10 November 2025
EMA/CHMP/331479/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 10-13 November 2025
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

10 November 2025, 09:30 – 19:30, virtual meeting/room 1C

11 November 2025, 08:30 – 19:30, virtual meeting/room 1C

12 November 2025, 08:30 – 19:30, virtual meeting/room 1C

13 November 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 10-13 November 2025. See November 2025 CHMP minutes (to be published post December 2025 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 10-13 November 2025

1.3. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 03 November 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Blarcamesine - EMEA/H/C/006475

treatment of Alzheimer's disease and dementia

Scope: Oral explanation

Action: Oral explanation to be held on 11 November 2025 at 14:00

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 25.04.2025.

2.1.2. Iloperidone - EMEA/H/C/006561

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

Scope: Oral explanation

Action: Oral explanation to be held on 12 November 2025 at 11:00

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 25.04.2025.

2.1.3. Imlunestrant - EMEA/H/C/006184

treatment of adult patients with advanced or metastatic breast cancer

Scope: Oral explanation

Action: Oral explanation to be held on 11 November 2025 at 09:00

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 25.04.2025.

2.1.4. Teduglutide - EMEA/H/C/006564

treatment of Short Bowel Syndrome

Scope: Oral explanation

Action: Oral explanation to be held on 12 November 2025 at 16:00

List of Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

2.2. Re-examination procedure oral explanations

2.2.1. Aqneursa - Levacetylleucine - Orphan - EMEA/H/C/006327

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

Scope: Oral explanation

Action: Oral explanation to be held on 12 November 2025 at 14:00

Opinion adopted on 24.07.2025.

See 3.5

2.3. Post-authorisation procedure oral explanations

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

Vanda Pharmaceuticals Netherlands B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski

Scope: Oral explanation

Action: Oral explanation to be held on 12 November 2025 at 14:00treatment of nighttime sleep disturbances in SMS in paediatric patients 3 years to 15 years of age, treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)

List of Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

See 4.1

2.3.2. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/II/0040

Vanda Pharmaceuticals Netherlands B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski

Scope: Oral explanation

Action: Oral explanation to be held on 12 November 2025 at 14:00

"Extension of indication to include the treatment of nighttime sleep disturbances in adults with Smith Magenis Syndrome (SMS) for HETLIOZ, based on results from study VP-VEC-162-2401. This is a double-blind, randomized, two-period crossover study evaluating the effects of tasimelteon vs. placebo on sleep disturbances of individuals with Smith-Magenis Syndrome (SMS). As a consequence, sections 4.1, 4.5, 5.1, 5.2 and 5.3 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. The RMP version 5.0 has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Request for Supplementary Information adopted on 25.04.2025, 30.01.2025.

See 5.1

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

Mirum Pharmaceuticals International B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: Oral explanation

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

List of Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 25.04.2025.

3.1.2. Enzalutamide - EMEA/H/C/006612

treatment of prostate cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

3.1.3. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 25.04.2025.

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

treatment of diabetes mellitus

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 14.12.2023.

3.1.5. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 25.04.2025.

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

to delay both the onset of Stage 3 type 1 diabetes (T1D)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 22.05.2025.

3.1.7. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 14.11.2024.

3.1.8. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 12.09.2025. List of Questions adopted on 16.04.2025.

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

3.2.1. Estetrol - EMEA/H/C/006213

hormone replacement therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.06.2025.

3.2.2. Semaglutide - EMEA/H/C/006426

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

3.2.3. Teriparatide - EMEA/H/C/006688

treatment of osteoporosis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.06.2025.

