15 September 2025
EMA/CHMP/276284/2025 Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 15-18 September 2025
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

15 September 2025, 09:30 – 19:30, virtual meeting/room 1C

16 September 2025, 08:30 – 19:30, virtual meeting/room 1C

17 September 2025, 08:30 – 19:30, virtual meeting/room 1C

18 September 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 15-18 September 2025. See September 2025 CHMP minutes (to be published post October 2025 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 15-18 September 2025

1.3. Adoption of the minutes

CHMP minutes for 21-24 July 2025 plenary meeting and 18-21 August 2025 written procedure.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 08 September 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Enzalutamide - EMEA/H/C/006612

treatment of prostate cancer

Scope: Oral explanation

Action: Oral explanation to be held on 15 September 2025 at 11:00

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.02.2025.

2.1.2. Hydrocortisone - PUMA - EMEA/H/C/005201

prevention of bronchopulmonary dysplasia in preterm infants born less than 28 weeks of gestation.

Scope: Oral explanation

Action: Oral explanation to be held on 17 September 2025 at 14:00

List of Outstanding Issues adopted on 19.06.2025. List of Questions adopted on 12.12.2024.

2.1.3. Nipocalimab - EMEA/H/C/006379

treatment of generalised Myasthenia Gravis

Scope: Oral explanation

Action: Oral explanation to be held on 16 September 2025 at 14:00

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

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 16 September 2025 at 16:00

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

2.1.5. Teduglutide - EMEA/H/C/006564

treatment of Short Bowel Syndrome

Scope: Oral explanation

Action: Oral explanation to be held on 17 September 2025 at 09:00

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.02.2025.

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 15 September 2025 at 14:00

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.02.2025.

2.2. Re-examination procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 16 September 2025 at 11:00

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.

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. Keytruda – Pembrolizumab - EMA/VR/0000245108

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Oral explanation

Action: Oral explanation to be held on 17 September 2025 at 11:00

See 5.1

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

Mirum Pharmaceuticals International B.V.; treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) and progressive familial intrahepatic cholestasis (PFIC)

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: Oral explanation

Action: Oral explanation to be held on 17 September 2025 at 16:00

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.02.2025.

See 4.1

2.3.3. SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0052

Clinuvel Europe Limited

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: Oral explanation

Action: Oral explanation to be held on 16 September 2025 at 09:00

Request for Supplementary Information adopted on 22.05.2025, 27.02.2025, 14.11.2024, 30.05.2024.

See 9.1

2.4. Referral procedure oral explanations

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

Pfizer Europe MA EEIG

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

Scope: Oral explanation

Action: Oral explanation to be held on 15 September 2025 at 16:00

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

See 10.1

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Denosumab - EMEA/H/C/006734

treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.06.2025.

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

Accelerated assessment

treatment of non-cystic fibrosis bronchiectasis

Scope: Opinion

Action: For adoption

List of Questions adopted on 22.07.2025.

3.1.3. Denosumab - EMEA/H/C/006239

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.03.2025.

3.1.4. Denosumab - EMEA/H/C/006797

treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

3.1.5. Clesrovimab - EMEA/H/C/006497

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.03.2025.

Third party intervention

3.1.6. Golimumab - EMEA/H/C/006560

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis and ulcerative colitis

Scope: Opinion

Action: For adoption

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

3.1.7. Denosumab - EMEA/H/C/006490

treatment of osteoporosis and bone loss in postmenopausal women and in men

Scope: Opinion

Action: For adoption

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

3.1.8. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.02.2025.

3.1.9. Elinzanetant - EMEA/H/C/006298

treatment of moderate to severe vasomotor symptoms (VMS)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.02.2025.

3.1.10. Denosumab - EMEA/H/C/006238

treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

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

3.1.11. Rivaroxaban - EMEA/H/C/006643

prevention of atherothrombotic events

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.02.2025.

