26 January 2026
EMA/CHMP/390303/2025 Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 26-29 January 2026
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

26 January 2026, 09:30 – 19:30, virtual meeting/room 1C

27 January 2026, 08:30 – 19:30, virtual meeting/room 1C

28 January 2026, 08:30 – 19:30, virtual meeting/room 1C

29 January 2026, 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 26-29 January 2026. See January 2026 CHMP minutes (to be published post February 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 26-29 January 2026

1.3. Adoption of the minutes

CHMP minutes for 22-25 June 2025, 20-23 July 2025, 15-18 September 2025, 13-16 October 2025 meetings

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 19 January 2025

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Tolebrutinib - EMEA/H/C/006386

treatment of non-relapsing secondary progressive multiple sclerosis (nrSPMS) in adults

Scope: Oral explanation

Action: Oral explanation to be held on 28 January 2026 at 09:00

List of Outstanding Issues adopted on 11.12.2025, 16.10.2025. List of Questions adopted on 19.06.2025.

2.1.2. Trofinetide - Orphan - EMEA/H/C/006482

Acadia Pharmaceuticals (Netherlands) B.V.; treatment of Rett syndrome in adults and paediatric patients 2 years of age and older

Scope: Oral explanation

Action: Oral explanation to be held on 27 January 2026 at 14:00

List of Outstanding Issues adopted on 16.10.2025. List of Questions adopted on 22.05.2025.

2.1.3. 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 28 January 2026 at 16:00

List of Outstanding Issues adopted on 13.11.2025, 18.09.2025. List of Questions adopted on 25.04.2025.

2.2. Re-examination procedure oral explanations

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

Chiesi Farmaceutici S.p.A.

Scope: Oral explanation

Action: Oral explanation to be held on 27 January 2026 at 09:00

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

See 5.3

2.2.2. 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: Oral explanation

Action: Oral explanation to be held on 27 January 2026 at 16:00

Opinion adopted on 16.10.2025. List of Outstanding Issues adopted on 19.06.2025. List of Questions adopted on 30.01.2025.

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. Kerendia - Finerenone - EMA/X/0000248026

Bayer AG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Bianca Mulder

Scope: Oral explanation

Action: Oral explanation to be held on 28 January 2026 at 11:00

See 4.1

2.3.2. EURneffy - Epinephrine - EMA/X/0000248440

Alk-Abello A/S

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

Scope: Oral explanation

Action: Oral explanation to be held on 27 January 2026 at 11:00

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Estetrol - EMEA/H/C/006213

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 13.11.2025. List of Questions adopted on 19.06.2025.

3.1.2. Lutetium (177Lu) chloride - EMEA/H/C/006596

used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with Lutetium (177Lu) chloride

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 16.10.2025. List of Questions adopted on 22.05.2025.

3.1.3. Semaglutide - EMEA/H/C/006426

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 13.11.2025. List of Questions adopted on 24.07.2025.

3.1.4. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 11.12.2025, 18.09.2025. List of Questions adopted on 27.03.2025.

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

immunisation for the prevention of influenza disease

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 13.11.2025. List of Questions adopted on 24.07.2025.

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

3.2.1. Liraglutide - EMEA/H/C/006620

treatment of diabetes and weight management

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

3.2.3. Liraglutide - EMEA/H/C/006615

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

3.2.4. Lurbinectedin - Orphan - EMEA/H/C/006673

Pharma Mar S.A.; Maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 16.10.2025.

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

3.3.1. Icotrokinra hydrochloride - EMEA/H/C/006730

treatment of plaque psoriasis in adults and adolescents 12 years or older

Scope: List of questions

Action: For adoption

3.3.2. Pegfilgrastim - EMEA/H/C/006085

reduction of neutropoenia in adults

Scope: List of questions

Action: For adoption

3.3.3. Omalizumab - EMEA/H/C/006756

treatment of asthma and chronic rhinosinusitis with nasal polyps

Scope: List of questions

Action: For adoption

3.3.4. Bevacizumab - Orphan - EMEA/H/C/006392

Laboratoires Delbert; treatment of adult patients with hereditary haemorrhagic telangiectasia

Scope: List of questions

Action: For adoption

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

3.4.1. Senaparib - EMEA/H/C/006708

maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer

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

Action: For adoption

List of Questions adopted on 11.12.2025.