3.2.4. Trivalent influenza vaccine (recombinant, prepared in cell culture) - EMEA/H/C/006674

immunisation for the prevention of influenza disease

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

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

3.3.1. Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated - EMEA/H/C/006692

prophylaxis of influenza

Scope: List of questions

Action: For adoption

3.3.2. Clostridium botulinum, serotype E, neurotoxin (150 kDa) - EMEA/H/C/006420

temporary improvement in the appearance of moderate to severe lines between the eyebrows

Scope: List of questions

Action: For adoption

3.3.3. Catequentinib - Orphan - EMEA/H/C/006317

CATS Consultants GmbH; treatment of synovial sarcoma or leiomyosarcoma

Scope: List of questions

Action: For adoption

3.3.4. Denosumab - EMEA/H/C/006626

prevention of skeletal related events and treatment of giant cell tumour of bone

Scope: List of questions

Action: For adoption

3.3.5. Levodopa / Carbidopa - EMEA/H/C/006629

treatment of adult patients with Parkinson’s disease

Scope: List of questions

Action: For adoption

3.3.6. Tarlatamab - Orphan - EMEA/H/C/006451

Amgen Europe B.V.; treatment of extensive-stage small cell lung cancer

Scope: List of questions

Action: For adoption

3.3.7. Leriglitazone - Orphan - EMEA/H/C/006693

Minoryx Therapeutics S.L.; treatment of adrenoleukodystrophy

Scope: List of questions

Action: For adoption

3.3.8. Narsoplimab - Orphan - EMEA/H/C/005247

Omeros Ireland Limited; treatment of patients with haemopoietic stem cell transplant-associated thrombotic microangiopathy.

Scope: List of questions

Action: For adoption

3.3.9. Norucholic acid - Orphan - EMEA/H/C/006515

Dr. Falk Pharma GmbH; treatment of primary sclerosing cholangitis (PSC) in adults.

Scope: List of questions

Action: For adoption

3.3.10. Ensitrelvir - EMEA/H/C/006063

treatment of coronavirus disease 2019 (COVID-19)

Scope: List of questions

Action: For adoption

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

No items

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

3.5.1. Aqneursa - Levacetylleucine - 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

Opinion adopted on 24.07.2025.

3.5.2. 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: Opinion

Action: For adoption

Opinion adopted on 24.07.2025

3.5.3. REZUROCK - 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: Appointment of re-examination rapporteurs, adoption of timetable

Action: For adoption

3.6. Initial applications in the decision-making phase

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

Teva GmbH; treatment of tardive dyskinesia

Scope: Revised assessment report adopted via written procedure on 05.11.2025.

Action: For information

Opinion adopted on 16.10.2025, 19.06.2025. List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 25.07.2024.

3.6.2. Enflonsia - Clesrovimab - EMEA/H/C/006497

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

Scope: Revised opinion

Action: For adoption

Opinion adopted on 18.09.2025. List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 27.03.2025.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Insulin aspart – EMEA/H/C/006720

treatment of diabetes mellitus

Scope: Withdrawal of marketing authorisation application

Action: For information

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

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

Scope: Withdrawal of marketing authorisation application

Action: For information

Opinion adopted on 24.07.2025

3.7.3. Ensifentrine – EMEA/H/C/006742

maintenance treatment in symptomatic adult patients with chronic obstructive pulmonary disease (COPD).

Scope: Withdrawal of 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. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/X/0039

Vanda Pharmaceuticals Netherlands B.V.; treatment of nighttime sleep disturbances in SMS in paediatric patients 3 years to 15 years of age, treatment of Non-24-Hour Sleep-Wake

Disorder (Non-24)

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 Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

See 2.3

4.1.2. 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 Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 25.04.2025.

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 Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

See 2.3

4.1.4. 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 Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 27.03.2025.

4.1.5. 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 Outstanding Issues adopted on 18.09.2025. 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. 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) and quality variations.