3.1.12. Ustekinumab - EMEA/H/C/006667

treatment of Crohn’s disease and ulcerative colitis

Scope: List of questions

Action: For adoption

3.1.13. Denosumab - EMEA/H/C/006722

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

Scope: Opinion

Action: For adoption

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

3.1.14. Denosumab - EMEA/H/C/006552

prevention of skeletal related events in adults and treatment of adults and skeletally mature adolescents with giant cell tumour of bone

Scope: Opinion

Action: For adoption

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

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

3.2.1. Blarcamesine - EMEA/H/C/006475

treatment of Alzheimer's disease and dementia

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2025.

3.2.2. Donidalorsen - Orphan - EMEA/H/C/006554

Otsuka Pharmaceutical Netherlands B.V.; for routine prevention of recurrent attacks of hereditary angioedema (HAE)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2025.

3.2.3. Iloperidone - EMEA/H/C/006561

treatment of schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2025.

3.2.4. Germanium (68Ge) chloride / Gallium (68Ga) chloride - EMEA/H/C/006639

indicated for in vitro radiolabelling of specific carrier molecules to be used for positron emission tomography (PET) imaging

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2025.

3.2.5. Insulin glargine - EMEA/H/C/006136

treatment of diabetes mellitus

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

3.2.6. Imlunestrant - EMEA/H/C/006184

treatment of adult patients with advanced or metastatic breast cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2025.

3.2.7. Doxecitine / Doxribtimine - PRIME - Orphan - EMEA/H/C/005119

UCB Pharma; indicated for the treatment of paediatric and adult patients with thymidine kinase 2 deficiency (TK2d) with an age of symptom onset on or before 12 years

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.03.2025.

3.2.8. COVID-19 mRNA vaccine - EMEA/H/C/006428

Active immunisation to prevent COVID 19 caused by SARS-CoV-2 in individuals 12 years of age and older.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2025.

3.2.9. Denosumab - EMEA/H/C/006492

Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, treatment of bone loss associated with hormone ablation in men with prostate cancer and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2025.

3.2.10. Teplizumab - PRIME - EMEA/H/C/005496

To delay both the onset of Stage 3 type 1 diabetes (T1D) and the progression of Stage 3 T1D

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.05.2025.

3.2.11. Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human Wiskott-Aldrich syndrome protein - Orphan - ATMP - EMEA/H/C/006525

Fondazione Telethon Ets; treatment of patients with Wiskott-Aldrich Syndrome (WAS)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 16.04.2025.

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

3.3.1. Diazoxide choline - Orphan - EMEA/H/C/006576

Soleno Therapeutics Europe Limited; treatment of adult and paediatric patients with Prader-Willi syndrome (PWS)

Scope: List of questions

Action: For adoption

3.3.2. Nerandomilast - EMEA/H/C/006405

treatment of adult patients with Idiopathic Pulmonary Fibrosis (IPF) and adult patients with Progressive Pulmonary Fibrosis (PPF).

Scope: List of questions

Action: For adoption

3.3.3. Colchicine - EMEA/H/C/006653

indicated to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in patients with atherosclerotic disease or with multiple risk factors for cardiovascular disease.

Scope: List of questions

Action: For adoption

3.3.4. Lerodalcibep - EMEA/H/C/006694

is indicated in adults with primary hypercholesterolaemia (heterozygous familial (HeFH) and non-familial) or mixed dyslipidaemia as an adjunct to diet.

Scope: List of questions

Action: For adoption

3.3.5. Palbociclib - EMEA/H/C/006624

treatment of breast cancer factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer: in combination with an aromatase inhibitor; in combination with fulvestrant in women who have received prior endocrine therapy

Scope: List of questions

Action: For adoption

3.3.6. Alpelisib - Orphan - EMEA/H/C/006539

Novartis Europharm Limited; treatment of adult and paediatric patients aged 2 years and older with severe or life-threatening manifestations of PIK3CA-related overgrowth spectrum (PROS)

Scope: List of questions

Action: For adoption

3.3.7. Onasemnogene abeparvovec - Orphan - ATMP - EMEA/H/C/006498

Novartis Europharm Limited; treatment of 5q spinal muscular atrophy (SMA)

Scope: List of questions

Action: For adoption

3.3.8. Sasanlimab - EMEA/H/C/006641

Treatment of BCG-naive, high-risk, non-muscle invasive bladder cancer

Scope: List of questions

Action: For adoption

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

3.4.1. 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: Request by the applicant for an extension to the clock stop to respond to the list of questions adopted in July 2025.