3.4.2. Navepegritide - Orphan - EMEA/H/C/006627

Ascendis Pharma Growth Disorders A/S; treatment of achondroplasia in children

Scope: Third party intervention

Action: For information

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

3.5.1. 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: Opinion

Action: For adoption

Opinion adopted on 16.10.2025. List of Outstanding Issues adopted on 19.06.2025. List of Questions adopted on 30.01.2025.

See 2.2

3.5.2. Blarcamesine Anavex - Blarcamesine - EMEA/H/C/006475

Anavex Germany GmbH; treatment of Alzheimer's disease and dementia

Scope: Re-examination rapporteurs were appointed via written procedure on 14 January 2025

Action: For adoption

Opinion adopted on 11.12.2025. List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 25.04.2025.

3.6. Initial applications in the decision-making phase

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

Merck Sharp & Dohme B.V.; prevention of infections with respiratory syncytial virus (RSV) and lower respiratory tract disease (LRTD)

Scope: Revised timetable adopted via written procedure on 19.12.2025.

Action: For information

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

No items

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

Pfizer Europe MA EEIG

Rapporteur: Finbarr Leacy

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

Action: For adoption

4.1.2. 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

See 2.3

4.1.3. 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

See 2.3

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. 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

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

4.3.1. Gardasil 9 - Human papillomavirus 9-valent Vaccine (Recombinant, adsorbed) - EMA/X/0000310883

Merck Sharp & Dohme B.V.

Rapporteur: Kristina Dunder

Scope: "Extension application to introduce a new pharmaceutical form suspension for injection.

Additionally, product information includes an update to the polysorbate excipient statement in the SmPC and package leaflet, in accordance with the Annex of the Excipients Guideline (Version 4), ensuring alignment with current regulatory standards."

Action: For adoption

4.3.2. Skyrizi - Risankizumab - EMA/X/0000296763

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new strength of 55 mg solution for injection grouped with a type II variation C.I.6.a to include treatment of paediatric plaque psoriasis (6 to < 18 years) for Skyrizi, based on final results from study M19-977 and interim results from study M19-973. M19-977 is a randomized, active-controlled, efficacy assessor-blinded study to evaluate pharmacokinetics, safety, and efficacy of risankizumab in patients from 6 to less than 18 years of age with moderate to severe plaque psoriasis; M19-973 is a phase 3 multicentre, single-arm, open-label extension study to assess the safety, tolerability, and efficacy of risankizumab in subjects with moderate to severe plaque psoriasis who have completed participation in study M19-977. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.4, 6.5, 6.6, and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.0 of the RMP has also been submitted."

Action: For adoption

4.3.3. Vyepti - Eptinezumab - EMA/X/0000296350

H. Lundbeck A/S

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: For adoption

4.3.4. Wegovy - Semaglutide - EMA/X/0000296344

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Mari Thorn

Scope: "Extension application to introduce a new pharmaceutical form (tablet), associated with four new strengths (1.5 mg, 4 mg, 9mg and 25 mg) and a new route of administration (oral use)."

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

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

Vanda Pharmaceuticals Netherlands B.V.

Scope: Adoption of timetable

Action: For adoption

Opinion adopted on 13.12.2025. List of Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

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. Abiraterone Mylan - Abiraterone acetate – WS – EMA/VR/0000291298

Mylan Pharmaceuticals Limited

Rapporteur: John Joseph Borg, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Grouped application comprising of 3 Extension of indication variations for ABIRATERONE MYLAN, as follows:

C.I.6: to update the currently approved indication for metastatic hormone sensitive prostate cancer (mHSPC) patients to also include non-high risk mHSPC

C.I.6: to include the treatment of newly diagnosed mHSPC in adult men in combination with ADT and docetaxel in patients who are fit for chemotherapy

C.I.6: to include the treatment of newly diagnosed high risk non-metastatic hormone sensitive prostate cancer (HSPC) in adult men in combination with ADT and radiotherapy

The variations are based on literature data. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted."