Action: For adoption

4.2.2. EURneffy – Epinephrine - EMA/X/0000248440

Alk-Abello A/S

Rapporteur: Ewa Balkowiec Iskra, Co-Rapporteur: Elita Poplavska, PRAC Rapporteur: Terhi Lehtinen

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

Action: For adoption

4.2.3. Kerendia – Finerenone - EMA/X/0000248026

Bayer AG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Bianca Mulder

Scope: Extension application to introduce a new strength 40 mg for film-coated tablets, grouped with a type II variations C.I.6: Extension of indication to include the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in adults for KERENDIA, based on final results from the phase 3 study FINEARTS-HF (20103); this is a randomized, double-blind, placebo-controlled phase 3 study evaluating the efficacy and safety of finerenone on morbidity and mortality in participants with symptomatic heart failure with left ventricular ejection fraction (LVEF) ≥40%.; Type II variation C.I.13: Submission of the final report from non-clinical study T105281-7, R-14405 - Juvenile toxicology study in rats; Type IB variation C.I.z: Minor correction of numbers in the currently approved SmPC due to a previously communicated GCP violation affecting the FIDELIO-DKD and FIGARO-DKD trials.

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

Action: For adoption

4.2.4. Symtuza – Darunavir / Cobicistat / Emtricitabine / Tenofovir alafenamide - EMA/X/0000248421

Janssen Cilag International

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension application to add a new strength of 675 mg/150 mg/ 20mg/ 10 mg film-coated tablets grouped with an Extension of indication (C.I.6) to include treatment of human immunodeficiency virus type 1 (HIV 1) infection in paediatric patients (aged 6 years and older with body weight at least 25 kg) for SYMTUZA, based on the 24-week interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicentre, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1, 6.3, 6.4, 6.5 and 8 of the SmPC are updated. The Annex II, Labelling and Package Leaflet are updated accordingly. Version 9.1 of the RMP has also been submitted. Furthermore, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet.

Action: For adoption

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. SARCLISA – Isatuximab - EMA/X/0000281242

Sanofi Winthrop Industrie

Rapporteur: Peter Mol, PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (1400 mg) and a new route of administration (subcutaneous use). The RMP (version 3.0) is updated in accordance.

Action: For adoption

4.3.2. Sivextro – Tedizolid phosphate - EMA/X/0000282136

Merck Sharp & Dohme B.V.

Rapporteur: Fátima Ventura, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension application to introduce a new pharmaceutical form (powder for oral suspension, 200 mg). The RMP (version 8.1) is updated in accordance. Additionally, the marketing authorisation holder took the opportunity to align the PI with the latest QRD template.

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. BESPONSA - Inotuzumab ozogamicin - EMA/VR/0000257310

Pfizer Europe MA EEIG;

Rapporteur: Filip Josephson, PRAC Rapporteur: Dirk Mentzer

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

5.1.2. Dupixent - Dupilumab - EMA/VR/0000248778

Sanofi Winthrop Industrie;

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

Scope: Extension of indication to include treatment of adults with bullous pemphigoid (BP) for DUPIXENT, based on final results from study R668-BP-1902 (LIBERTY-BP ADEPT); this is a phase 2/3, multicentre, randomized, double blind, placebo-controlled, parallel group study to assess the efficacy and safety of dupilumab in adult patients with bullous pemphigoid; 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 12.0 of the RMP has also been submitted.

Action: For adoption

5.1.3. Efmody - Hydrocortisone - EMA/VR/0000282500

Neurocrine Netherlands B.V.;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of adrenal insufficiency (AI) in adolescents aged 12 years and over and adults for Efmody, based on final results from study DIUR-016-AI; this is a double-blind, double-dummy, two-way cross-over, randomised, phase II study of efficacy, safety and tolerability of modified-release hydrocortisones: Chronocort (Efmody) versus Plenadren, in AI. Consequently, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, e-mail of MAH was updated. Version 2.0 of the RMP has also been submitted.