Action: For adoption

List of Questions adopted on 24.07.2025.

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

treatment of melanoma

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in July 2025

Action: For information

List of questions adopted on 24.07.2025

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

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

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

Scope: Opinion

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.

See 2.2

3.5.2. Aqneursa - 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: Appointment of re-examination rapporteurs, timetable

Opinion adopted on 24.07.2025

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

TETEC Tissue Engineering Technologies AG; repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV

Scope: Appointment of re-examination rapporteurs, timetable

Opinion adopted on 24.07.2025

3.5.4. Nurzigma - Pridopidine - Orphan - EMEA/H/C/006261

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

Scope: Appointment of re-examination rapporteurs, timetable

Opinion adopted on 24.07.2025

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Midazolam - EMEA/H/C/005657

conscious sedation before and during diagnostic or therapeutic procedures with or without local anaesthesia and premedication before induction of anaesthesia

Scope: Withdrawal of initial marketing authorisation application

Action: For information

List of questions adopted on 19.06.2025

3.7.2. Midazolam - EMEA/H/C/005658

treatment of prolonged, acute, convulsive seizures in adults, adolescents, children and toddlers (from 2 years of age).

Scope: Withdrawal of initial marketing authorisation application

Action: For information

List of questions adopted on 19.06.2025

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. 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 Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.03.2025.

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 night-time 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 Outstanding Issues adopted on 24.07.2025. 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.; treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) and progressive familial intrahepatic cholestasis (PFIC)

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 Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.02.2025.

See 2.3

4.1.4. Lunsumio - Mosunetuzumab - Orphan - EMEA/H/C/005680/X/0015

Roche Registration GmbH;

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

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

Action: For adoption

List of Questions adopted on 25.04.2025.

4.1.5. 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 Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 25.04.2025.

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. Koselugo - Selumetinib - Orphan - EMEA/H/C/005244/X/0018/G

AstraZeneca AB;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

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

Action: For adoption

List of Questions adopted on 25.04.2025.

4.2.2. Livmarli - Maralixibat - Orphan - EMEA/H/C/005857/X/0016

Mirum Pharmaceuticals International B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to add a new strength (19 mg/ml oral solution). In addition, the MAH took the opportunity to implement editorial changes in sections 4.2 and 4.8. of the SmPC and Point 4 of PL of Livmarli, 9.5 mg/ml oral solution."

Action: For adoption

List of Questions adopted on 27.03.2025.

4.2.3. 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 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 Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.03.2025.

4.2.4. Saphnelo - Anifrolumab - EMEA/H/C/004975/X/0023

AstraZeneca AB;

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new route of administration (subcutaneous use) and a new strength (120 mg)."

Action: For adoption

List of Questions adopted on 22.05.2025.

4.2.5. Spinraza - Nusinersen - Orphan - EMEA/H/C/004312/X/0038

Biogen Netherlands B.V.;

Rapporteur: Fátima Ventura, PRAC Rapporteur: Karin Bolin

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

Action: For adoption

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. Keytruda – Pembrolizumab - EMA/X/0000248795

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

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

The RMP (version 49.1) is updated in accordance.

Action: For adoption

4.3.2. Namuscla – Mexiletine - EMA/X/0000258210

Lupin Europe GmbH

Rapporteur: Fátima Ventura, PRAC Rapporteur: Eva Jirsová

Scope: Extension application to add new strengths of 62 mg and 83 mg grouped with an Extension of indication to include the symptomatic treatment of myotonia in children and adolescents (from 6 to 18 years of age) with non-dystrophic myotonic disorders for NAMUSCLA, based on final results from study MEX-NM-301 as well as population pharmacokinetic analysis of mexiletine in healthy volunteers and myotonic patients; MEX-NM-301 is an open-label, multi-centre, single arm, interventional study to describe the steady-state PK, safety, and efficacy of mexiletine in paediatric patients (6 to <18 years of age) with myotonic disorders. As a consequence, sections 4.1, 4.2 and 5.1 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 introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet.

