



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2026
EMA/CHMP/41571/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 23-26 February 2026

Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

23 February 2026, 09:00 – 19:30, virtual meeting/room 2E

24 February 2026, 08:30 – 19:30, virtual meeting/room 2E

25 February 2026, 08:30 – 19:30, virtual meeting/room 2E

26 February 2026, 08:30 – 15:00, virtual meeting/room 2E

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 ongoing 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 February 2026. See February 2026 CHMP minutes (to be published post March 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 23-26 February 2026

1.3. Adoption of the minutes

CHMP minutes for 10-13 November 2025 meeting

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

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 25 February 2026 at 09:00

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

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

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

Scope: Oral explanation

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

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

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

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

Scope: Oral explanation

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

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.

2.1.4. Remibrutinib - EMEA/H/C/006313

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

Scope: Oral explanation

Action: Oral explanation to be held on 25 February 2026 at 14:00

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

2.1.5. Mavorixafor - Orphan - EMEA/H/C/006496

X4 Pharmaceuticals (Austria) GmbH; Treatment of WHIM syndrome

Scope: Oral explanation

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

List of Outstanding Issues adopted on 11.12.2025. List of Questions adopted on 22.05.2025.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Olumiant – Baricitinib - EMA/X/0000257923

Eli Lilly Nederland B.V.

Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski

Scope: Oral explanation

Action: Oral explanation to be held on 25 February 2026 at 11:00

See 4.1

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

Janssen Cilag International

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

Scope: Oral explanation

Action: Oral explanation to be held on 24 February 2026 at 14:00

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Acoziborole - Article 58 - EMEA/H/W/006686

Accelerated assessment

treatment of first and second-stage human African Trypanosomiases due to *Trypanosoma brucei gambiense*

Scope: Opinion

Action: For adoption

List of Questions adopted on 09.12.2025.

3.1.2. Insulin lispro - EMEA/H/C/006158

treatment of diabetes mellitus

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 11.12.2025. List of Questions adopted on 25.01.2024.

3.1.3. 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: Opinion

Action: For adoption

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

3.1.4. Insulin aspart - EMEA/H/C/006187

treatment of diabetes mellitus from 1 year of age

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 11.12.2025. List of Questions adopted on 25.01.2024.

3.1.5. Iloperidone - EMEA/H/C/006561

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

Scope: Opinion

Action: For adoption

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

3.1.6. Etanercept - EMEA/H/C/006738

Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis, paediatric plaque psoriasis

Scope: Opinion

Action: For adoption

List of Questions adopted on 16.10.2025.

3.1.7. Influenza and COVID-19 vaccine - EMEA/H/C/006472

immunisation for the prevention of diseases associated with seasonal influenza viruses and SARS-CoV-2

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 11.12.2025. List of Questions adopted on 22.05.2025.

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

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

Scope: Opinion

Action: For adoption

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

3.1.9. [Levodopa / Carbidopa - EMEA/H/C/006429](#)

treatment of motor fluctuations in patients with Parkinson's disease

Scope: Opinion

Action: For adoption

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

3.1.10. [Paltusotine - Orphan - EMEA/H/C/006636](#)

Crinetics Pharmaceuticals Europe GmbH; Maintenance treatment in adult patients with acromegaly

Scope: Opinion

Action: For adoption

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

3.1.11. [Pertuzumab - EMEA/H/C/006583](#)

treatment of breast cancer in adults

Scope: Opinion

Action: For adoption

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

3.1.12. [Tocilizumab - EMEA/H/C/006416](#)

treatment of rheumatoid arthritis and other immunological conditions

Scope: Opinion

Action: For adoption

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

3.1.13. [Teriparatide - EMEA/H/C/006688](#)

treatment of osteoporosis

Scope: Opinion

Action: For adoption

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

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

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 18.09.2025.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 13.11.2025.

3.2.3. Nerandomilast - EMEA/H/C/006405

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 18.09.2025.

3.2.4. Colchicine - EMEA/H/C/006653

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 18.09.2025.

3.2.5. Lerodalcibep - EMEA/H/C/006694

is indicated in adults with primary hypercholesterolaemia (heterozygous familial (HeFH) and

non-familial) or mixed dyslipidaemia as an adjunct to diet.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 18.09.2025.

3.2.6. Palbociclib - EMEA/H/C/006624

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 18.09.2025.

3.2.7. Plozasiran - Orphan - EMEA/H/C/006579

Arrowhead Pharmaceuticals Ireland Limited; treatment of familial chylomicronaemia syndrome (FCS).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.06.2025.