Action: For adoption

5.1.2. Akeega – Niraparib / Abiraterone acetate - EMA/VR/0000282377

Janssen Cilag International

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include AKEEGA with prednisone or prednisolone for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and HRR-mutations (germline and/or somatic), based on interim results from study 67652000PCR3002 (AMPLITUDE); this is a phase 3 randomized, placebo-controlled, double-blind study of niraparib in combination with abiraterone acetate and prednisone versus abiraterone acetate and prednisone for the treatment of participants with deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-sensitive Prostate cancer (mCSPC); 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 3.1 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. In addition, the MAH is requesting an additional year of market protection for a new indication."

Action: For adoption

5.1.3. Braftovi – Encorafenib - EMA/VR/0000304994

Pierre Fabre Medicament

Rapporteur: Martin Mengel, PRAC Rapporteur: Rugile Pilviniene

Scope: "Extension of indication to include, in combination with cetuximab and FOLFOX, the first line treatment of adult patients with metastatic colorectal cancer with a BRAF V600E mutation for BRAFTOVI, based on the interim results from the pivotal Study C4221015 (BREAKWATER). This is an open-label, multicentre, 3-arm, randomized Phase 3 study of encorafenib plus cetuximab (EC) alone or in combination with mFOLFOX6 versus standard of care chemotherapy in first-line participants with BRAF V600E-mutant mCRC. 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. The version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

5.1.4. CRYSVITA - Burosumab - EMA/VR/0000263400

Kyowa Kirin Holdings B.V.

Rapporteur: Kristina Dunder

Scope: "Extension of indication to include treatment of X-linked hypophosphataemia (XLH) in paediatric patients from birth to less than 1 year of age for CRYSVITA, based on final results from study BUR-CL207; this is a phase 1/2 Open-label, Multicentre, Non-randomized Study to Evaluate Safety, Pharmacodynamics, Pharmacokinetics and Effect of Burosumab in Paediatric Patients from Birth to Less than 1 Year of Age with XLH; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance."

Action: For adoption

5.1.5. Dupixent – Dupilumab - EMA/VR/0000282164

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 (CSU) in children aged 2 to 11 years whose disease is inadequately controlled by H1 antihistamines and who are naive to anti-IgE therapy for CSU for DUPIXENT, based on the results from study PKM16982; this is a multi-centre, single-arm study to investigate the pharmacokinetics and safety of dupilumab in male and female participants ≥2 years to <12 years of age with uncontrolled chronic spontaneous urticaria (CSU). Consequently, 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 14.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template."

Action: For adoption

5.1.6. 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

5.1.7. HETRONIFLY - Serplulimab - EMA/VR/0000282407

Accord Healthcare S.L.U.

Rapporteur: Eva Skovlund, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include HETRONIFLY in combination with carboplatin and pemetrexed is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung carcinoma who do not have EGFR or ALK positive mutations based on interim results from study HLX10-002-NSCLC301; this is a pivotal Phase III clinical study. As a consequence, sections 4.1, 4.8, 5.1, 5.2 of of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted."

Action: For adoption

5.1.8. HETRONIFLY - Serplulimab - EMA/VR/0000284402

Accord Healthcare S.L.U.

Rapporteur: Eva Skovlund, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include, in combination with fluoropyrimidine- and platinum-based chemotherapy, the first-line treatment of adult patients with unresectable, locally advanced/recurrent or metastatic oesophageal squamous cell carcinoma whose tumours express PD-L1 with a CPS ≥ 1 for HETRONIFLY, based on results from study HLX10-007-EC301; this is a randomized, double-blind, multi-centre, phase III clinical study comparing the clinical efficacy and safety of HLX10 or placebo combined with chemotherapy in first-line treatment of locally advanced/metastatic esophageal squamous cell carcinoma (ESCC) patients. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted."