Action: For adoption

4.3.3. Omlyclo – Omalizumab - EMA/X/0000248400

Celltrion Healthcare Hungary Kft.

Rapporteur: Finbarr Leacy

Scope: Extension application to introduce a new strength of 300 mg for Omlyclo solution for injection. The new strength is indicated for the treatment of asthma (adults, adolescents and children), chronic rhinosinusitis with nasal polyps (adults) and chronic spontaneous urticaria (adult and adolescents).

Action: For adoption

4.3.4. Orladeyo – Berotralstat - EMA/X/0000268892

Biocryst Ireland Limited

Rapporteur: Finbarr Leacy, Co-Rapporteur: Margareta Bego, PRAC Rapporteur: Julia Pallos

Scope: Extension application to introduce a new pharmaceutical form associated with new strengths (78 mg, 96 mg,108 and 132 film - coated granules). The new presentations are indicated to include treatment for paediatric patients aged 2 to less than 12 years. The extension application is grouped with a type II clinical variation (C.I.4). 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 and Labelling are updated in accordance. Version 2.1 of the RMP has also been submitted.

Action: For adoption

4.3.5. REZOLSTA – Darunavir / Cobicistat - EMA/X/0000268372

Janssen Cilag International

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (600 mg darunavir/90 mg cobicistat dispersible tablet). The new presentation is indicated to include treatment for paediatric patients aged ⩾ 3 years and older weighing at least 15 kg and less than 25 kg. The extension application is grouped with a type II clinical variation (C.I.4) to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 in order to add efficacy and PK data in children based on final results from study GS-US-215-0128; this is a Phase 2/3, Multicentre, Open-label, Multicohort Study Evaluating Pharmacokinetics (PK), Safety, and Efficacy of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 Infected, Virologically Suppressed Paediatric Participants. The Package Leaflet and Labelling are updated in accordance. Version 7.2 of the RMP has also been submitted.

Action: For adoption

4.3.6. Rybrevant – Amivantamab – EMA/X/0000268898

Janssen Cilag International

Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

Scope: Extension application to add a new strength of 2400 mg and 3520 mg (solution for injection) grouped with the following variations:

C.I.4: Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 6.6 in order to include the Q3W dosing regimen based on data from relevant cohorts from the Phase 2 bridging study PALOMA-2 (NSC2002) and supported by data from the Phase 1 PALOMA study (NSC1003). The Package Leaflet and Labelling are updated accordingly. The RMP version 7.1 has also been submitted.

C.I.4: Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 6.6 in order to introduce a new Q4W dosing regimen based on data from the PALOMA-2 study (NSC2002) and supported by data from the Phase 1 PALOMA study (NSC1003). The Package Leaflet and Labelling are updated accordingly. The RMP version 7.1 has also been submitted.

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. AREXVY – Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E - EMA/VR/0000276225

GlaxoSmithKline Biologicals

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 18 years of age and older for AREXVY, based on results from study 222253 (RSV OA=ADJ-025); this is a Phase 3b, open-label study to evaluate the non-inferiority of the immune response and to evaluate the safety of the RSVPreF3 OA investigational vaccine in adults 18-49 years of age at increased risk of respiratory syncytial virus disease, compared to older adults ⩾60 years of age. As a consequence, sections 4.1, 4.6, 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. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.1.2. ASPAVELI – Pegcetacoplan - EMA/VR/0000248937

Swedish Orphan Biovitrum AB (publ)

Rapporteur: Alexandre Moreau, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of adults and adolescents aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulopathy (IC-MPGN) for ASPAVELI, based on interim results from study APL2-C3G-310; this is a randomized, placebo-controlled, double-blinded, multicentre study to evaluate the safety and efficacy of twice-weekly s.c. infusions of pegcetacoplan in patients diagnosed with C3G or primary IC-MPGN and results from Phase 2 study APL2-C3G-204, an open-label, randomized, controlled study to evaluate the efficacy and safety of pegcetacoplan in posttransplant recurrence of C3G or primary IC-MPGN. 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 3.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

Action: For adoption

5.1.3. BIMERVAX – COVID-19 vaccine (recombinant, adjuvanted) - EMA/VR/0000257408

Hipra Human Health S.L.