3.2.8. Ranibizumab - EMEA/H/C/006634

treatment of adults with neovascular (wet) age-related macular degeneration (AMD), visual impairment and other retinopathies

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 16.10.2025.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 18.09.2025.

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

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

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 12.09.2025.

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

3.3.1. Denecimig - EMEA/H/C/006344

prophylaxis of bleeding episodes in patients with haemophilia A

Scope: List of questions

Action: For adoption

3.3.2. Relacorilant - Orphan - EMEA/H/C/006731

Corcept Therapeutics Netherlands B.V.; treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer

Scope: List of questions

Action: For adoption

3.3.3. Povorcitinib - EMEA/H/C/006727

treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults

Scope: List of questions

Action: For adoption

3.3.4. Riociguat - EMEA/H/C/006838

treatment of Chronic thromboembolic pulmonary hypertension (CTEPH) in adults and treatment of Pulmonary arterial hypertension (PAH) in adults and children from 6 years of age

Scope: List of questions

Action: For adoption

3.3.5. Ruxolitinib - EMEA/H/C/006791

treatment of myelofibrosis (MF) in adults, treatment of polycythaemia vera (PV) in adults and treatment of Graft versus host disease (GvHD) in adults and children

Scope: List of questions

Action: For adoption

3.3.6. RABIES VIRUS (INACTIVATED) STRAIN WISTAR (PM/WI 38-1503-3M) - Article 28 – OPEN - EMEA/H/C/006602

pre-exposure and post-exposure prophylaxis against rabies in all age groups

Scope: List of questions

Action: For adoption

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

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

Scope: List of questions

Action: For adoption

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

3.4.1. Azacitidine - EMEA/H/C/006695

Treatment of myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) and acute myeloid leukaemia (AML)

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.

3.5. 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: Adoption of timetable; questions to the SAG-N

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 opinion. Revised dataset submitted by the applicant

Action: For adoption

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

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Sasanlimab - EMEA/H/C/006641

treatment of bladder cancer

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Questions adopted on 18.09.2025.

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

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

4.1.1. Camcevi – Leuprorelin - EMA/X/0000258054

Accord Healthcare S.L.U.

Rapporteur: Johanna Lähteenvujo, PRAC Rapporteur: Amelia Cupelli

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

Action: For adoption

4.1.2. Jorveza – Budesonide - EMA/X/0000257468

Dr. Falk Pharma GmbH

Rapporteur: Janet Koenig, PRAC Rapporteur: Zane Neikena

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

Action: For adoption

4.1.3. Olumiant – Baricitinib - EMA/X/0000257923

Eli Lilly Nederland B.V.

Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski

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

Action: For adoption

See 2.3

4.1.4. OPDIVO – Nivolumab - EMA/X/0000304427

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Dirk Mentzer

Scope: Extension application to add a new strength of 300 mg solution for injection.

Action: For adoption

4.1.5. Scemblix – Asciminib - EMA/X/0000256688

Novartis Europharm Limited

Rapporteur: Martin Mengel, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Eva Jirsová

Scope: Extension application to introduce a new strength (100 mg film-coated tablets) grouped with a type II variation (C.I.6.a) to add a new indication (treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) harbouring the T315I mutation), based on final results from study CABL001X2101 and study CABL001A2004. Study CABL001X2101 is a Phase I, multicentre, open-label, dose escalation FIH study to define the MTD/RDEs, to characterize safety and tolerability, and to assess the PK profile and preliminary evidence of efficacy of asciminib given as single agent or in combination with either nilotinib or imatinib or dasatinib in patients with Ph+ CML or Ph+ ALL. Study CABL001A2004 assessed the real-world effectiveness of asciminib and treatment patterns in patients with Chronic Myeloid Leukaemia with T315I mutation. As a consequence, sections 1, 2, 3, 4, 5, 6 and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

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

Janssen Cilag International

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

Scope: Extension application to add a new strength of 675 mg/150 mg/ 20mg/ 10 mg film-coated tablets grouped with an Extension of indication (C.I.6) to include treatment of human immunodeficiency virus type 1 (HIV 1) infection in paediatric patients (aged 6 years and older with body weight at least 25 kg) for SYMTUZA, based on the 24-week interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicentre, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and

Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1, 6.3, 6.4, 6.5 and 8 of the SmPC are updated. The Annex II, Labelling and Package Leaflet are updated accordingly. Version 9.1 of the RMP has also been submitted. Furthermore, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet.

