cohort (TRANSCEND-NHL-001); this is a Phase 1, Multicentre, Open-Label Study of JCAR017, CD19-targeted Chimeric Antigen Receptor (CAR) T Cells, for Relapsed and Refractory (R/R) B-cell Non-Hodgkin Lymphoma (NHL). As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package leaflet is updated in accordance. Version 7.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet.

Quality variation

Action: For adoption

5.1.5. Cejemly – Sugemalimab - EMA/VR/0000261157

Cstone Pharmaceuticals Ireland Limited

Rapporteur: Filip Josephson, PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include the treatment of unresectable stage III non-small-cell lung cancer (NSCLC) with no sensitising EGFR mutations, or ALK, ROS1 genomic tumour aberrations in adults whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy for CEJEMLY, based on final results from study CS1001-301; this is a Phase III, multicentre, randomised, double-blind, placebo-controlled study assessing the efficacy and safety of sugemalimab as consolidation therapy versus placebo in participants with locally advanced or unresectable stage III NSCLC who have not progressed after concurrent or sequential chemoradiotherapy. 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 2.0 of the RMP has also been submitted.

Action: For adoption

5.1.6. Clopidogrel Zentiva - Clopidogrel - EMEA/H/C/000975/II/0092

Zentiva k.s.;

Rapporteur: Fátima Ventura, PRAC Rapporteur: Carla Torre

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

Action: For adoption

Request for Supplementary Information adopted on 25.04.2025.

5.1.7. CRYSVITA – Burosumab - EMA/VR/0000263400

Kyowa Kirin Holdings B.V.

Rapporteur: Kristina Dunder

Scope: Extension of indication to include treatment of X-linked hypophosphataemia (XLH) in paediatric patients from birth to less than 1 year of age for CRYSVITA, based on final results from study BUR-CL207; this is a phase 1/2 Open-label, Multicentre, Non-randomized Study to Evaluate Safety, Pharmacodynamics, Pharmacokinetics and Effect of Burosumab in Paediatric Patients from Birth to Less than 1 Year of Age with XLH; 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.

Action: For adoption

5.1.8. Elucirem/ Vueway – Gadopiclenol - EMA/VR/0000249008

Guerbet, Bracco Imaging S.p.A

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include treatment of new population (0 to 2 years of age patients) for ELUCIREM / VUEWAY, based on final results from study GDX-44-015; this is a phase ii clinical study concerning gadopiclenol pharmacokinetics, safety and efficacy in paediatric patients < 2 years of age undergoing contrast-enhanced MRI; extension of indication is also supported with the non-clinical data. 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 0.4 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to remove Annex IV from the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.9. Eylea – Aflibercept - EMA/VR/0000264981

Bayer AG

Rapporteur: Jean-Michel Race, PRAC Rapporteur: Zoubida Amimour

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

C.I.6: Extension of indication to include the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch, central and hemiretinal RVO) for EYLEA, based on results from study 22153 (QUASAR); this is a randomized, double-masked, active-controlled Phase 3 study of the efficacy and safety of aflibercept 8 mg in macular oedema secondary to retinal vein occlusion. 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 accordingly. The RMP version 36.1 has also been submitted.

C.I.4: Update of section 4.2 of the SmPC in order to change posology recommendations of the approved indications nAMD and DME based on the results from study 22153 (QUASAR) and post-hoc analysis of the pivotal studies 20968 (PULSAR), 21091 (PHOTON) and Phase II study 21086 (CANDELA).

Action: For adoption

5.1.10. Gazyvaro – Obinutuzumab - EMA/VR/0000244907

Roche Registration GmbH

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of adult patients with active lupus nephritis who are receiving standard therapy for GAZYVARO, based on results from study Regency (CA41705). This is an ongoing, Phase III, randomized, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of obinutuzumab administered at standard infusion rates in patients with ISN/RPS 2003 Class III or IV lupus nephritis treated with standard-of-care therapy.

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

Action: For adoption

5.1.11. Iclusig – Ponatinib - EMA/VR/0000263550

Incyte Biosciences Distribution B.V.

Rapporteur: Filip Josephson, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of adult patients with newly-diagnosed Ph+ ALL for ICLUSIG, based on interim results from study Ponatinib-3001 (PhALLCON); this is a phase 3, randomized, open-label, multicentre study comparing ponatinib versus imatinib, administered in combination with reduced intensity chemotherapy, in patients with newly diagnosed Ph+ ALL; supportive data were derived from two single-arm, open-label

clinical studies (AP24534 11 001 in combination with chemotherapy and INCB 84344-201 as monotherapy). 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 23.2 of the RMP has also been submitted. In addition, earlier approved updates were incorporated to the PI.