Action: For adoption

5.1.4. Fasenra - Benralizumab - EMA/VR/0000288520

AstraZeneca AB;

Rapporteur: Paulo Paixão, PRAC Rapporteur: David Olsen

Scope: Extension of indication to include treatment of adults and adolescents with hypereosinophilic syndrome (HES) for FASENRA, based on interim results from study D3254C00001 (NATRON); this is a multicentre, randomised, double-blind, parallel-group, placebo-controlled, 24-week phase III study with an open-label extension to evaluate the efficacy and safety of benralizumab in patients with HES; 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 8 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial and administrative updates to the PI and to update the list of local representatives in the Package Leaflet. Furthermore, section 6.5 of the SmPC was updated.

Action: For adoption

5.1.5. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/II/0040

Vanda Pharmaceuticals Netherlands B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of nighttime sleep disturbances in adults with Smith Magenis Syndrome (SMS) for HETLIOZ, based on results from study VP-VEC-162-2401. This is a double-blind, randomized, two-period crossover study evaluating the effects of tasimelteon vs. placebo on sleep disturbances of individuals with Smith-Magenis Syndrome (SMS). As a consequence, sections 4.1, 4.5, 5.1, 5.2 and 5.3 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. The RMP version 5.0 has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection." 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 25.04.2025, 30.01.2025.

See 2.3

5.1.6. HETRONIFLY - Serplulimab - EMA/VR/0000290021

Accord Healthcare S.L.U.;

Rapporteur: Eva Skovlund, PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include HETRONIFLY in combination with carboplatin and nab-paclitaxel is indicated for the first-line treatment of adult patients with unresectable, locally advanced or metastatic squamous non-small cell lung carcinoma based on final results from study HLX10-004-NSCLC303; this is a randomized, double-blind, multi-centre, phase III pivotal study, was conducted to compare the clinical efficacy and safety of serplulimab combined with chemotherapy (carboplatin and nab-paclitaxel) versus placebo combined with chemotherapy (carboplatin and nab-paclitaxel). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP Version 1.3 has been submitted.

Action: For adoption

5.1.7. 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

5.1.8. IMCIVREE - Setmelanotide - EMA/VR/0000288021

Rhythm Pharmaceuticals Netherlands B.V.;

Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Anna Mareková

Scope: Extension of indication to include reduction in hunger (or hyperphagia) and BMI/BMI z-score, improvement of metabolic parameters, and increase in energy expenditure in adults and children 4 years of age and above, following rapid and severe weight gain associated with hypothalamic injury and/or impairment for IMCIVREE, based on results from study RM-493-040 as well as supportive study RM-493-030. RM-493-040 is a phase 3, double blind, randomized, placebo-controlled trial to evaluate the efficacy and safety of setmelanotide in patients with acquired hypothalamic obesity, while RM-493-030 is a phase 2, open-label 20-week study to evaluate the safety and efficacy of setmelanotide in subjects with hypothalamic obesity. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are being updated. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to introduce editorial and administrative changes to the PI.

Action: For adoption

5.1.9. Imfinzi - Durvalumab - EMA/VR/0000289524

AstraZeneca AB;

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: David Olsen

Scope: Extension of indication for IMFINZI in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adults with BCG-naive, high-risk non-muscle-invasive bladder cancer (NMIBC), based on results from the POTOMAC study. POTOMAC is a phase 3, randomized multi-centre, open-label, global study to determine the efficacy and safety of durvalumab + BCG (induction + maintenance) combination therapy vs BCG (induction + maintenance) alone, and durvalumab + BCG (induction only) combination therapy vs BCG (induction + maintenance) alone for the treatment of patients with high-risk NMIBC. 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 with the SmPC. In addition, the Applicant took the opportunity to implement editorial changes to SmPC sections 4.2 and 5.1. Version 15 (Succession 1) of the RMP has also been submitted.