Rapporteur: Beata Maria Jakline Ullrich, Co-Rapporteur: Daniela Philadelphy

Scope: Extension of indication to include the use of BIMERVAX in adolescents aged 12 years and above, based on interim results from the ongoing study HIPRA-HH-3. HIPRA-HH-3 is an open-label, multi-centre, non-inferiority study to assess the safety and immunogenicity of BIMERVAX as heterologous booster for the prevention of COVID-19 in adolescents from 12 years of age to less than 18 years of age. 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. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

Action: For adoption

5.1.4. Dupixent – Dupilumab - EMA/VR/0000257461

Sanofi Winthrop Industrie

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents 12 years and older, whose disease is inadequately controlled by H1 antihistamines and who are naive to anti-IgE therapy for CSU for DUPIXENT, based on final results from 2 studies: EFC16461 (CUPID) study A and study C; both of them were phase 3, randomized, double-blind, placebo-controlled, multi-center, parallel-group study of dupilumab in patients with CSU who remain symptomatic despite the use of H1 antihistamine treatment in patients naïve to omalizumab. As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI.

Action: For adoption

5.1.5. Feraccru – Ferric maltol - EMA/VR/0000268118

Norgine B.V.

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of paediatric population (adolescents aged 12 years and above) for FERACCRU, based on results from phase 1 study ST10-01-103, phase 3 study ST10-01-305 and a supportive phase 1 study ST10-01-104. 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 9.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

Action: For adoption

5.1.6. 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

See 2.3

5.1.7. Koselugo – Selumetinib - EMA/VR/0000245231

AstraZeneca AB

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

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

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

Action: For adoption

5.1.8. LUTATHERA - Lutetium (177Lu) oxodotreotide - Orphan - EMEA/H/C/004123/II/0058

Advanced Accelerator Applications;

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of unresectable or metastatic, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adolescents aged 12 years and older for LUTATHERA based on primary analysis results from study CAAA601A32201 (also referred to as NETTER-P) as well as results from modelling and simulation analysis of PK and dosimetry data of Lutathera in adolescents. NETTER-P study is a Phase II, multicentre open-label study which evaluated the safety and

dosimetry of Lutathera in adolescent patients with somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) and pheochromocytoma and paragangliomas (PPGLs). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 11 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 19.06.2025, 27.03.2025.

5.1.9. Norvir – Ritonavir - EMA/VR/0000249795

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

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

Action: For adoption

5.1.10. EMA/VR/0000271728 Tafinlar - Dabrafenib Mekinist - Trametinib

Novartis Europharm Limited

Rapporteur: Filip Josephson, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of unresectable or metastatic melanoma with a BRAF V600 mutation and adjuvant treatment of Stage III melanoma with a BRAF V600 mutation for adolescents aged 12 years and older for TAFINLAR and MEKINIST, based on an extrapolation report using a modelling and simulation approach to demonstrate PK, PD and efficacy of dabrafenib and trametinib in adolescent patients. 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. RMP versions 13.0 and 21.0 for Tafinlar and Mekinist, respectively, have also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and to update list of local representatives in the Package Leaflet.

Action: For adoption

5.1.11. 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

5.1.12. Uplizna - Inebilizumab - EMEA/H/C/005818/II/0012

Amgen Europe B.V.;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include treatment of adult patients with Immunoglobulin G4-Related Disease (IgG4-RD) for UPLIZNA, based on primary analysis results from study MITIGATE (VIB0551.P3.S2) for all subjects from the completed 52-week randomised-controlled period. This is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adult subjects with IgG4-RD. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to bring it in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 19.06.2025, 27.02.2025.