Action: For adoption

5.1.12. Invokana - Canagliflozin - EMEA/H/C/002649/II/0069

Janssen-Cilag International N.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include treatment of paediatric patients with type 2 diabetes mellitus aged 10 years old and older for INVOKANA, based on final results from study JNJ-28431754DIA3018 as well as study JNJ-28431754DIA1055. Study JNJ-28431754DIA3018 is a double-blind, placebo-controlled, 2-arm, parallel-group, multicentre Phase 3 study in participants with T2DM >10 and <18 years of age who had inadequate glycaemic control (ie, HbA1c of >6.5% to <11.0%). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI and update the list of local representatives in the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 27.03.2025, 14.11.2024.

5.1.13. Keytruda – Pembrolizumab - EMA/VR/0000245108

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

5.1.14. LIBTAYO – Cemiplimab - EMA/VR/0000264999

Regeneron Ireland Designated Activity Company

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include adjuvant treatment of adult patients with Cutaneous Squamous Cell Carcinoma (CSCC) at high risk of recurrence after surgery and radiation for LIBTAYO, based on interim results from study R2810-ONC-1788; this is a phase 3, randomized, placebo-controlled, double-blind study of adjuvant cemiplimab versus placebo after surgery and radiation therapy in patients with high risk CSCC; As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the warnings for the excipients, proline and polysorbate to reflect EU guidance (Section 4.4) and also updated Annex IID of the PI in line with the updates made to the RMPv4.2 to consolidate the aRMMs.

Action: For adoption

5.1.15. mRESVIA - Respiratory syncytial virus mRNA vaccine (nucleoside modified) - EMA/VR/0000248175

Moderna Biotech Spain S.L.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Jean-Michel Dogné

Scope: To modify the approved therapeutic indication to include active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV for mRESVIA, based on results from Study mRNA-1345-P303 (Part A) - A Phase 3 Study to Evaluate the Immunogenicity and Safety of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus, in High-risk Adults. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC and the corresponding sections of the Package Leaflet are updated accordingly. The updated RMP Version 1.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI. As part of the application, the MAH also requests an extension of the market protection by one additional year.

Action: For adoption

5.1.16. Neuraceq - Florbetaben (18F) - EMA/VR/0000227744

Life Molecular Imaging GmbH

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include monitoring of the biological treatment response to pharmacological and non-pharmacological interventions for NEURACEQ, based on supporting literature. As a consequence, sections 4.1, 4.4 and 5.1 of the SmPC are updated. The Package Leaflet (PL) is updated in accordance. Version 6.91 of the RMP has also been submitted. In addition, the MAH took the opportunity to include the proposal to discontinue the inclusion of a paper copy of the SmPC with the product package.

Action: For adoption

5.1.17. Noxafil – Posaconazole - EMA/VR/0000263360

Merck Sharp & Dohme B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Zoubida Amimour

Scope: Extension of indication for NOXAFIL to include treatment of patients two years of age and older for invasive aspergillosis (IA) based on final results from study MK-5592-104 (P104); this is a Phase 2, open-label, noncomparative clinical study that evaluated the safety, efficacy, and PK of POS in paediatric participants aged 2 to <18 years with IA. 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 18.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the PI.

Action: For adoption

5.1.18. Recarbrio - Imipenem / Cilastatin / Relebactam - EMA/VR/0000265089

Merck Sharp & Dohme B.V.

Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to extend the approved adult indications for RECARBRIO to include treatment of paediatric population from birth to <18 years of age, based on final results from two paediatric studies (MK-7655A-021 and MK-7655A-020); phase 2/3 study MK-7655A-021 addressed safety, tolerability, efficacy and PK, and phase 1b study MK-7655A-020 addressed PK, safety, and tolerability of MK-7655A in paediatric subjects from birth to less than 18 years of age with confirmed or suspected gram-negative infections. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and implement minor editorial corrections.

Action: For adoption

5.1.19. Scemblix – Asciminib - EMA/VR/0000265010

Novartis Europharm Limited

Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová

Scope: A grouped application consisting of:

C.I.6.a: Extension of indication to include treatment of adult patients with newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in chronic phase (CP) for SCEMBLIX, based on primary and key secondary analysis results from study CABL001J12301 (ASC4FIRST, J12301); this is an ongoing Phase III, multi-centre, open-label, randomized study of oral asciminib (80 mg once daily, q.d.) versus Investigator selected tyrosine kinase inhibitor (TKI) in patients with newly diagnosed Ph+ CML-CP, with the primary and key secondary objectives to compare the major molecular response (MMR) rates at Week 48 and Week 96, respectively. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. RMP version 4.0 has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.

