23 March 2026
EMA/CHMP/67141/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 23-26 March 2026
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

23 March 2026, 09:30 – 19:30, virtual meeting/room 2C

24 March 2026, 08:30 – 19:30, virtual meeting/room 2C

25 March 2026, 08:30 – 19:30, virtual meeting/room 2C

26 March 2026, 08:30 – 15:00, virtual meeting/room 2C

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 23-26 March 2026. See March 2026 CHMP minutes (to be published post April 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 23-26 March 2026

1.3. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 16 March 2026.

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 25 March 2026 at 11:00

List of Outstanding Issues adopted on 29.01.2026, 11.12.2025, 16.10.2025. List of Questions adopted on 19.06.2025.

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 24 March 2026 at 11:00

List of Outstanding Issues adopted on 29.01.2026. List of Questions adopted on 24.07.2025.

2.2. Re-examination procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 24 March 2026 at 16:00

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

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. PLUVICTO - Lutetium (177Lu) vipivotide tetraxetan - EMA/VR/0000288073

Novartis Europharm Limited

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

Scope: Oral explanation

Action: Oral explanation to be held on 25 March 2026 at 16:00

See 5.1

2.3.2. SOGROYA - Somapacitan - EMA/VR/0000264734

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Dennis Lex

Scope: Oral explanation

Action: Oral explanation to be held on 24 March 2026 at 09:00

See 5.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Nadofaragene firadenovec - ATMP - EMEA/H/C/005856

treatment of adult patients with high-grade (HG), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 05.12.2025. List of Questions adopted on 16.04.2025.

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 11.12.2025. List of Questions adopted on 24.07.2025.

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.02.2026. List of Questions adopted on 13.11.2025.

3.1.4. Leniolisib - Orphan - EMEA/H/C/005927

Pharming Technologies B.V.; treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.05.2024, 25.01.2024, 09.11.2023, 20.07.2023. List of Questions adopted on 24.01.2023.

3.1.5. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 29.01.2026. List of Questions adopted on 16.10.2025.

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

3.2.1. *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 outstanding issues

Action: For adoption

List of Questions adopted on 13.11.2025.

3.2.2. Camizestrant - EMEA/H/C/006494

treatment of adults with locally advanced or metastatic breast cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 16.10.2025.

3.2.3. Linerixibat - Orphan - EMEA/H/C/006241

Glaxosmithkline Trading Services Limited; treatment of cholestatic pruritus in adult patients with primary biliary cholangitis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 16.10.2025.

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

treatment of melanoma

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 18.07.2025.

3.2.5. Allogeneic faecal microbiota, pooled - Orphan - EMEA/H/C/006678

MaaT PHARMA; treatment of adult patients with acute-graft-versus-host disease (aGvHD)

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. Apixaban - EMEA/H/C/006752

prevention of venous thromboembolic events (VTE), stroke and systemic embolism; treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) in adults. Treatment of VTE in children from 28 days to < 18 years of age.

Scope: List of questions

Action: For adoption

3.3.2. Insulin aspart - EMEA/H/C/006677

treatment of diabetes mellitus from 1 year of age

Scope: List of questions

Action: For adoption

3.3.3. Ensartinib - EMEA/H/C/006757

the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).

Scope: List of questions

Action: For adoption

3.3.4. Insulin aspart - EMEA/H/C/006864

treatment of diabetes mellitus from 1 year of age

Scope: List of questions

Action: For adoption

3.3.5. Zopapogene imadenovec - Orphan - ATMP - EMEA/H/C/006508

FGK Representative Service GmbH; treatment of respiratory papillomatosis in adults

Scope: List of questions

Action: For information

3.3.6. Pimicotinib - PRIME - Orphan - EMEA/H/C/006383

Merck Europe B.V.; treatment of tenosynovial giant cell tumour in adults and adolescents from 12 years of age

Scope: List of questions

Action: For adoption

3.3.7. Etripamil - EMEA/H/C/006292

indicated for the rapid conversion of paroxysmal supraventricular tachycardia (PSVT) episodes to sinus rhythm in adults.