Action: For adoption

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. 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

4.2.2. Orladeyo – Berotralstat - EMA/X/0000268892

Biocryst Ireland Limited

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

Scope: Extension application to introduce a new pharmaceutical form associated with new strengths (78 mg, 96 mg, 108 and 132 film-coated granules). The new presentations are indicated to include treatment for paediatric patients aged 2 to less than 12 years. The extension application is grouped with a type II clinical variation (C.I.4). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2.1 of the RMP has also been submitted.

Action: For adoption

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

Janssen Cilag International

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli

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

Action: For adoption

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

4.3.1. Iclusig – Ponatinib - EMA/X/0000296489

Incyte Biosciences Distribution B.V.

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

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength (5 mg hard capsule) grouped with an Extension of Indication to include treatment of paediatric patients aged 6 years and older with chronic phase chronic myeloid leukaemia (CP-CML) who are resistant or intolerant to at least one tyrosine kinase inhibitor for ICLUSIG, based on interim results from study INCB 84344-102 and a final results from early-terminated study Ponatinib-1501; the first is an ongoing open-label, single-arm, Phase 1/2 study evaluating the safety and efficacy of ponatinib MONOTHERAPY for the treatment of R/R leukaemia, lymphomas, or solid tumours in paediatric participants. The second is a Phase 1/2, single-arm, open-label, multicentre study designed to evaluate the safety, tolerability, PK, and efficacy of ponatinib when administered IN COMBINATION WITH multiagent CHEMOTHERAPY in paediatric patients with Ph+ ALL, Ph+ MPAL, or Ph-like ALL who had a relapse, were resistant or intolerant to at least 1 prior BCR-ABL1 TKI therapy, or had the T315I mutation. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1 and 6.5 of the SmPC are updated. Package Leaflet is updated accordingly. The RMP version 23.4 has also been submitted.

Action: For adoption

4.3.2. RINVOQ – Upadacitinib - EMA/X/0000304823

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength and change of pharmacokinetics (1 mg/ml oral solution) grouped with an extension of indication (C.I.6.a) to include the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older based on clinical data and results from clinical phase 1 study (study M15-340). As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC have been updated. The Package Leaflet has been updated accordingly. Version 17 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II.

Action: For adoption

4.3.3. Wegovy – Semaglutide - EMA/X/0000304416

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: Extension application to add a new strength of 7.2 mg in a single dose pen-injector.

Action: For adoption

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

No items.

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

No items.

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

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

5.1.1. AQUIPTA – Atogepant - EMA/VR/0000310717

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Janet Koenig, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Rugile Pilviniene

Scope: A grouped application comprised of 1 Type II Variation and 3 Quality Type I Variations, as follows:

Type II (C.I.6): Extension of indication to include acute treatment of migraine with or without aura in adults, based on interim results from study M24-305; this is a 24-week, global, Phase 3, multicentre, randomized, double blind, placebo-controlled, multiple-migraine attack study with an open label period to evaluate the safety and efficacy of atogepant in adult participants for the acute treatment of migraine (ECLIPSE). As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.2 of the RMP has also been submitted.

Action: For adoption

5.1.2. 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

5.1.3. Fasenra – Benralizumab - EMA/VR/0000288520

AstraZeneca AB

Rapporteur: Paulo Paixão, PRAC Rapporteur: David Olsen

Scope: Extension of indication to include treatment of adults and adolescents with hypereosinophilic syndrome (HES) for FASENRA, based on interim results from study D3254C00001 (NATRON); this is a multicentre, randomised, double-blind, parallel-group, placebo-controlled, 24-week phase III study with an open-label extension to evaluate the efficacy and safety of benralizumab in patients with HES; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial and administrative updates to the PI and to update the list of local representatives in the Package Leaflet. Furthermore, section 6.5 of the SmPC was updated.

Action: For adoption

5.1.4. 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

5.1.5. HETRONIFLY – Serplulimab - EMA/VR/0000290021

Accord Healthcare S.L.U.

Rapporteur: Eva Skovlund, PRAC Rapporteur: Jan Neuhauser

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

Action: For adoption

5.1.6. 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

5.1.7. Keytruda – Pembrolizumab - EMA/VR/0000293815

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include in combination with paclitaxel, with or without bevacizumab, the treatment of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma in adults whose tumours express PD-L1 with a CPS \geq 1 and who have received one or two prior systemic treatment regimens for KEYTRUDA, based on interim results from study PB96V01MK3475 (KEYNOTE-B96); this is a Phase 3, randomized, double-blind study of pembrolizumab in combination with paclitaxel with or without bevacizumab for the treatment of platinum-resistant recurrent ovarian cancer. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 50.1 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

5.1.8. [Keytruda – Pembrolizumab - EMA/VR/0000312515](#)

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment of adults with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin containing chemotherapy for KEYTRUDA, based on interim results from study KEYNOTE-905, an open label, randomised, interventional phase 3 study. As consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 51.1 of the RMP has also been submitted.