Action: For adoption

5.1.9. Hympavzi – Marstacimab - EMA/VR/0000304590

Pfizer Europe MA EEIG

Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Extension of indication to include treatment of routine prophylaxis of bleeding episodes in patients 12 years of age and older with haemophilia A with factor VIII inhibitors or haemophilia B with factor IX inhibitors for HYMPAVZI, based on final results from study B7841005 and interim results from supportive study B7841007. Study B7841005 this is an open-label study in adolescent and adult severe (coagulation factor activity ≤2%) with or without inhibitors comparing standard treatment to PF-06741086 Prophylaxis. Study B7841007 is an open-label extension study to evaluate the long-term safety, tolerability, and efficacy of marstacimab prophylaxis in severe (coagulation factor activity <1%) haemophilia A participants with or without inhibitors or moderately severe to severe haemophilia B participants (coagulation factor activity ≤2%) with or without inhibitors. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted."

Action: For adoption

5.1.10. 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

5.1.11. Imfinzi – Durvalumab - EMA/VR/0000282058

AstraZeneca AB

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: David Olsen

Scope: "Extension of indication for IMFINZI to include in combination with FLOT chemotherapy as neoadjuvant and adjuvant treatment, followed by adjuvant IMFINZI monotherapy, for the treatment of adults with resectable gastric or gastro-oesophageal junction adenocarcinoma , based on interim results from study MATTERHORN, (D910GC00001); this is a randomized, double-blind, placebo-controlled, phase 3 study of neoadjuvant-adjuvant durvalumab and FLOT chemotherapy followed by adjuvant durvalumab in patients with resectable gastric and gastroesophageal junction cancer

(GC/GEJC); As a consequence, sections 4.1, 4.2, 4.5, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14.0 of the RMP has also been submitted."

Action: For adoption

5.1.12. Inaqovi - Decitabine / Cedazuridine - EMA/VR/0000304730

Otsuka Pharmaceutical Netherlands B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Extension of indication to include treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy for INAQOVI in combination with venetoclax, based on interim results from study ASTX727-07; this is a single-arm, open-label pharmacokinetic, safety, and efficacy study of ASTX727 in combination with venetoclax in adult patients with acute myeloid leukaemia; As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.3 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 bring editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection."

Action: For adoption

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

Eli Lilly Nederland B.V.

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: "Update of sections 4.1, 4.8 and 5.1 of the SmPC based on final 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. The Package Leaflet is updated accordingly. Version 4.2 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 13.11.2025, 22.05.2025, 27.02.2025.

5.1.14. Mylotarg - Gemtuzumab ozogamicin - EMA/VR/0000304835

Pfizer Europe MA EEIG

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

Scope: "Extension of indication to include, in combination with mitoxantrone and cytarabine (AraC), the treatment of paediatric patients aged 1 year to less than 18 years with newly diagnosed CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL) for MYLOTARG, based on results from study MyeChild 01 (WI203680). This is a Phase 3, randomised, open-label, multicentre study incorporating an embedded dose finding study in children with newly diagnosed AML/high risk MDS /isolated myeloid

sarcoma (de novo or secondary). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet."

Action: For adoption

5.1.15. Noxafil – Posaconazole - EMA/VR/0000263360

Merck Sharp & Dohme B.V.

Rapporteur: Nicolas Beix, 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

5.1.16. OPDIVO – Nivolumab - EMA/VR/0000282199

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Peter Mol, PRAC Rapporteur: Dirk Mentzer

Scope: "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

5.1.17. OPDIVO – Nivolumab - EMA/VR/0000304938

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Peter Mol

Scope: "Extension of indication to include OPDIVO for the treatment of adults and adolescents 12 years of age and older with previously untreated Stage III or IV classical Hodgkin Lymphoma (cHL), based on results from the pivotal study CA2098UT (SWOG 1826), a Phase 3, randomized, open-label study of nivolumab (Opdivo) + AVD (N-AVD) versus brentuximab vedotin (Adcetris) + AVD (Bv-AVD) in patients (age ≥12 years) with newly diagnosed, advanced stage cHL. 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 51.0 of the RMP has also been submitted."