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

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

Scope: Opinion

Third-party intervention

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.

See 2.2

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

Action: For adoption

Opinion adopted on 26.02.2026. List of Outstanding Issues adopted on 16.10.2025. List of Questions adopted on 22.05.2025.

3.5.3. Iloperidone Vanda Pharmaceuticals - Iloperidone - EMEA/H/C/006561

Vanda Pharmaceuticals Netherlands B.V.; treatment of schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder

Scope: Appointment of re-examination rapporteurs, timetable

Action: For adoption

Opinion adopted on 26.02.2026. List of Outstanding Issues adopted on 13.11.2025, 18.09.2025. List of Questions adopted on 25.04.2025.

3.6. Initial applications in the decision-making phase

No items

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. LOJUXTA - Lomitapide - EMA/X/0000258068

Chiesi Farmaceutici S.p.A.

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Bianca Mulder

Scope: Extension application to add a new strength of 2 mg hard capsules.
This application is grouped with

- type II variation (C.I.6.a): an Extension of Indication to include treatment of paediatric patients aged 5 years and older with homozygous familial hypercholesterolaemia (HoFH) for LOJUXTA, based on final results from the pivotal paediatric study APH-19; this is a phase 3, single-arm, open-label, international, multi-centre study to evaluate the efficacy and safety of lomitapide in paediatric patients with homozygous familial hypercholesterolaemia (HOFH) on stable lipid-lowering therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Annex II and Package Leaflet are updated accordingly. The RMP version 7.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.

- 3 x type IB variations (C.I.7.b): to delete the 30 mg, 40 mg and 60 mg strengths from the Lojuxta marketing authorisation (EU/1/13/851/004 - 006).

Action: For adoption

4.1.2. NAMUSCLA - Mexiletine - EMA/X/0000258210

Lupin Europe GmbH

Rapporteur: Fátima Ventura, PRAC Rapporteur: Eva Jirsová

Scope: Extension application to add new strengths of 62 mg and 83 mg grouped with an Extension of indication to include the symptomatic treatment of myotonia in children and adolescents (from 6 to 18 years of age) with non-dystrophic myotonic disorders for NAMUSCLA, based on final results from study MEX-NM-301 as well as population pharmacokinetic analysis of mexiletine in healthy volunteers and myotonic patients; MEX-NM-301 is an open-label, multi-centre, single arm, interventional study to describe the steady-state PK, safety, and efficacy of mexiletine in paediatric patients (6 to <18 years of age) with myotonic disorders. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet.

This application is grouped with Quality variations.

Action: For adoption

4.1.3. 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

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

No items

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

No items

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. ANZUPGO - Delgocitinib - EMA/VR/0000315280

LEO PHARMA A/S;

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Margareta Bego, PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include treatment of adolescents 12 years and older with moderate to severe chronic hand eczema (CHE) for whom topical corticosteroids are inadequate or inappropriate for ANZUPGO, based on final results from study LP0133-1426 (DELTA TEEN); this is a phase 3 pivotal clinical trial to evaluate efficacy and safety of twice-daily applications of delgocitinib cream compared with cream vehicle for a 16-week treatment period in adolescents 12-17 years of age with moderate to severe chronic hand eczema. The trial is a randomized, double-blind, vehicle-controlled study. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 1.1 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.