C.I.4: Update of sections 4.2, 4.5, 5.1, 5.2 and 5.3 of the SmPC in order to introduction of a new posology regimen based on results from studies CABL001J12301 and CABL001A2302 (ASC4OPT, A2302). CABL001A2302 is an ongoing Phase IIIb, multi-centre, open-label, treatment optimization study of oral asciminib (80 mg daily, randomized to 40 mg b.i.d. or 80 mg q.d.) in patients with Ph+ CML-CP previously treated with two or more TKIs, with the primary objective to estimate the MMR rate at Week 48 of all the patients (40 mg b.i.d. and 80 mg q.d.) with no evidence of MMR at baseline. The Package Leaflet is updated accordingly. RMP version 4.0 has also been submitted.

Action: For adoption

5.1.20. SIRTURO – Bedaquiline - EMA/VR/0000249065

Janssen Cilag International

Rapporteur: Filip Josephson, PRAC Rapporteur: Karin Bolin

Scope: Extension of indication to include treatment of paediatric patients (2 years to less than 5 years of age and weighing at least 7 kg) with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to at least rifampicin and isoniazid, for SIRTURO, based on the Week 24 primary analysis from Cohort 3 (≥2 to <5 years of age) of Study TMC207-C211; this is an open-label, multicentre, single-arm study to evaluate pharmacokinetics, safety/tolerability, antimycobacterial activity and dose selection of bedaquiline in children (birth to <18 years) with multidrug-resistant-TB (MDR-TB). Long-term follow-up to Week 120 in participants of Cohort 1 (≥12 to <18 years of age) and Cohort 2 (≥5 to <12 years of age) have also been submitted. 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 11.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and introduce minor changes to the PI.

Action: For adoption

5.1.21. Sogroya – Somapacitan - EMA/VR/0000264734

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber

Scope: Grouped extension of indication application to include treatment of children born small for gestational age (SGA), Noonan syndrome (NS) and idiopathic short stature (ISS) for SOGROYA, based on interim results from the pivotal, confirmatory phase 3 study NN8640-4467 supported by the phase 3 study NN8640-4469 and the phase 2 study NN8640-4245. Study 4467 is a study comparing the effect and safety of once weekly dosing of somapacitan with daily Norditropin as well as evaluating long-term safety of somapacitan in a basket study design in children with short stature either born small for gestational age or with Turner syndrome, Noonan syndrome, or idiopathic short stature. Study 4469 is a study evaluating the safety and efficacy of once-weekly dosing of somapacitan in a basket study design in paediatric participants with short stature either born small for gestational age or with turner syndrome, Noonan syndrome or idiopathic short stature. Study 4245 is a dose-finding trial evaluating the effect and safety of once-weekly treatment of somapacitan compared to daily Norditropin in children with short stature born small for gestational age

with no catch-up growth by 2 years of age or older. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.22. Taltz - Ixekizumab - EMEA/H/C/003943/II/0053

Eli Lilly and Co (Ireland) Limited;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include treatment of juvenile idiopathic arthritis for TALTZ, based on week 16 results from study I1F-MC-RHCG; this is a multicentre, open-label, efficacy, safety, tolerability, and pharmacokinetic study (COSPIRIT-JIA) of subcutaneous ixekizumab with adalimumab reference arm, in children from 2 to less than 18 years of age with juvenile idiopathic arthritis subtypes of enthesitis-related arthritis (including juvenile-onset ankylosing spondylitis) and juvenile psoriatic arthritis was performed to evaluate the efficacy and safety of ixekizumab for 16 weeks after treatment initiation. 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 8.1 of the RMP has also been submitted. Furthermore, the PI is in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 27.03.2025, 14.11.2024.

5.1.23. Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0018

Beone Medicines Ireland Limited;

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication for Tevimbra in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, for the treatment of adult patients with resectable NSCLC based on interim results from study BGB-A317-315. Study BGB-A317-315 is a phase 3 randomized, placebo-controlled, double-blind study to compare the efficacy and safety of neoadjuvant treatment with tislelizumab plus platinum-based doublet chemotherapy followed by adjuvant tislelizumab versus neoadjuvant treatment with placebo plus platinum-based doublet chemotherapy followed by adjuvant placebo in patients with resectable Stage II or IIIA NSCLC. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.7 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 27.03.2025.

5.1.24. TEZSPIRE – Tezepelumab - EMA/VR/0000245013

AstraZeneca AB

Rapporteur: Finbarr Leacy, Co-rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include treatment of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) for Tezspire, based on results from study WAYPOINT (D5242C00001); this is a global, multicentre, randomised, double-blind, parallel-group, placebo-controlled study that evaluated the efficacy and safety of tezepelumab compared with placebo in the treatment of CRSwNP. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to update the PI and the Package Leaflet in accordance with the latest EMA excipients guideline.