Action: For adoption

5.1.18. Opdualag - Nivolumab / Relatlimab - EMA/VR/0000303785

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Peter Mol, PRAC Rapporteur: Dirk Mentzer

Scope: "Extension of indication to include patients with tumour cell PD-L1 expression ≥ 1% in the first-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older for OPDUALAG, based on updated descriptive 4-year data from pivotal Study CA224047; this is a randomized, double-blind phase 2/3 study of relatlimab combined with nivolumab versus nivolumab in participants with previously untreated metastatic or unresectable melanoma; 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. In addition, the Marketing authorisation holder (MAH) took the opportunity to remove Annex IV from the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection."

Action: For adoption

5.1.19. Palynziq – Pegvaliase - EMA/VR/0000302032

Biomarin International Limited

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Rhea Fitzgerald

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

C.I.6: Extension of indication to include treatment of adolescent patients aged 12 to <16 years with PKU for PALYNZIQ, based on interim results from study 165-306; this is a Phase 3 open label, randomized, controlled, 2-arm, multicentre study designed to evaluate the safety and efficacy of pegvaliase in adolescent participants 12 to <18 years old with PKU. 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. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the PI to include editorial changes and remove references to the route of administration of adrenaline (injection) to allow physicians to prescribe any approved adrenaline device.

C.I.4: Update of section 4.6 of the SmPC in order to update information on pregnancy based on a comprehensive assessment of all pregnancy and breastfeeding reports received from all sources.

The RMP version 5.0 has also been submitted."

Action: For adoption

5.1.20. Privigen - Human normal immunoglobulin - EMA/VR/0000304719

CSL Behring GmbH

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Dirk Mentzer

Scope: "A grouped application consisting of a quality variation and

C.I.6: Extension of indication to include treatment of patients with measles pre/post-exposure prophylaxis in whom active immunisation is contraindicated or not advised, for PRIVIGEN, in alignment with the IVIg core SmPC (EMA/CHMP/BPWP/94038/2007 Rev); As a consequence, sections 2, 4.1, 4.2 and 5.2 of the SmPC. The Package Leaflet is updated accordingly. The RMP version 9 has also been submitted"

Action: For adoption

5.1.21. Retsevmo – Selpercatinib - EMA/VR/0000282012

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include paediatric patients 2 years and older with: (1) Advanced RET fusion-positive thyroid cancer who are radioactive iodine-refractory, (2) Advanced RET-mutant medullary thyroid cancer, (3) Advanced RET fusion-positive solid tumours, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted, for RETSEVMO, based on final results from study J2G-OX-JZJJ (LOXO RET 18036, LIBRETTO-121); this is a multicentre, open-label Phase 1/2 study in paediatric patients with advanced solid or primary CNS tumours harbouring an activating RET alteration. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.6 of the SmPC are updated. The Package Leaflet and labelling are updated in accordance. Version 15.1 of the RMP has also been submitted.

Action: For adoption

5.1.22. SOTYKTU - Deucravacitinib - EMA/VR/0000282554

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Nicolas Beix, Co-Rapporteur: Margareta Bego, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include, for SOTYKTU, alone or in combination with conventional synthetic disease modifying antirheumatic drugs (DMARDs), the treatment of active psoriatic arthritis (PsA) in adults who have had an inadequate response or who have been intolerant to a prior DMARD therapy, based on results from the following phase 3 studies: Study IM011-054 (POETYK PsA-1); this is a phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of deucravacitinib in participants with active psoriatic arthritis who are naïve to biologic disease-modifying anti-rheumatic drugs, and Study IM011-055 (POETYK PsA-2); this is a multi-centre, randomized, double-blind, placebo-controlled phase 3 study to evaluate the efficacy and safety of BMS-986165 in participants with active psoriatic arthritis (PsA) who are naïve to biologic disease modifying anti-rheumatic drugs or had previously received TNFα inhibitor treatment. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, as well as introduce administrative changes to the PI."