5.1.13. Winrevair – Sotatercept - EMA/VR/0000278021

Merck Sharp & Dohme B.V.

Rapporteur: Patrick Vrijlandt

Scope: Extension of indication to include in combination with other pulmonary arterial hypertension (PAH) therapies treatment of adult patients with PAH World Health Organisation Functional Class IV for WINREVAIR, based on interim results from study ZENITH (also referred as MK-7962-006 and A011-14); this is a phase 3, randomized, double-blind, placebo-controlled study to evaluate sotatercept when added to maximum tolerated background therapy in participants with pulmonary arterial hypertension (PAH) World Health Organization (WHO) Functional Class (FC) III or FC IV at high risk of mortality; 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. In addition, the MAH removed the first PSUR commitment following 6 months post authorisation as it has already been fulfilled. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.14. WS2806/G
BiResp Spiromax - Budesonide / Formoterol
DuoResp Spiromax - Budesonide / Formoterol

Teva Pharma B.V.;

Lead Rapporteur: John Joseph Borg, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "A grouped application consisting of:

C.I.6: Extension of the asthma indication to include the anti-inflammatory reliever (AIR) use for DuoResp Spiromax and BiResp Spiromax, based on the latest GINA report, the European Respiratory Society guidelines, and literature data. In addition, the Applicant referred to changes made for Symbicort (UK). As a consequence, sections 4.1, 4.2, 4.4, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI introduced editorial changes, and is brought in line with the latest QRD template version. The RMP version 4.0 has also been submitted.
C.I.2.a: To update sections 4.5, and 5.1 of the SmPC following assessment of the same change for the reference product Symbicort Turbohaler (SE/H/0229/001- 002) and also Symbicort (UK)."

Action: For adoption

5.1.15. ZYNYZ – Retifanlimab – Orphan – EMA/VR/0000247788

Incyte Biosciences Distribution B.V.

Rapporteur: Peter Mol, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication to include in combination with carboplatin and paclitaxel treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC) for ZYNYZ, based on interim results from study INCMGA 0012-303 (POD1UM-303/InterAACT-2); this is a phase 3 global, multicenter, double-blind randomized study of carboplatin-paclitaxel with retifanlimab or placebo in participants with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal not previously treated with systemic chemotherapy; 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 Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection. As part of the application, the MAH is requesting a 1-year extension of the market protection.

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

6.1.1. Human serum albumin - EMEA/H/D/006611

use in Assisted Reproductive Technologies (ART)

Scope: Opinion

Action: For adoption

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

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

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. Navepegritide – H0006627

indicated for the treatment of achondroplasia in patients 2 years of age and older whose epiphyses are not closed

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. SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0052

Clinuvel Europe Limited

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: "Update of section 4.2 of the SmPC in order to update the posology recommendations by removing the current recommendation of a maximum of four implants per year, based on a literature review and analysis of safety data. The Package Leaflet is updated accordingly. The RMP version 9.8 has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial change to the Product Information."

Action: For adoption

Request for Supplementary Information adopted on 22.05.2025, 27.02.2025, 14.11.2024, 30.05.2024.

See 2.3

9.1.2. Evusheld – tixagevimab / cilgavimab – EMEA/H/C/005788

AstraZeneca AB; Pre-exposure prophylaxis and treatment of COVID-19

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Christophe Focke

Scope: Withdrawal of marketing authorization

Action: For information

9.1.3. Tremfya – Guselkumab - EMA/VR/0000257541

Janssen Cilag International

Rapporteur: Beata Maria Jakline Ullrich; PRAC Rapporteur: Gabriele Maurer

Scope: Update of sections 4.2, 4.5, 4.8, 5.1, and 5.2 of the SmPC in order to add subcutaneous induction dosing for the ulcerative colitis (UC) indication based on interim results from study CNTO1959UCO3004 listed as a category 3 study in the RMP; this is a phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the efficacy and safety of guselkumab subcutaneous induction therapy in participants with moderately to severely active UC; the Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted. In addition, the MAH took the opportunity to bring editorial changes to the PI.