Action: For adoption

5.1.10. MINJUVI - Tafasitamab - EMA/VR/0000255975

Incyte Biosciences Distribution B.V.;

Rapporteur: Alexandre Moreau, Co-Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include in combination with lenalidomide and rituximab treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least one line of systemic therapy for MINJUVI, based on interim results from study INCMOR 0208-301 (inMIND); this is a phase 3, randomized, double-blind, placebo-controlled, multicentre study to evaluate the efficacy and safety of tafasitamab plus lenalidomide and rituximab vs lenalidomide and rituximab in patients with relapsed/refractory (R/R) follicular lymphoma grade 1 to 3a or R/R marginal zone lymphoma. As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.11. Mounjaro - Tirzepatide - EMEA/H/C/005620/II/0038

Eli Lilly Nederland B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of symptomatic chronic heart failure with preserved ejection fraction (HFpEF) in adults with obesity for MOUNJARO, based on results from the Phase 3 trial I8F-MC-GPID (SUMMIT). SUMMIT was a randomized, multicentre, international, placebo-controlled, double-blind, parallel-arm study in participants with HFpEF and obesity. The study was designed to evaluate the effect of tirzepatide compared with placebo on both clinical and symptomatic or functional outcomes. As a consequence, sections 4.1, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 22.05.2025, 27.02.2025.

5.1.12. 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

5.1.13. Olumiant - Baricitinib - EMA/VR/0000288098

Eli Lilly Nederland B.V.;

Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of adolescent patients (12 to less than 18 years) with severe alopecia areata for OLUMIANT, based on results from study I4V-MC-JAIO; this is a Phase 3, double-blind, randomised, placebo-controlled trial to evaluate the efficacy, safety, and pharmacokinetics of baricitinib in children from 6 years to less than 18 years of age with alopecia areata. 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 26.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.14. Pluvicto - Lutetium (177Lu) vipivotide tetraxetan - EMA/VR/0000288073

Novartis Europharm Limited;

Rapporteur: Janet Koenig, Co-Rapporteur: Peter Mol, PRAC Rapporteur: John Joseph Borg

Scope: Extension of indication to include treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after having progressed on androgen receptor pathway inhibitor (ARPI) and for whom chemotherapy is not yet clinically indicated for PLUVICTO, based on interim results from study CAAA617B12302 (PSMAfore); this is a phase III, open-label, multi-centre, randomized study comparing 177Lu-PSMA-617 vs. a change of androgen receptor-directed therapy in the treatment of taxane naïve men with progressive metastatic castrate resistant prostate cancer; 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 3.0 of the RMP has also been submitted to include clinical data from the PSMAfore study to support the addition of the new therapeutic indication.

Action: For adoption

5.1.15. 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

5.1.16. Stelara - Ustekinumab - EMA/VR/0000290099

Janssen Cilag International;

Rapporteur: Jayne Crowe, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of moderately to severely active Crohn's disease in paediatric patients from the age of 2 years and older, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy, for STELARA, based on final results from the Phase 3 open-label CNTO1275CRD3004 study and the supportive results from the Phase 1 PK CNTO1275CRD1001 study. Study CNTO1275CRD3004 is a Phase 3 study of the efficacy, safety, and pharmacokinetics of ustekinumab as open-label intravenous induction treatment followed by randomized double-blind subcutaneous ustekinumab maintenance in paediatric participants 2 to <18 years of age with moderately to severely active Crohn’s disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are being updated. The Package Leaflet is updated accordingly. The RMP version 32.1 has also been submitted. In addition, the MAH took the opportunity to introduce editorial, formatting and administrative changes to the PI, bringing it in line with the latest QRD template. In addition, the MAH updated the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.17. 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 the recombinant von Willebrand factor (rVWF) with or without ADVATE (octocog alfa) 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 von Willebrand disease (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

5.1.18. 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

5.2.1. OPDIVO - Nivolumab - EMA/VR/0000282199

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Peter Mol, PRAC Rapporteur: Gabriele Maurer