Action: For adoption

5.1.23. 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

Request for Supplementary Information adopted on 18.09.2025.

5.1.24. ZYNYZ - Retifanlimab – Orphan - EMA/VR/0000247788

Incyte Biosciences Distribution B.V.

Rapporteur: Peter Mol, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Dirk Mentzer

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, multicentre, 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."

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

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

Chiesi Farmaceutici S.p.A.

Scope: Opinion

"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.

See 2.2

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

Vanda Pharmaceuticals Netherlands B.V.

Scope: Update of timetable

Action: For adoption

Opinion adopted on 12.11.2025. Request for Supplementary Information adopted on 25.04.2025, 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/006913

to detect genomic alterations including short variants, rearrangements, and select copy number alterations in 324 genes across 16 cellular pathways and genomic signatures associated with cancer

Scope: List of questions

Action: For adoption

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006887

assay for the detection of single nucleotide variants coding five IDH1 mutations (R132C, R132H, R132G, R132S, and R132L) in DNA

Scope: Opinion

Action: For adoption

6.3.3. In vitro diagnostic medical device - EMEA/H/D/006863

in vitro diagnostic test that uses high throughput parallel sequencing technology to detect sequence variations (SNVs, deletions, insertions, and fusions) in 46 cancer related genes

Scope: Opinion

Action: For adoption

6.3.4. In vitro diagnostic medical device - EMEA/H/D/006914

in vitro diagnostic test that uses targeted next-generation sequencing to enable assessment of Homologous Recombination Deficiency (HRD)

Scope: Opinion

Action: For adoption

6.3.5. In vitro diagnostic medical device - EMEA/H/D/006859

laboratory use in the qualitative immunohistochemical detection of MSH6 protein in formalin-fixed, paraffin-embedded (FFPE) tissue specimens by light microscopy

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

8.1.1. Asundexian – H0006640

indicated for the prevention of ischaemic stroke in adult patients after a non-cardioembolic ischaemic stroke or a transient ischaemic attack (TIA)

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. Darzalex – Daratumumab - EMA/VR/0000312940

Janssen Cilag International

Rapporteur: Boje Kvorning Pires Ehmsen

Scope: Update of section 4.2 of the SmPC in order to introduce, upon physician's discretion, the possibility of self-administration of Darzalex SC by patients or their caregivers, based on results from four human factor studies. The Package Leaflet is updated accordingly. In addition, the Labelling section is updated to include information in Braille.

Action: For adoption

9.1.2. Gazyvaro – Obinutuzumab - EMA/VR/0000313033

Roche Registration GmbH

Rapporteur: Boje Kvorning Pires Ehmsen

Scope: Update of section 4.2 of the SmPC in order to include the administration of obinutuzumab as a short duration infusion (SDI) based on data from clinical studies and literature. The Package Leaflet is updated accordingly.

Action: For adoption

9.1.3. Bydureon – Exenatide - EMEA/H/C/002020

AstraZeneca AB; treatment of type 2 diabetes mellitus

Rapporteur: Kristina Dunder, Co-Rapporteur: Patrick Vrijlandt

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.4. Byetta – Exenatide - EMEA/H/C/000698

AstraZeneca AB; treatment of type 2 diabetes mellitus

Rapporteur: Kristina Dunder, Co-Rapporteur: Patrick Vrijlandt

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.5. Lumark - Lutetium (177Lu) chloride – EMEA/H/C/002749

I.D.B. Holland B.V.; used only for the radiolabelling of carrier molecules

Rapporteur: Nicolas Beix, Co-Rapporteur: Antonio Gomez-Outes

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.6. Winrevair – Sotatercept - EMA/VR/0000272214

Merck Sharp & Dohme B.V.