Action: For adoption

5.1.25. VEYVONDI - Vonicog alfa - EMA/VR/0000264863

BAXALTA INNOVATIONS GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of haemorrhage in children aged less than 18 years for VEYVONDI, based on results from studies 071102 and SHP677-304. Study 071102 is a phase 3, prospective, multicentre, uncontrolled, open-label clinical study to determine the efficacy, safety, and tolerability of rVWF with or without ADVATE in the treatment and control of bleeding episodes, the efficacy and safety of rVWF in elective and emergency surgeries, and the pharmacokinetics (PK) of rVWF in children diagnosed with severe VWD; study SHP677-304 is a phase 3B, prospective, open-label, uncontrolled, multicentre study on long term safety and efficacy of vonicog alfa in paediatric and adult subjects with severe VWD.

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 accordingly. Version 6.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity 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

5.1.26. Xerava – Eravacycline - EMA/VR/0000265697

Paion Pharma GmbH

Rapporteur: Filip Josephson

Scope: Extension of indication to include treatment of complicated intra-abdominal infections (cIAI) from the age of 8 years and older for XERAVA, based on final results from study TP-434-028; this is a phase 1, open-label, multicentre study to determine the pharmacokinetics and safety of intravenous eravacycline in children with suspected or confirmed bacterial infection; As a consequence, sections 4.1, 4.2, 5.1, 5.2, and 6.6 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. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

Action: For adoption

5.2. Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

No items

5.3. Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006768

qualitative determination of antibodies to adeno-associated virus serotype 74 (AAVrh74) in human serum and/or plasma

Scope: Opinion

Action: For adoption

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006723

to determine HER2 gene status by enumeration of the ratio of the HER2 gene to Chromosome 17 by light microscopy

Scope: Opinion

Action: For adoption

List of questions adopted on 19.06.2025.

6.3.3. In vitro diagnostic medical device - EMEA/H/D/006724

semi-quantitative detection of HER2 antigen by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded breast carcinoma, gastric carcinoma, and biliary tract cancer

Scope: Opinion

Action: For adoption

List of questions adopted on 19.06.2025.

6.4. Companion diagnostics – follow-up consultation

No items

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

7.1. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. Acoziborole – H0006686

treatment of Human African Trypanosomiasis (HAT or sleeping sickness) caused by *T.b. gambiense*

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

8.2. Priority Medicines (PRIME)

Information related to priority medicines cannot be released at present time as these contain commercially confidential information

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Amvuttra - Vutrisiran - Orphan - EMEA/H/C/005852/II/0015

Alnylam Netherlands B.V.;

Rapporteur: Janet Koenig, Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Liana Martirosyan

Scope: Revised assessment report

Action: For adoption

Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 30.01.2025.

9.1.2. Tecovirimat SIGA – Tecovirimat - EMA/S/0000248804

Siga Technologies Netherlands B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber

Scope: Annual reassessment

Action: For adoption

9.1.3. WS2780 Riltrava Aerosphere-EMEA/H/C/005311/WS2780/0017 Trixeo Aerosphere-EMEA/H/C/004983/WS2780/0024

AstraZeneca AB

Lead Rapporteur: Finbarr Leacy, Lead PRAC Rapporteur: Jan Neuhauser

Scope: Quality

Action: For adoption

Request for Supplementary Information adopted on 22.05.2025, 30.01.2025.

9.1.4. Fluenz Tetra - Influenza vaccine (live attenuated, nasal) – EMEA/H/C/002617

AstraZeneca AB; Prophylaxis of influenza in individuals 24 months to less than 18 years.

Rapporteur: Christophe Focke, Co-Rapporteur: Ingrid Wang

Scope: Withdrawal of marketing authorization

Action: For information

9.1.5. Volibris – Ambrisentan - EMA/VR/0000266441

Glaxosmithkline (Ireland) Limited

Rapporteur: Antonio Gomez-Outes

Scope: Update of sections 4.2 and 5.3 of the SmPC in order to update the recommendations for the paediatric population, based on non-clinical data. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI.

Action: For adoption

9.1.6. COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000275515

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson

Scope: Quality

Action: For adoption

9.1.7. BIMERVAX - COVID-19 vaccine (recombinant, adjuvanted) - EMA/VR/0000279224

Hipra Human Health S.L.

Rapporteur: Beata Maria Jakline Ullrich

Scope: Quality

Action: For adoption

9.1.8. Spikevax - COVID-19 mRNA vaccine - EMA/VR/0000278795

Moderna Biotech Spain S.L.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: For adoption

9.1.9. Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells – ATMP - EMEA/H/C/002450/R/0058

Holostem S.r.l.

Rapporteur: Egbert Flory, CHMP coordinators: Jan Mueller-Berghaus and Paolo Gasparini

Scope: Revised opinion adopted via written procedure on 01.07.2025.