Action: For adoption

9.1.4. Zynlonta - Loncastuximab tesirine - EMA/R/0000281443

Swedish Orphan Biovitrum AB (publ)

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Eva Jirsová

Scope: Renewal of conditional marketing authorization

Action: For adoption

9.1.5. Enhertu - Trastuzumab deruxtecan - EMA/R/0000282648

Daiichi Sankyo Europe GmbH

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Carla Torre

Scope: Renewal of conditional marketing authorization

Action: For adoption

9.1.6. LEQEMBI – Lecanemab - EMA/VR/0000290573

Eisai GmbH

Rapporteur: Alexandre Moreau

Scope: Update of section 4.2 of the SmPC in order to change the section "Monitoring for Amyloid Related Imaging Abnormalities (ARIA)" to add an MRI prior to the 3rd infusion based on data within the initial MAA and post marketing reporting. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the PI, to update the list of local representatives in the Package Leaflet and to include 'histidine' in the list of excipients.

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

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: List of outstanding issues/ opinion

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

See 2.4

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

No items

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

September 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 September 2025

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at September 2025 PDCO

Action: For information

Report from the PDCO meeting held on 09-12 September 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 01-04 September 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 Infectious Diseases Working Party Vice-Chair

The position of vice-chair of the IDWP is currently available.

Action: For election

Nomination(s) received

14.3.4. Draft reflection paper on Patient Experience Data (PED)

A multidisciplinary drafting group including representatives from PCWP and HCPWP but also many other WPs and committees has drafted a reflection paper on patient experience data.

The document is presented to the CHMP 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

14.8.1. Update of the Business Pipeline report for the human scientific committees

Q3-2025 initial marketing authorisation application submissions with eligibility request to central procedure

Action: For information

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)*

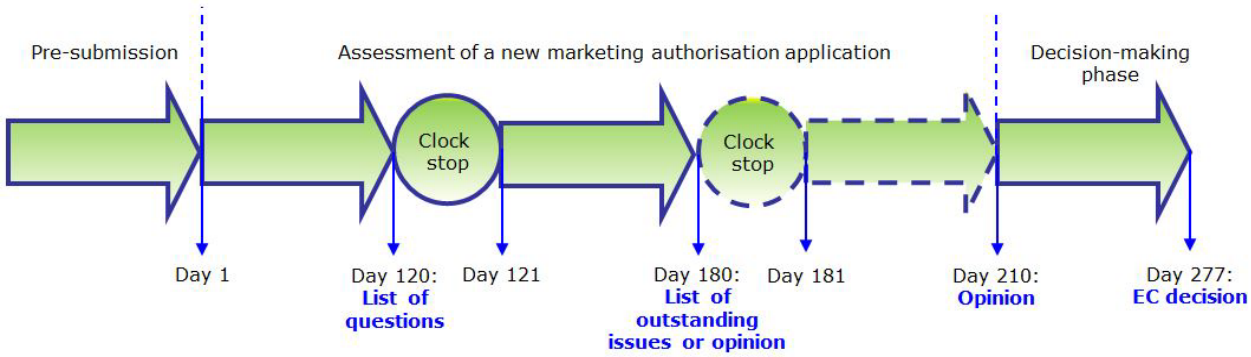
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (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

15 September 2025
EMA/CHMP/276462/2025

Annex to 15-18 September 2025 CHMP Agenda

Pre-submission and post-authorisations issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for September 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

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 01-04 September 2025 PRAC:

Signal of tattoo associated skin reaction Dabrafenib; trametinib; vemurafenib; cobimetinib; encorafenib, binimetinib – TAFINLAR; FINLEE; MEKINIST; SPEXOTRAS; ZELBORAF; COTELLIC; BRAFTOVI; MEKTOVI (CAP) Rapporteur: various, Co-Rapporteur: various, PRAC Rapporteur: various PRAC recommendation on a variation **Action:** For adoption
Signal of atypical haemolytic uraemic syndrome Dinutuximab beta – QARZIBA (CAP) Rapporteur: Peter Mol, Co-Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Gabriele Maurer PRAC recommendation on a variation **Action:** For adoption
Signal of hepatitis B reactivation Osimertinib – TAGRISSO (CAP) Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Eva Skovlund, PRAC Rapporteur: Bianca Mulder PRAC recommendation on a variation **Action:** For adoption
Signal of lipoatrophy Somatrogon – NGENLA (CAP) Rapporteur: Finbarr Leacy, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Liana Martirosyan 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 September 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 24.07.2025, 27.03.2025.	
VEYVONDI - Vonicog alfa - EMEA/H/C/004454/II/0036/G Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 04.09.2025. Request for Supplementary Information adopted on 15.05.2025, 05.12.2024.	Positive Opinion adopted by consensus on 04.09.2025.

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

Dovprela - Pretomanid - EMEA/H/C/005167/II/0022, Orphan Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson, "Update of section 4.2 of the SmPC in order to add clarifications on administration instructions based on post marketing data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement an editorial correction to section 5.1 of the SmPC." Request for Supplementary Information adopted on 22.05.2025, 14.11.2024.	

B.5.3. CHMP-PRAC assessed procedures

PONVORY - Ponesimod - EMEA/H/C/005163/II/0018/G Laboratoires Juvise Pharmaceuticals, Rapporteur: Peter Mol, PRAC Rapporteur: Karin Erneholm, "Grouped application comprised of two Type II Variations, as follows: C.I.13: Submission of the final report from study AC-058B202; this is a Multicentre, Randomized, Double-blind, Parallel-group Extension to Study AC-058B201 to Investigate the Long-term Safety, Tolerability, and Efficacy of 10, 20, and 40 mg/day Ponesimod, an Oral S1P1 Receptor Agonist, in Patients with	Positive Opinion adopted by consensus on 04.09.2025.

Relapsing-remitting Multiple Sclerosis. C.I.13: Submission of the final report from study AC-058B303 (OPTIMUM-LT); this is a Multicentre, Non-Comparative Extension to Study AC-058B301, to Investigate the Long-Term Safety, Tolerability, and Control of Disease of Ponesimod 20 mg in Subjects with Relapsing Multiple Sclerosis. Section 5.1 of the SmPC is updated. The RMP is also updated to version 4.1." Opinion adopted on 04.09.2025. Request for Supplementary Information adopted on 05.06.2025, 13.03.2025.	
SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0052 Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of section 4.2 of the SmPC in order to update the posology recommendations by removing the current recommendation of a maximum of four implants per year, based on a literature review and analysis of safety data. The Package Leaflet is updated accordingly. The RMP version 9.8 has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial change to the Product Information." Request for Supplementary Information adopted on 22.05.2025, 27.02.2025, 14.11.2024, 30.05.2024.	

B.5.4. PRAC assessed procedures

PRAC Led **Firazyr - Icatibant - EMEA/H/C/000899/II/0061** Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Update of section 4.6 based on final results from the Icatibant Outcome Survey (IOS) registry listed as a category 3 study in the RMP; this is a prospective, observational disease registry. The RMP version 8.1 is acceptable. In addition, the MAH took the opportunity to implement editorial changes to the PI and to bring the PI in line with	Positive Opinion adopted by consensus on 04.09.2025.

the latest QRD template version 10.4." Opinion adopted on 04.09.2025. Request for Supplementary Information adopted on 05.06.2025, 13.02.2025.

B.5.5. CHMP-CAT assessed procedures

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

PRAC Led **WS2771** **Tecartus-** **EMEA/H/C/005102/WS2771/0054** **Yescarta-** **EMEA/H/C/004480/WS2771/0084** Kite Pharma EU B.V., Lead PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Boje Kvorning Pires Ehmsen, "Submission of an updated RMP version 4.3 for Tecartus and version 11.1 for Yescarta following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040), and of a PASS protocol for a framework for the sampling and testing of secondary malignancies of T-cell origin." Request for Supplementary Information adopted on 16.05.2025, 24.01.2025.

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.