Rapporteur: Patrick Vrijlandt

Scope: Update of section 4.8 of the SmPC in order to add "Intrapulmonary shunt" to the list of adverse drug reactions (ADRs) with frequency uncommon based on post-marketing data; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. The Dutch patient leaflet for the "Driving and using machines" statement has been revised as agreed with CBG-MEB.

Action: For adoption

9.1.7. Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMA/PSUR/0000296493

Pfizer Europe MA EEIG

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan

Scope: PRAC recommendation for adoption

Action: For adoption

9.1.8. Palforzia - Defatted powder of Arachis hypogaea L., semen (peanuts) - EMEA/H/C/004917

Stallergenes; desensitization of children and adolescents to peanut allergy

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Thalia Marie Estrup Blicher

Action: For information

9.1.9. Ocrevus – Ocrelizumab - EMA/VR/0000313041

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher

Scope: CHMP request for PRAC advice;

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

Action: For adoption

9.1.10. Zegalogue – dasiglucagon – EMEA/H/C/006214

Zealand Pharma A/S; treatment of severe hypoglycaemia in adults, adolescents, and children aged 6 years and over with diabetes mellitus

Rapporteur: Paolo Gasparini, Co-Rapporteur: Hjalti Kristinsson

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.11. Arixtra – Fondaparinux sodium – EMEA/H/C/000403

Viatris Healthcare Limited

Rapporteur: Kristina Dunder

Scope: DHPC and communication plan

The DHPC and communication plan have been adopted via written procedure on 13 January 2026.

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: Finbarr Leacy, Referral Co- Rapporteur: Vilma Petrikaite

Scope: Draft List of experts for SAG and timetable update

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

January 2026 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

13.3.1. EC Request for EMA scientific opinion

Action: For discussion

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 co-opted membership

The 3-year co-opted member mandate for Bruno Delafont comes to an end on 26.03.2026. His area of expertise is Biostatistics and clinical trial methodology.

The nomination procedure foresees that the CHMP should decide on their areas of expertise in order to proceed with the nominations.

The election is anticipated at the February 2026 plenary meeting.

Action: For endorsement

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 January 2026

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at January 2026 PDCO

Action: For information

Agenda of the PDCO meeting held on 27-30 January 2026

Action: For information

14.2.3. Joint CHMP-PDCO membership mandate renewal

The Paediatric Regulation foresees five members, with their alternates, of the Committee for Medicinal Products for Human Use, having been appointed to that Committee in accordance with Article 61(1) of Regulation (EC) No 726/2004. These five members with their alternates shall be appointed to the Paediatric Committee by the Committee for Medicinal Products for Human Use.

CHMP is invited to retroactively confirm the renewal of the joint CHMP-PDCO membership mandate for Dana Gabriela Marina and Simona Badoi from 24.06.2025 to 23.06.2028.

Action: For endorsement

14.2.4. Call for interest for joint CHMP-CAT membership

According to the ATMP Regulation, CAT membership includes five members or co-opted members of the CHMP from five Member States, with alternates either proposed by their respective Member State or, in the case of co-opted members of the CHMP, identified by the latter on the advice of the corresponding co-opted member.

CHMP members are invited to express interest to step in the position for a joint CHMP-CAT membership by Wednesday 18 February 2026.

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 12-15 January 2026.

Action: For information

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

14.3.3. Election of Chair - Rheumatology-Immunology Working Party (RIWP)

Following the call for nominations launched in November 2025, CHMP will elect the Chair from the candidate(s) who submitted nominations.