Action: For adoption

5.1.2. 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

5.1.3. CAPVAXIVE - Pneumococcal polysaccharide conjugate vaccine (21-valent) - EMA/VR/0000294070

Merck Sharp & Dohme B.V.;

Rapporteur: Kristina Dunder, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné

Scope: Extension of indication to include active immunization of children and adolescents 2 to less than 18 years of age for CAPVAXIVE, based on final results from study V116-013 (P013V116); this is a phase 3, randomized, double-blind study to evaluate the safety, tolerability, and immunogenicity of V116 in children and adolescents with increased risk of pneumococcal disease; As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, and 6.6 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

5.1.4. DATROWAY - Datopotamab deruxtecan - EMA/VR/0000316654

Daiichi Sankyo Europe GmbH;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include, as monotherapy, the first-line treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy for DATROWAY, based on final results from study D926PC00001 (TROPION-Breast02). This is a Phase 3, randomised, open-label, 2 arm, multicentre, international study assessing the efficacy and safety of Dato-DXd compared with investigator's choice chemotherapy in participants with locally recurrent inoperable or metastatic TNBC who are not candidates for PD-1/PD-L1 inhibitor therapy. 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 1.1 of the RMP has also been submitted. In addition, the 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

5.1.5. 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

5.1.6. FERACCRU - Ferric maltol - EMA/VR/0000268118

Norgine B.V.;

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

Scope: Extension of indication to include treatment of paediatric population (adolescents aged 12 years and above) for FERACCRU, based on results from phase 1 study ST10-01-103, phase 3 study ST10-01-305 and a supportive phase 1 study ST10-01-104. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the PI. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

Action: For adoption

5.1.7. 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 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. IBRANCE - Palbociclib - EMA/VR/0000316536

Pfizer Europe MA EEIG;

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

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

Action: For adoption

5.1.11. IMCIVREE - Setmelanotide - EMA/VR/0000288021

Rhythm Pharmaceuticals Netherlands B.V.;

Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Miroslava Gocova

Scope: Extension of indication to include reduction in hunger (or hyperphagia) and BMI (Body Mass Index)/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

5.1.12. IMFINZI - Durvalumab - EMA/VR/0000289524

AstraZeneca AB;

Rapporteur: Thalia Marie Estrup Blicher, 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

5.1.13. ISTURISA - Osilodrostat - EMA/VR/0000315678

Recordati Rare Diseases;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include the treatment of endogenous Cushing’s syndrome in adolescents and children aged 6 years and older for ISTURISA, based on results from study CLCI699C2203; this is a Phase II, multicentre, open-label, non-comparative study to evaluate the pharmacokinetics, pharmacodynamics, and tolerability of osilodrostat in children and adolescent patients with Cushing’s disease. As a consequence, sections 4.1,

4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted.

Action: For adoption

5.1.14. JAYPIRCA - Pirtobrutinib - EMA/VR/0000316267

Eli Lilly Nederland B.V.;

Rapporteur: Alexandre Moreau, Co-Rapporteur: Edward Laane, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

5.1.15. KEYTRUDA - Pembrolizumab - EMA/VR/0000316576

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: A grouped application consisting of:

C.I.6. Extension of indication for KEYTRUDA for subcutaneous use to include treatment of melanoma for adolescents aged 12 years and older based on an extrapolation approach from adults to adolescents using pharmacokinetics modelling and simulation. 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 52.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to implement some minor editorial and formatting changes in the PI.

C.I.6. Extension of indication for KEYTRUDA for subcutaneous use to include treatment of classical Hodgkin lymphoma for adolescents aged 12 years and older based on an extrapolation approach from adults to adolescents using pharmacokinetics modelling and simulation. 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.

Action: For adoption

5.1.16. MAVIRET - Glecaprevir / Pibrentasvir - EMA/VR/0000316551

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Nicolas Beix, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension of indication to include treatment of Acute HCV for MAVIRET, based on final results from study M20-350; this is a multicentre, single-arm prospective study to evaluate safety and efficacy of GLE/PIB 8-week treatment in adults and adolescents with acute hepatitis C virus (HCV) infection. 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 10.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.17. MEKINIST/TAFINLAR - Trametinib/Dabrafenib – WS - EMA/VR/0000271728

Novartis Europharm Limited;

Rapporteur: Filip Josephson, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of unresectable or metastatic melanoma with a BRAF V600 mutation and adjuvant treatment of Stage III melanoma with a BRAF V600 mutation for adolescents aged 12 years and older for TAFINLAR and MEKINIST, based on an extrapolation report using a modelling and simulation approach to demonstrate PK, PD and efficacy of dabrafenib and trametinib in adolescent patients. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. RMP versions 13.0 and 21.0 for Tafinlar and Mekinist, respectively, have also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and to update list of local representatives in the Package Leaflet.