Scope: Questions to the SAG-O

Extension of indication for OPDIVO to include treatment of patients paediatric and adults, with relapsed/refractory classical Hodgkin Lymphoma, based on results from study CA209744; a phase 2, open-label study of nivolumab + brentuximab vedotin for children, adolescents, and young adults with R/R CD30+ classical Hodgkin lymphoma after failure of first-line therapy, followed by brentuximab vedotin + bendamustine for participants with a suboptimal response. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 44.0 of the RMP has also been submitted

Action: For adoption

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

5.3.1. Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0007

Chiesi Farmaceutici S.p.A.,

Re-examination Rapporteur: to be appointed

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan

Scope: Appointment of re-examination rapporteur and timetable;

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

Action: For adoption

Opinion adopted on 16.10.2025. Request for Supplementary Information adopted on 19.06.2025, 30.01.2025.

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/006882

detection of single nucleotide variants (SNVs), insertions and deletions (indels) in seventy-four (74) genes, copy number amplifications (CNAs) in eighteen (18) genes, fusion in six (6) genes, and microsatellite instability (MSI)-High status

Scope: Opinion

Action: For adoption

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006840

detection of a novel panel of seven (7) monomorphic biomarkers for identification of microsatellite instability (MSI) in colorectal cancer tissue

Scope: Opinion

Action: For adoption

6.3.3. In vitro diagnostic medical device - EMEA/H/D/006809

targeted next-generation sequencing to detect variants in 517 genes using nucleic acids extracted from formalin-fixed, paraffin embedded (FFPE) tumour tissue samples from cancer patients with solid malignant neoplasms

Scope: Opinion

Action: For adoption

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

8.2. 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. Celdoxome pegylated liposomal – Doxorubicin – EMEA/H/C/005330

Baxter Holding B.V.; treatment of breast cancer, ovarian cancer, multiple myeloma, AIDS related Kaposi's sarcoma (KS)

Rapporteur: Paulo Paixao, Co-Rapporteur: Carolina Prieto Fernandez

Scope: Withdrawal of marketing authorisation due to sunset clause

Action: For information

9.1.2. Integrilin – Eptifibatide – EMEA/H/C/000230

GlaxoSmithKline (Ireland) Limited; prevention of early myocardial infarction

Rapporteur: Alexandre Moreau, Co-Rapporteur: Paolo Gasparini

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.3. Lenalidomide Mylan – Lenalidomide – EMEA/H/C005306

Mylan Pharmaceuticals Limited;

Rapporteur: Anastasia Mountaki

Scope: DHPC letter and Communication Plan adopted via written procedure on 21.10.2025

Action: For information

9.1.4. LIBTAYO – Cemiplimab – EMEA/H/C004844

Regeneron Ireland;

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Johanna Lähteenvuo

Scope: DHPC letter and Communication Plan adopted via written procedure on 21.10.2025

Action: For information

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

Advanced Accelerator Applications

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: Revised opinion adopted via written procedure on 21.10.2025.

Action: For information

Opinion adopted on 18.09.2025. Request for Supplementary Information adopted on 19.06.2025, 27.03.2025.

9.1.6. Omidria - Phenylephrine/Ketorolac – EMEA/H/C/003702

Rayner Surgical (Ireland) Limited; maintenance of mydriasis, prevention of miosis and reduction of ocular pain

Rapporteur: Jayne Crowe, Co-Rapporteur: Robert Porszasz

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.7. Suboxone - Buprenorphine/Naloxone – EMEA/H/C/000697

Indivior Europe Limited; treatment of opioid drug dependence

Rapporteur: Janet Koenig, Co-Rapporteur: Finbarr Leacy

Scope: Withdrawal of marketing authorisation

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. Tecovirimat SIGA - Tecovirimat - EMA/REF/0000287477

Siga Technologies Netherlands B.V.;

Referral Rapporteur: Jayne Crowe, Referral Co- Rapporteur: Vilma Petrikaite

Scope: List of outstanding issues

Action: For adoption

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Tecovirimat SIGA. The review was prompted by emerging data from clinical trials, which raised concerns about a potential lack of efficacy. These findings need to be reviewed in the context of all available data and their potential impact on the benefit-risk of Tecovirimat SIGA in its authorised indications.