Nomination(s) received

Action: For election

14.3.4. SAG Oncology

Appointment of the newly elected SAG Oncology Chair and Vice-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

Draft CHMP workplan for 2026

CHMP: Bruno Sepodes

Action: For adoption

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)*

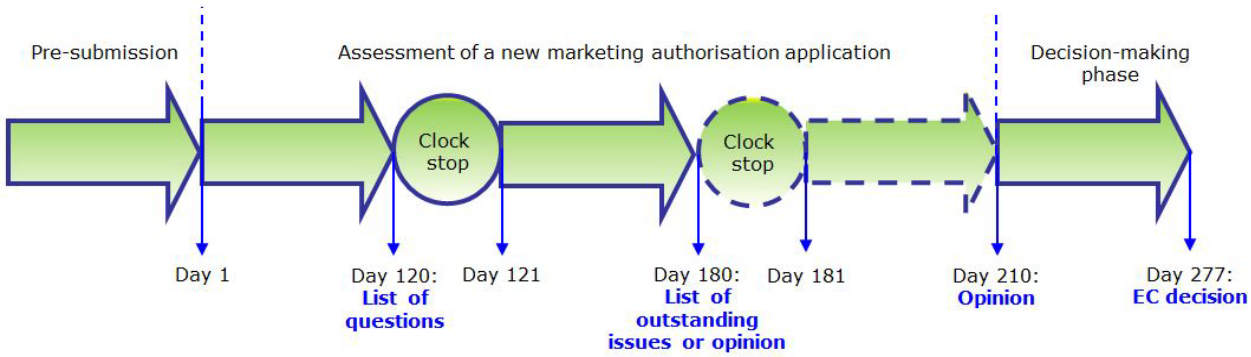
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

26 January 2026
EMA/CHMP/390356/2025

Annex to 26-29 January 2026 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 January 2026: **For adoption**

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

Final Outcome of Rapporteurship allocation for January 2026: **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 12-15 January 2026
PRAC

Signal of renal-limited thrombotic microangiopathy Pegylated liposomal doxorubicin – CAELYX PEGYLATED LIPOSOMAL; CELDOXOME PEGYLATED LIPOSOMAL; ZOLSKETIL PEGYLATED LIPOSOMAL (CAP) Rapporteur: various, Co-Rapporteur: various, PRAC Rapporteur: various PRAC recommendation on a variation **Action:** For adoption
Signal of growth acceleration Erdafitinib – BALVERSA (CAP) Rapporteur: Martin Mengel, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder PRAC recommendation on a variation **Action:** For adoption

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/0004/G, Orphan Immedica Pharma AB, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "A grouped application comprised of 8 Type II variations as follows: 1 Type II (C.I.4): Update of section 5.2 of the SmPC in order to update ganaxolone metabolite pattern at steady state based on re-analysis of 1042-TQT-1001 listed as a category 3 study in the RMP to evaluate the ganaxolone steady-state metabolite. 7 Type II (C.I.13): Submission of the final non-clinical study reports for the in vitro DDI potential and in vivo PK of the metabolite M17 listed as category 3 studies in the RMP.	Positive Opinion adopted by consensus on 15.01.2026.

The RMP version 4.0 has been agreed. In addition, the MAH took the opportunity to introduce updates to the PI that reflect clarifications and typographical corrections, including to sections 4.2 and 4.4 of the SmPC." Opinion adopted on 15.01.2026. Request for Supplementary Information adopted on 24.07.2025, 27.03.2025, 25.07.2024, 11.04.2024.	
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0015/G, Orphan Immedica Pharma AB, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "A grouped application consisting of five Type II variations, as follows: C.I.13: Submission of the final report from non-clinical study 1022-9241 listed as a category 3 study in the RMP. This is a 26-Week Toxicity Study of Ganaxolone Metabolite, M2, by Oral Gavage in the Sprague-Dawley rat with a 2-Week Recovery Period. 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/Foetal Development in CD (Sprague Dawley) IGS Rat. 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. Update of section 5.3 of the SmPC to reflect the relevant results of the metabolites studies. The RMP version 4.0 has been agreed."	Positive Opinion adopted by consensus on 15.01.2026.

Opinion adopted on 15.01.2026.
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

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

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. Timetables – 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.