Action: For adoption

5.1.18. MEKINIST/TAFINLAR – Trametinib/ Dabrafenib – WS - EMA/VR/0000278305

Novartis Europharm Limited;

Rapporteur: Peter Mol, PRAC Rapporteur: David Olsen

Scope: Extension of indication to include treatment of differentiated thyroid cancer (DTC) for TAFINLAR and MEKINIST based on primary analysis from pivotal study CDRB436J12301. This is a randomized, double-blind, placebo-controlled Phase 3 study to evaluate the efficacy and safety of dabrafenib plus trametinib in previously treated patients with locally advanced or metastatic, radio-active iodine refractory BRAF V600E mutation-positive differentiated thyroid 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 14.0 and Version 22.0 of the RMPs for Tafinlar and Mekinist, respectively, have also been submitted.

Action: For adoption

5.1.19. MENQUADFI - Meningococcal Group A, C, W and Y conjugate vaccine - EMA/VR/0000281377

Sanofi Winthrop Industrie;

Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Jean-Michel Dogné

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

Action: For adoption

5.1.20. MRESVIA - Respiratory syncytial virus mRNA vaccine (nucleoside modified) - EMA/VR/0000312911

Moderna Biotech Spain S.L.;

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

Scope: Extension of indication to include active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in all adults 18 years of age and older for mRESVIA, based on results from Study mRNA-1345-P101, Study mRNA-1345-P301, Study mRNA-1345-P303 Part A, and Study mRNA-1345-P302 Part A and Part B. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP has also been submitted.

Action: For adoption

5.1.21. OPZELURA - Ruxolitinib - EMA/VR/0000313318

Incyte Biosciences Distribution B.V.;

Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adam Przybylkowski

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

Action: For adoption

5.1.22. 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

See 2.3

5.1.23. 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

5.1.24. SOGROYA - Somapacitan - EMA/VR/0000264734

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Dennis Lex

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

dose-finding trial evaluating the effect and safety of once-weekly treatment of somapacitan compared to daily Norditropin in children with short stature born small for gestational age with no catch-up growth by 2 years of age or older. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

See 2.3

5.1.25. 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

5.1.26. STELARA - Ustekinumab - EMA/VR/0000316205

Janssen Cilag International;

Rapporteur: Ruth Kieran, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of ulcerative colitis in paediatric patients from the age of 2 years and older for STELARA, based on results from study CNTO1275PUC3001; this 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 Ulcerative Colitis. 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 32.2 of the RMP has also been submitted.

Action: For adoption

5.1.27. TRIMBOW - Beclometasone / Formoterol / Glycopyrronium bromide - EMA/VR/0000315173

Chiesi Farmaceutici S.p.A.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include treatment of asthma for TRIMBOW 88/5/9 mcg DPI, based on existing data from the development of Trimbow 87/5/9 mcg pressurised metered dose inhaler in COPD and Asthma, Trimbow 172/5/9 mcg pressurised metered dose inhaler in Asthma and Trimbow 88/5/9 mcg Dry powder inhaler in COPD, as well as on new data coming from the PK 2 study (CLI-05993BB1-01) and on the interim results of the ongoing PASS (TRIBE) study in COPD. As a consequence, sections 4.1, 4.2, 4.4, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 11.1 of the RMP has also been submitted.