Action: For information

10. Referral procedures

10.1. Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004

10.1.1. Oxbryta - Voxelotor - EMEA/H/A-20/1538/C/004869/0014

Pfizer Europe MA EEIG

Referral Rapporteur: Patrick Vrijlandt, Referral Co- Rapporteur: Alexandre Moreau

Scope: Revised timetable

Action: For adoption

The EC initiated a procedure under Article 20 of Regulation (EC) No 726/2004 to assess the benefit-risk balance of Oxbryta in its authorised indication. The initiation of the review follows an imbalance of deaths between voxelotor and placebo observed in clinical trials. The findings from these emerging safety data need to be further reviewed, taking into account all available data, to determine whether there is an impact on the benefit-risk balance of Oxbryta in its authorised indication.

List of outstanding issues adopted 22.05.2025, 12.12.2024. List of questions adopted on 29.07.2024

10.1.2. IXCHIQ - Chikungunya vaccine (live) - EMA/REF/0000269473

Valneva Austria GmbH

Referral PRAC Rapporteur: Gabriele Maurer

Scope: Opinion

Action: For adoption

Review of the benefit-risk balance following procedure triggered by the European Commission (EC) under Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data; PRAC recommendation.

10.2. Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004

10.2.1. Colistimethate sodium (CMS) – EMEA/H/A-5(3)/1524

Various MAHs

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Ewa Balkowiec Iskra

Scope: Discussion

Action: For discussion

Review of the ratio of polymyxins E1 and E2 in colistin starting material and of the

(sulfomethylation) composition profile of CMS finished product.

List of outstanding issues adopted on 21.03.2024, 22.02.2024, 22.05.2025. List of questions adopted on 22.06.2023.

10.3. Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004

No items

10.4. Disagreement between Member States on application for medicinal product (potential serious risk to public health) –under Article 29(4) of Directive 2001/83/EC

No items

10.5. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC

No items

10.6. Community Interests - Referral under Article 31 of Directive 2001/83/EC

No items

10.7. Re-examination Procedure under Article 32(4) of Directive 2001/83/EC

No items

10.8. Procedure under Article 107(2) of Directive 2001/83/EC

No items

10.9. Disagreement between Member States on Type II variation– Arbitration procedure initiated by MAH under Article 6(13) of Commission Regulation (EC) No 1084/2003

No items

10.10. Procedure under Article 29 of Regulation (EC) 1901/2006

No items

10.11. Referral under Article 13 Disagreement between Member States on Type II variation– Arbitration procedure initiated by Member State under Article 13 (EC) of Commission Regulation No 1234/2008

No items

11. Pharmacovigilance issue

11.1. Early Notification System

July 2025 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

Information related to GMP inspections will not be published as it undermines the purpose of such inspections

12.2. GCP inspections

Information related to GCP inspections will not be published as it undermines the purpose of such inspections

12.3. Pharmacovigilance inspections

Information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections

12.4. GLP inspections

Information related to GLP inspections will not be published as it undermines the purpose of such inspections

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

Information related to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to contain commercially confidential information

No items

13.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by Proxy

No items

14.1.2. CHMP membership

No items

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for July 2025

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at July 2025 PDCO

Action: For information

Agenda from the PDCO meeting held on 22-25 July 2025

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Action: For adoption

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 07-10 July 2025. Table of conclusions

Action: For information

Scientific advice letters: Information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.

14.3.3. Election of Oncology Working Party Vice-Chair

The position of vice-chair is currently being held by Olli Tenhunen (Finland).

Action: For election

Nomination(s) received

14.3.4. Election of 3Rs Working Party Chair and Vice-Chair

Action: For election

Nomination(s) received

14.3.5. Election of CNSWP Vice-chair

Action: For election

Nomination(s) received

14.3.6. Election of VWP Vice-chair

Action: For election

Nomination(s) received

14.3.7. CVSWP Response to the CHMP request on indication wording

Discussion on the indication wording

Action: For discussion

14.3.8. Nomination of CHMP representatives to the PCWP and HCPWP

Nomination of a CHMP representative (and alternate) for each working party for the mandate June 2025 to May 2028.

Nomination(s) received

Action: For endorsement

14.3.9. ICH Q3E draft Guideline on Extractables and Leachables - Step 2b

The ICH Q3E Expert Working Group has completed a draft guideline covering the assessment and control of extractables and leachables (E&L). The document is presented for adoption for a 4-month public consultation.

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

14.6. Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

Analysis of requests for clock-stop extensions and feedback from GIREX

Action: For discussion

Explanatory notes

The notes below give a brief explanation of the main sections and headings in the CHMP agenda and should be read in conjunction with the agenda or the minutes.