Action: For adoption

5.1.9. [Mounjaro – Tirzepatide - EMA/VR/0000310637](#)

Eli Lilly Nederland B.V.

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, or stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease for MOUNJARO, based on final results from study I8F-MC-GPGN (SURPASS-CVOT). SURPASS-CVOT was a Phase 3, event-driven, multicentre, international, randomized, double-blind, active-comparator, parallel-group study to assess the effect of tirzepatide versus dulaglutide on major adverse cardiovascular events in participants with type 2 diabetes. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI.

Action: For adoption

5.1.10. 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

5.1.11. Ocrevus – Ocrelizumab - EMA/VR/0000309389

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include treatment of paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (RRMS) for OCREVUS, based on primary analysis results from the pivotal phase III study (WN42086/Operetta 2) and primary and updated results from a supportive phase II study (WA39085/Operetta 1). Operetta 1 is an open-label, parallel-group, dose-finding Phase II study to determine the dosing regimen of ocrelizumab to be further investigated in Operetta 2, and Operetta 2 is a Phase III, randomized, double-blind, double-dummy, parallel-group, multicentre, non-inferiority study to evaluate the efficacy and safety of intravenous ocrelizumab in comparison with fingolimod. As a consequence, sections 2, 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 15.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce updates to other sections of the SmPC and PL as per previous procedures linguistic review comments (sodium, pH and osmolality), updates to comply with the Excipient Guideline (polysorbates), changes to the list of local representatives in the Package Leaflet, as well as editorial and clarification changes to the PI.

Action: For adoption

5.1.12. Olumiant – Baricitinib - EMA/VR/0000288098

Eli Lilly Nederland B.V.

Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of adolescent patients (12 to less than 18 years) with severe alopecia areata for OLUMIANT, based on results from study I4V-MC-JAIO; this is a Phase 3, double-blind, randomised, placebo-controlled trial to evaluate the efficacy, safety, and pharmacokinetics of baricitinib in children from 6 years to less than 18 years of age with alopecia areata. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 26.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and to update the list of local

representatives in the Package Leaflet.

Action: For adoption

5.1.13. [Padcev – Enfortumab vedotin - EMA/VR/0000312495](#)

Astellas Pharma Europe B.V.

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include PADCEV, in combination with pembrolizumab, for use as neoadjuvant treatment and continued as adjuvant treatment following radical cystectomy, is indicated for the treatment of adult patients with muscle-invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy, based on interim results from study EV-303/KN-905; this is a randomized phase 3 study evaluating cystectomy with perioperative pembrolizumab and cystectomy with perioperative enfortumab, vedotin and pembrolizumab versus cystectomy alone in participants who are cisplatin-ineligible or decline cisplatin with muscle-invasive bladder cancer. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 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, and to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

5.1.14. [RINVOQ – Upadacitinib - EMA/VR/0000312506](#)

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include the treatment of severe alopecia areata (AA) in adult and adolescents 12 years and older for RINVOQ, based on interim results from 2 pivotal, Phase 3 studies (M23-716 Study 1 and Study 2); those are randomized, double blind, placebo-controlled, multi-centre studies of Upadacitinib evaluating the efficacy and safety of Upadacitinib 15 mg QD and 30 mg QD versus placebo for the treatment of severe AA in subjects who are at least 12 years of age. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Annex II are updated in accordance. Version 18.0 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.15. [Stelara – Ustekinumab - EMA/VR/0000290099](#)

Janssen Cilag International

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

Scope: Extension of indication to include treatment of moderately to severely active Crohn's disease in paediatric patients from the age of 2 years and older, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy, for STELARA, based on final results from the Phase 3 open-label CNTO1275CRD3004 study and

the supportive results from the Phase 1 PK CNTO1275CRD1001 study. Study CNTO1275CRD3004 is a Phase 3 study of the efficacy, safety, and pharmacokinetics of ustekinumab as open-label intravenous induction treatment followed by randomized double-blind subcutaneous ustekinumab maintenance in paediatric participants 2 to <18 years of age with moderately to severely active Crohn's disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are being updated. The Package Leaflet is updated accordingly. The RMP version 32.1 has also been submitted. In addition, the MAH took the opportunity to introduce editorial, formatting and administrative changes to the PI, bringing it in line with the latest QRD template. In addition, the MAH updated the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.16. [Tepkinly – Epcoritamab - EMA/VR/0000311043](#)