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. AQUIPTA – Atogepant - EMA/VR/0000315259

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Janet Koenig

Scope: Update on the procedure.

Update section 5.1 of the SmPC based on the primary analysis of results from TEMPLE study M22-061. This is a randomized, double-blind, parallel-group, active controlled trial with open-label safety extension to evaluate the Tolerability, Safety, and Efficacy of Atogepant versus Topiramate, in subjects requiring preventive treatment of migraine.

Action: For information

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

6.1.1. Human serum albumin - EMEA/H/D/006862

application to visible air leaks on the visceral pleura after standard visceral pleural closure techniques during resection of lung parenchyma

Scope: List of questions

Action: For adoption

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/006933

detection of the programmed death ligand 1 (PD-L1) by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissues

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

No items

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. RINVOQ – Upadacitinib - EMA/VR/0000322413

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder

Scope: Update of sections 4.2, 4.8, and 5.1 of the SmPC in order to update the posology recommendations for Giant Cell Arthritis and to update efficacy information based on final results from study M16-852 listed as a category 3 study in the RMP; this is a Phase 3, Multicentre, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Upadacitinib in Subjects with Giant Cell Arteritis.

Action: For adoption

9.1.2. MVABEA - Ebola vaccine (MVA-BN-Filo [recombinant]) – EMEA/H/C/005343

Janssen-Cilag International N.V.; indicated for active immunization for prevention of disease caused by Ebola virus

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Nicolas Beix

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.3. Zabdeno - Ebola vaccine (Ad26.ZEBOV-GP [recombinant]) – EMEA/H/C/005337

Janssen-Cilag International N.V.; is indicated for active immunization for prevention of disease caused by Ebola virus (Zaire ebolavirus species)

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Nicolas Beix

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.4. Zoledronic acid medac - Zoledronic acid – EMEA/H/C/002359

medac Gesellschaft fur klinische Spezialpraparate mbH; prevention of skeletal related events and treatment of tumour-induced hypercalcaemia (TIH)

Rapporteur: Alar Irs

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.5. Optruma - Raloxifene hydrochloride – EMEA/H/C/000185

Eli Lilly Nederland B.V.; treatment and prevention of osteoporosis

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Karin Janssen van Doorn

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.6. Ocrevus - Ocrelizumab - EMA/VR/0000313041

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher

Scope: PRAC advice to CHMP;

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

9.1.7. ROCTAVIAN - Valoctocogene roxaparvovec – ATMP - EMEA/H/C/005830

BioMarin International Limited; treatment of severe haemophilia A (congenital factor VIII deficiency)

Rapporteur: Violaine Closson Carella, CHMP Co-ordinators: Nicolas Beix and Daniela Philadelphy

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. TAVNEOS – Avacopan - EMA/REF/0000325221

Vifor Fresenius Medical Care Renal Pharma France

Referral Rapporteur: Kristina Dunder, Referral Co- Rapporteur: Outi Mäki-Ikola

Scope: List of outstanding issues/Opinion

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 Tavneos. The review was prompted by new information which raised questions regarding the data integrity of the ADVOCATE study, the pivotal trial supporting the marketing authorisation. The agency/CHMP was requested to assess the above concerns and whether there is an impact on the benefit-risk balance of Tavneos in its authorised indication. In addition, the EC requested the Agency/CHMP to give its opinion as to whether temporary measures are necessary to ensure the safe and effective use of this medicinal product.

List of questions adopted on 29.01.2026

10.1.2. Tecovirimat SIGA - Tecovirimat - EMA/REF/0000287477

Siga Technologies Netherlands B.V.

Referral Rapporteur: Finbarr Leacy, Referral Co- Rapporteur: Vilma Petrikaite

Scope: Opinion

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.