Oral explanations *(section 2)*

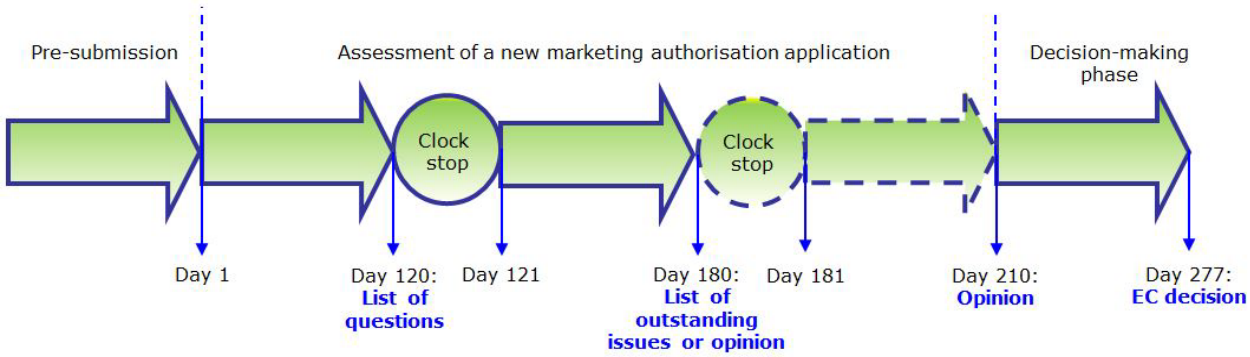
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (section 10) but can relate to any other issue for which the CHMP would like to discuss with company representatives in person.

Initial applications *(section 3)*

This section lists applications for marketing authorisations of new medicines that are to be discussed by the Committee.

Section 3.1 is for medicinal products nearing the end of the evaluation and for which the CHMP is expected to adopt an **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CHMP. The clock stop happens after day 120 and may also happen after day 180, when the CHMP has adopted a list of questions or outstanding issues to be addressed by the company. Related discussions are listed in the agenda under sections 3.2 (**Day 180 List of outstanding issues**) and 3.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 3.4, **update on ongoing new applications for centralised procedures**.

The assessment leads to an opinion from the CHMP by day 210. Following a CHMP opinion the European Commission takes usually 67 days to issue a legally binding decision (i.e. by day 277 of the procedure). CHMP discussions on products that have received a CHMP opinion and are awaiting a decision are listed under section 3.6, **products in the decision making phase**.

Extension of marketing authorisations according to Annex I of Reg. 1234/2008 *(section 4)*

Extensions of marketing authorisations are applications for the change or addition of new strengths, formulations or routes of administration to existing marketing authorisations. Extension applications follow a 210-day evaluation process, similarly to applications for new medicines (see figure above).

Type II variations - Extension of indication procedures *(section 5)*

Type II variations are applications for a change to the marketing authorisation which requires an update of the product information and which is not covered in section 4. Type II variations include applications for a new use of the medicine (extension of indication), for which the assessment takes up to 90 days. For the applications listed in this section, the CHMP may adopt an opinion or request supplementary information from the applicant.

Ancillary medicinal substances in medical devices *(section 6)*

Although the EMA does not regulate medical devices it can be asked by the relevant authorities (the so-called Notified Bodies) that are responsible for regulating these devices to give a scientific opinion on a medicinal substance contained in a medical device.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 *(section 3.5)*

This section lists applications for new marketing authorisation for which the applicant has requested a re-examination of the opinion previously issued by the CHMP.

Re-examination procedures *(section5.3)*

This section lists applications for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP.

Withdrawal of application *(section 3.7)*

Applicants may decide to withdraw applications at any stage during the assessment and a CHMP opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Procedure under article 83(1) of regulation (EC) 726/2004 (compassionate use) *(section 7)*

Compassionate use is a way of making available to patients with an unmet medical need a promising medicine which has not yet been authorised (licensed) for their condition. Upon request, the CHMP provides recommendations to all EU Member States on how to administer, distribute and use certain medicines for compassionate use.

Pre-submission issues *(section 8)*

In some cases the CHMP may discuss a medicine before a formal application for marketing authorisation is submitted. These cases generally refer to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation. In case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

Post-authorisation issues *(section 9)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 10)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. 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 EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

This section lists issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines. Feedback is provided by the PRAC. This section also refers to the early notification system, a system used to notify the European regulatory network on proposed EMA communication on safety of medicines.

Inspections Issues *(section 12)*

This section lists inspections that are undertaken for some medicinal products. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Innovation task force *(section 13)*

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes from the last ITF meeting as well as any related issue that requires discussion with the CHMP are listed in this section of the agenda. Further information on the ITF can be found here.

Scientific advice working party (SAWP) *(section 14.3.1)*

This section refers to the monthly report from the CHMP's Scientific Advice Working Party (SAWP) on scientific advice given to companies during the development of medicines. Further general information on SAWP can be found here.