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Peter Mol, PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Extension of indication to include in combination with rituximab and lenalidomide treatment of patients with relapsed/refractory follicular lymphoma (FL) for Tepkinly, based on interim results from study M20-638; this is a Phase 3, open-label study to evaluate safety and efficacy of epcoritamab in combination with rituximab and lenalidomide (R2) compared to R2 in subjects with relapsed or refractory follicular lymphoma (EPCORE FL-1). 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 3.2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.17. [Trodelvy – Sacituzumab govitecan - EMA/VR/0000312649](#)

Gilead Sciences Ireland Unlimited Company

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

Scope: Extension of indication for treatment of adult patients with PD-L1-negative metastatic triple-negative breast cancer or PD-L1-positive metastatic triple-negative breast cancer previously treated with an anti-PD-(L)1 agent in the curative setting for Trodelvy, based on results from study GS-US-592-6238 (ASCENT-03), which is a phase 3 study of sacituzumab govitecan (IMMU-132) versus treatment of physician's choice (TPC) in Patients With Previously Untreated, Locally Advanced, Inoperable or Metastatic Triple-Negative Breast Cancer Whose Tumours Do Not Express PD-L1 or in Patients Previously Treated With Anti-PD-(L)1 Agents in the Early Setting Whose Tumours Do Express PD-L1. As a consequence, sections 4.1, 4.4, 4.5, 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

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006931

qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene in non-small cell lung cancer (NSCLC) patients; defined EGFR mutations are detected using DNA isolated from formalin-fixed paraffin-embedded tumour tissue (FFPET) or circulating cell-free tumour DNA (cfDNA)

Scope: Opinion

Action: For adoption

6.3.2. 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: Opinion

Action: For adoption

6.3.3. 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

6.3.4. 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

6.4. **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. Rebisufligene etisparvovec – H0005536

for the treatment of children from birth to less than 18 years of age with mucopolysaccharidosis type IIIA (MPS IIIA, Sanfilippo syndrome type A)

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. Flud Tetra – Influenza vaccine (surface antigen, inactivated, adjuvanted) – EMEA/H/C/004993

Seqirus Netherlands B.V.; active immunisation against influenza in the elderly (65 years of age and older)

Rapporteur: Sol Ruiz, Co-Rapporteur: Patrick Vrijlandt

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.2. Flucelvax Tetra – influenza vaccine (surface antigen, inactivated, prepared in cell cultures) – EMEA/H/C/004814

Seqirus Netherlands B.V.; prophylaxis of influenza in adults and children from 6 months of age

Rapporteur: Sol Ruiz, Co-Rapporteur: Nicholas Beix

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.3. Xevudy – Sotrovimab – EMEA/H/C/005676

Glaxosmithkline Trading; treatment of coronavirus disease 2019 (COVID-19)

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Ruth Kieran

Scope: Withdrawal of marketing authorisation

Action: For information

10. Referral procedures

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

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

Siga Technologies Netherlands B.V.

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

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 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

10.6.1. Sodium oxybate syrup and oral solution for alcohol dependence - EMA/REF/0000278933

Various

Referral Rapporteur: John Joseph Borg, Referral Co- Rapporteur: Nicolas Beix

Scope: List of outstanding issues / Opinion

Action: For adoption

Procedure triggered by France (ANSM) requesting CHMP to issue an opinion on the benefit-risk balance of sodium oxybate-containing syrup and oral solution for the treatment of alcohol dependence in authorised products and pending marketing authorisation application (s) due to concerns about efficacy and the risks of abuse and misuse.

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

February 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 adoption

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by Proxy

No items

14.1.2. CHMP membership

No items

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for February 2026.

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at February 2026 PDCO

Action: For information

Agenda of the PDCO meeting held on 24-27 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. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 17-18 February 2026.

Action: For adoption

14.3.3. 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 February 2026.

Action: For information

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

14.3.4. SAWP composition

Chair: Paolo Foggi, Vice-Chairs: Pierre Demolis and Ewa Balkowiec Iskra

SAWP composition for re-nomination.

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

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

Action: For discussion

Explanatory notes

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

Oral explanations (section 2)

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

Initial applications (section 3)

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

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

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



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

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

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

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

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

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

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

Ancillary medicinal substances in medical devices (section 6)

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

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

(section 3.5)

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

Re-examination procedures (section 5.3)

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 Pharmacovigilance 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/



23 February 2026
EMA/CHMP/21453/2026

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

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

Final Outcome of Rapporteurship allocation for
February 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	None
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PRAC recommendations on signals adopted at
the PRAC meeting held on 09-12 February 2026
PRAC

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.