List of outstanding issues adopted on 26.02.2026, 13.11.2025. List of questions adopted on 24.07.2025

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

10.6.1. Ipidacrine-containing medicinal products – various - EMA/REF/0000271842

AS Grindeks, MD-Pharm S.R.O., Olpha AS

Referral Rapporteur: Ruth Kieran, Referral Co- Rapporteur: Elita Poplavska

Scope: List of outstanding issues/Opinion

Action: For adoption

Procedure triggered by Ireland requesting CHMP a review of ipidacrine-containing medicinal products. This was prompted by concerns regarding the efficacy data supporting the authorized indications of ipidacrine-containing medicinal products, as well as potential issues related with the effects of ipidacrine on hepatic safety.

List of outstanding issues adopted on 16.10.2026

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

March 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

Scope: CHMP 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. The Committee agreed that a co-opted member should be appointed in the following area of expertise: biostatistics and clinical trial methodology.

A call for nomination of a co-opted member was launched following the January 2026 plenary.

Nomination(s) received

Action: For election

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 March 2026

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at March 2026 PDCO

Action: For information

Agenda of the PDCO meeting held on 24-27 March 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 09-12 March 2026. Table of conclusions

Action: For information

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

14.3.3. BWP Vaccines Quality Operational Expert Group (BV-OEG) Influenza meeting

Chair: Koen Brusselmans

Scope: EU Strain selection for the Influenza Vaccines for the Season 2026/2027: Draft Report from the BV-OEG to the BWP

Action: For adoption

Scope: Draft EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2026/2027

Action: For adoption

14.3.4. Election of Vice-chair - Immune and Inflammatory Diseases Working Party (IIWP)

Following the call for nominations launched in January 2026, CHMP will elect the Vice-Chair from the candidate(s) who submitted nominations

Nomination(s) received

Action: For election

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

14.9.1. EMA Communication updates

Action: For information

14.9.2. CHMP assessment report (AR) template – Revamp Project - report on the completed pilot

Update on the pilot. Final report and recommendations.

Action: For discussion

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

15.1.2. ETF Update

Action: For information

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)*

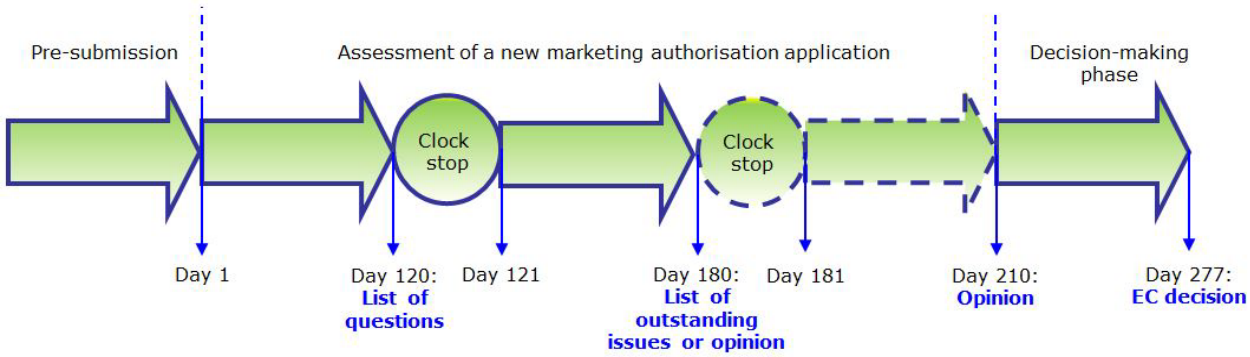
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

23 March 2026
EMA/CHMP/49470/2026

Annex to 23-26 March 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 March 2026: **For adoption**

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

Final Outcome of Rapporteurship allocation for March 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 09-12 March 2026 PRAC:

Signal of new aspect of the known risk of aseptic meningitis

IXCHIQ (CAP) – Chikungunya vaccine (live)

Rapporteur: Christophe Focke, Co-Rapporteur: Ruth Kieran, PRAC Rapporteur: Dirk Mentzer
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

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.