Satellite groups / other committees *(section 14.2)*

This section refers to the reports from groups and committees making decisions relating to human medicines: the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), the Committee for Orphan Medicinal Products (COMP), the Committee for Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmamacovigilance Risk Assessment Committee (PRAC).

Invented name issues *(section 14.3)*

This section list issues related to invented names proposed by applicants for new medicines. The CHMP has established the Name Review Group (NRG) to perform reviews of the invented names. The group's main role is to consider whether the proposed names could create a public-health concern or potential safety risk. Further information can be found here.

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 July 2025
EMA/CHMP/214221/2025

Annex to 21-24 July 2025 CHMP Agenda

Pre-submission and post-authorisations issues

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Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for July 2025: **For adoption**

A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications

Final Outcome of Rapporteurship allocation for July 2025: **For adoption**

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

B.1.1. Annual reassessment for products authorised under exceptional circumstances

Livmarli - Maralixibat -
EMEA/H/C/005857/S/0019, Orphan
Mirum Pharmaceuticals International B.V.,
Rapporteur: Janet Koenig, PRAC Rapporteur:
Adam Przybylkowski
Request for Supplementary Information adopted on 25.04.2025.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal

B.2.2. Renewals of Marketing Authorisations for unlimited validity

B.2.3. Renewals of Conditional Marketing Authorisations

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 07-10 July 2025 PRAC:

Signal of Progressive multifocal leukoencephalopathy

Varicella Vaccine (live); Measles, Mumps, Rubella and Varicella Vaccine (Live) - PROQUAD (CAP & NAP)

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Gabriele Maurer

PRAC recommendation on a variation
Action: For adoption

Signal of progressive multifocal leukoencephalopathy

Ciltacabtagene autoleucel, idecabtagene vicleucel, tisagenlecleucel – CARVYKTI, Abecma, Kymriah (CAP)

Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: multiple

PRAC recommendation on a variation
Action: For adoption

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its July 2025 meeting:

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

Scopes related to Chemistry, Manufacturing, and Controls cannot be released at the present time as these contain commercially confidential information.

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Idacio - Adalimumab - EMEA/H/C/004475/II/0024/G
Fresenius Kabi Deutschland GmbH, Rapporteur: Peter Mol, PRAC Rapporteur: Karin Bolin
Request for Supplementary Information adopted on 27.03.2025.

Pombiliti - Cipaglucosidase alfa - EMEA/H/C/005703/II/0019	Positive Opinion adopted by consensus on 03.07.2025.

Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt Opinion adopted on 03.07.2025. Request for Supplementary Information adopted on 25.04.2025.	
POTELIGEO - Mogamulizumab - EMEA/H/C/004232/II/0028/G, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Peter Mol Opinion adopted on 26.06.2025. Request for Supplementary Information adopted on 27.03.2025.	Positive Opinion adopted by consensus on 26.06.2025.
WS2780 **Riltrava Aerosphere-** **EMEA/H/C/005311/WS2780/0017** **Trixeo Aerosphere-** **EMEA/H/C/004983/WS2780/0024** AstraZeneca AB, Lead Rapporteur: Finbarr Leacy, Lead PRAC Rapporteur: Jan Neuhauser Request for Supplementary Information adopted on 22.05.2025, 30.01.2025.	See 9.1

B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0059/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "A grouped application consisting of: C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information with albendazole based on the post-marketing data and literature and to update information on drug-drug interactions with methadone and ethinyl estradiol based on the literature; the Package Leaflet is updated accordingly. C.I.4: Update of section 4.5 of the SmPC in order to update information on drug-drug interactions with calcium channel antagonists based on the cumulative safety data and literature." Request for Supplementary Information adopted on 15.05.2025, 23.01.2025.	
WS2818 **PecFent-** **EMEA/H/C/001164/WS2818/0062** Gruenenthal GmbH, Lead Rapporteur: Janet Koenig, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information	

between opioids and anticholinergics; the Package Leaflet is updated accordingly."
Request for Supplementary Information adopted on 15.05.2025, 13.03.2025.

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-EMEA/H/W/005362/WS2809/0021 Qdenga-EMEA/H/C/005155/WS2809/0022
Takeda GmbH, Lead Rapporteur: Sol Ruiz, "Update of section 4.8 of the SmPC in order to add eye pain to the list of adverse drug reactions (ADRs) with frequency uncommon based on post-marketing data; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI."
Request for Supplementary Information adopted on 20.03.2025.

B.5.3. CHMP-PRAC assessed procedures

Sunosi - Solriamfetol - EMEA/H/C/004893/II/0026
Atnahs Pharma Netherlands B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Julia Pallos, "Update of sections 4.6 and 5.2 of the SmPC in order to update information on lactation and breast-feeding based on results from the post-marketing lactation study JZP110-401 listed as a category 3 study in the RMP. This was a Phase 4, open-label, single-dose study to evaluate the PK of solriamfetol in the breast milk and plasma of healthy postpartum women following oral administration of a 150 mg solriamfetol tablet. The Package Leaflet is updated accordingly. The RMP version 1.3 has also been submitted."
Request for Supplementary Information adopted on 08.05.2025.

ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0004/G, Orphan
Immedica Pharma AB, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "A grouped application comprised of 8 Type II variations as follows:
1 Type II (C.I.4): Update of section 5.2 of the SmPC in order to update ganaxolone metabolite pattern at steady state based on re-analysis of

1042-TQT-1001 listed as a category 3 study in the RMP to evaluate the ganaxolone steady-state metabolite. 7 Type II (C.I.13): Submission of the final non-clinical study reports for the in vitro DDI potential and in vivo PK of the metabolite M17 listed as category 3 studies in the RMP. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to introduce updates to the PI that reflect clarifications and typographical corrections, including to sections 4.2 and 4.4 of the SmPC." Request for Supplementary Information adopted on 27.03.2025, 25.07.2024, 11.04.2024.	
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0015/G, Orphan Immedica Pharma AB, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "A grouped application consisting of five Type II variations, as follows: C.I.13: Submission of the final report from non-clinical study 1022-9241 listed as a category 3 study in the RMP. This is a 26-Week Toxicity Study of Ganaxolone Metabolite, M2, by Oral Gavage in the Sprague-Dawley rat with a 2-Week Recovery Period. The RMP version 3 has also been submitted. C.I.13: Submission of the final report from non-clinical study 20447815 listed as a category 3 study in the RMP. This is a An Oral (Gavage) Study of the Effects of M2 (Ganaxolone Metabolite) Administration on Embryo/Fetal Development in CD (Sprague Dawley) IGS Rat. The RMP version 3 has also been submitted. C.I.13: Submission of the final report from Weight of Evidence (WoE) assessment to evaluate the need for a 2-year carcinogenicity study in rats with GNX, listed as a category 3 study in the RMP. C.I.13: Submission of the final report from WoE assessment to evaluate the need for a 2-year carcinogenicity study in rats with M2, listed as a category 3 study in the RMP.	Request for supplementary information adopted with a specific timetable.

C.I.13: Submission of the final report from WoE assessment to evaluate the need for a juvenile toxicity study with M2, listed as a category 3 study in the RMP. ” Request for Supplementary Information adopted on 10.07.2025, 13.03.2025.	

B.5.4. PRAC assessed procedures

PRAC Led **Enbrel - Etanercept - EMEA/H/C/000262/II/0255** Pfizer Europe MA EEIG, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gomez-Outes, “Update of the RMP version 7.9 to remove the important risks of “Aplastic Anaemia and Pancytopenia”, “Congestive Heart Failure in Adult Subjects” and “Acute Ischaemic Cardiovascular Events in Adults Subjects” and the missing information “Immunogenicity Profile and Related Clinical Outcomes of Etanercept Manufactured using the revised process in a Real-life Post-marketing Setting’’ from the list of SCs. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI as well as to update the list of local representatives in the Package Leaflet and align the PI with the QRD version 10.4.” Opinion adopted on 10.07.2025. Request for Supplementary Information adopted on 10.04.2025, 16.01.2025.	Positive Opinion adopted by consensus on 10.07.2025.
PRAC Led **Mimpara - Cinacalcet - EMEA/H/C/000570/II/0076** Amgen Europe B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, “Submission of the final report from study 20180204 listed as a category 3 study in the RMP. This is a non-interventional observational registry study to evaluate the use and safety of cinacalcet among paediatric patients with secondary hyperparathyroidism (HPT).” Opinion adopted on 10.07.2025. Request for Supplementary Information adopted on 13.03.2025.	Positive Opinion adopted by consensus on 10.07.2025.

B.5.5. CHMP-CAT assessed procedures

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

B.5.8. Unclassified procedures and worksharing procedures of type I variations

B.5.9. Information on withdrawn type II variation / WS procedure

B.5.10. Information on type II variation / WS procedure with revised timetable

D. Annex D - Post-Authorisation Measures (PAMs), (Details on PAMs including description and conclusion, for adoption by CHMP in that given month, or finalised ones with PRAC recommendation and no adoption by CHMP needed)

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

Information related to plasma master files cannot be released at the present time as these contain commercially confidential information.

E.1. PMF Certification Dossiers

E.2. Time Tables – starting & ongoing procedures: For information

PMF timetables starting and ongoing procedures	Tabled in MMD and sent by post mail (folder E).

F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver

G. ANNEX G

G.1. Final Scientific Advice (Reports and Scientific Advice letters):

Information related to Scientific Advice cannot be released at the present time as these contain commercially confidential information.

G.2. PRIME

Some information related to PRIME cannot be released at the present time as these contain commercially confidential information.