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

November 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 November 2025

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at November 2025 PDCO

Action: For information

Agenda of the PDCO meeting held on 11-14 November 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, Vice-Chairs: Pierre Demolis and Ewa Balkowiec Iskra

Report from the SAWP meeting held on 27 – 30 October 2025.

Action: For information

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

14.3.3. QWP response to CMDh question

Action: For adoption

14.3.4. Appointment of SAG Neurology Chair

Action: For endorsement

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)*

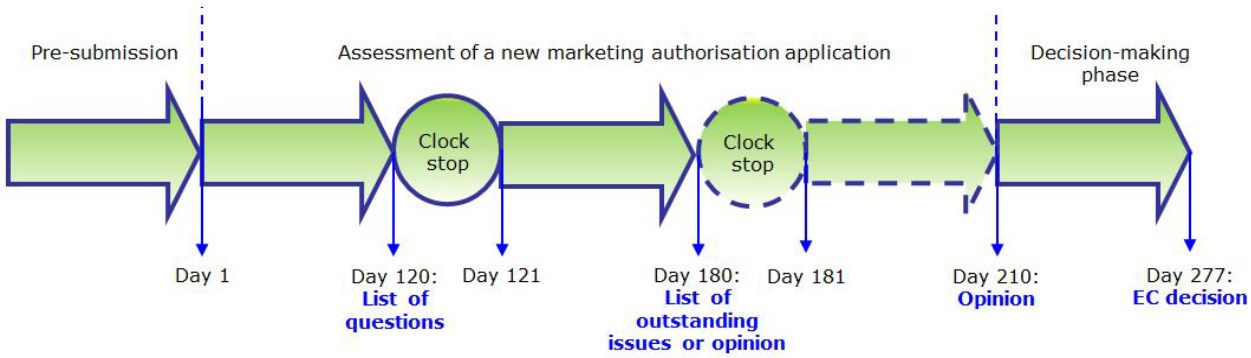
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

10 November 2025
EMA/CHMP/336401/2025

Annex to 10-13 November 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 November 2025: **For adoption**

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

Final Outcome of Rapporteurship allocation for November 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 27-30 October 2025 PRAC:

Signal of hypogammaglobulinaemia

TEPKINLY (CAP) – Epcoritamab

Rapporteur: Peter Mol, Co-Rapporteur: Ingrid Wang, PRAC Rapporteur: Maria Martinez Gonzalez
PRAC recommendation on a variation
Action: For adoption

Signal of anaphylactic reaction

DATROWAY (CAP) – Datopotamab deruxtecan

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Mari Thorn
PRAC recommendation on a variation
Action: For adoption

Signal of cutaneous vasculitis

BOSULIF (CAP) - Bosutinib

Rapporteur: Martin Mengel, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Martin Huber
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 November 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

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

B.5.3. CHMP-PRAC assessed procedures

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-	Request for supplementary information adopted with a specific timetable.

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. 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 30.10.2025, 10.07.2025, 13.03.2025.	

B.5.4. PRAC assessed procedures

B.5.5. CHMP-CAT assessed procedures

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

PRAC Led **Tecartus - Brexucabtagene autoleucel - EMEA/H/C/005102/II/0051, Orphan, ATMP** Kite Pharma EU B.V., PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Peter Mol, "Submission of the final study report for the non-interventional study KT-EU-472-5966 titled	

"Quantitative Testing of Health Care Professional Knowledge About Tecartus Risk Minimisation Measures'' listed as a category 3 study in the RMP.” Request for Supplementary Information adopted on 13.06.2025, 06.12.2024.

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.