26 February 2026
EMA/CHMP/140189/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 23-26 February 2026

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

Disclaimers

Some of the information contained in this set of minutes 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, these minutes are a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes 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

The Chairperson opened the meeting by welcoming all participants. The meeting was held remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared. Restrictions applicable to this meeting are captured in the list of participants included in the minutes.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure. All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified. The members of the EEA-EFTA States agreed with the recommendation of the CHMP, unless otherwise specified.

1.2. Adoption of agenda

CHMP agenda for 23-26 February 2026.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 10-13 November 2025 meeting.

The CHMP adopted the minutes from the 10-13 November 2025 meeting.

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

The CHMP adopted the minutes from the 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.

The CHMP agreed that an oral explanation was not needed at this time.

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

Participation of patient representative

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

An oral explanation was held on 24 February 2026. The presentation by the applicant focused on the clinical data in support of the application.

See 3.2.

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.

The CHMP agreed that an oral explanation was not needed at this time.

2.1.4. Rhapsido - Remibrutinib - EMEA/H/C/006313

Novartis Europharm Limited; 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

New active substance (Article 8(3) of Directive No 2001/83/EC)

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

The CHMP agreed that an oral explanation was not needed at this time.

See 3.1.

2.1.5. Xolremdi - 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

New active substance (Article 8(3) of Directive No 2001/83/EC)

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

The CHMP agreed that an oral explanation was not needed at this time.

See 3.1.

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

The CHMP agreed that an oral explanation was not needed at this time.

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

The CHMP agreed that an oral explanation was not needed at this time.

See 4.2

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

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

Accelerated assessment

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

Scope: Opinion

Action: For adoption

Article 58 of Regulation (EC) No 726/2004

List of Questions adopted on 09.12.2025.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted the scientific opinion for Acoziborole Winthrop in accordance with Article 58 of Regulation (EC) No. 726/2004.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 25 February 2026.

The CHMP endorsed the EMA press release.

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

Gan & Lee Pharmaceuticals Europe GmbH; treatment of diabetes mellitus

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been

addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 19 February 2026.

The CHMP adopted the similarity assessment report

3.1.3. 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: Opinion

Action: For adoption

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

The Committee was reminded of the status of this application.

The Committee adopted a negative opinion by consensus, recommending the refusal of the granting of the marketing authorisation. The CHMP adopted the CHMP assessment report.

The question-and-answer document was circulated for information.

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

Gan & Lee Pharmaceuticals Europe GmbH; treatment of diabetes mellitus from 1 year of age

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 19 February 2026.

The CHMP adopted the similarity assessment report .

3.1.5. Fubelv - Etanercept - EMEA/H/C/006738

Biosimilar Collaborations Ireland Limited; 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

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

List of Questions adopted on 16.10.2025.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

3.1.6. 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: Opinion

Action: For adoption

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

The Committee was reminded of the status of this application.

The Committee adopted a negative opinion by consensus, recommending the refusal of the granting of the marketing authorisation. The CHMP adopted the CHMP assessment report.

The question-and-answer document was circulated for information.

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

Moderna Biotech Spain S.L.; immunisation for the prevention of diseases associated with seasonal influenza viruses and SARS-CoV-2

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that single-stranded, 5'-capped messenger RNAs (mRNAs) produced using a cell-free in vitro transcription from the corresponding DNA template, encoding seasonal influenza haemagglutinin (HA) glycoproteins: A/H1N1, A/H3N2, B/Victoria are new active substances, as claimed by the applicant.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 20 February 2026.

The CHMP endorsed the EMA press release.

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

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

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a conditional marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that Tovorafenib is a new active substance, as claimed by the applicant.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report
The CHMP noted the letter of recommendations dated 27 February 2026.
The CHMP endorsed the EMA press release.

3.1.9. Onerji - Levodopa / Carbidopa - EMEA/H/C/006429

Tanabe Pharma GmbH; treatment of motor fluctuations in patients with Parkinson's disease

Scope: Opinion

Action: For adoption

Known active substance (Article 8(3) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

3.1.10. Palsonify - Paltusotine - Orphan - EMEA/H/C/006636

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

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that Paltusotine is a new active substance, as claimed by the applicant.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

3.1.11. Poherdy - Pertuzumab - EMEA/H/C/006583

Organon N.V.; treatment of breast cancer in adults

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation

timetable.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

The CHMP adopted a DHPC letter and Communication Plan

3.1.12. Rhapsido - Remibrutinib - EMEA/H/C/006313

Novartis Europharm Limited; treatment of chronic spontaneous urticaria in patients with inadequate response to H1 antihistamine

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that Remibrutinib is a new active substance, as claimed by the applicant.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 20 February 2026.

See 2.1.

3.1.13. Tuyory - Tocilizumab - EMEA/H/C/006416

Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.); treatment of rheumatoid arthritis and other immunological conditions

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 24 February 2026.

3.1.14. Xolremdi - Mavorixafor - Orphan - EMEA/H/C/006496

X4 Pharmaceuticals (Austria) GmbH; Treatment of WHIM syndrome

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation under exceptional circumstances by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that Mavorixafor is a new active substance, as claimed by the applicant.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 24 February 2026.

The CHMP endorsed the EMA press release.

See 2.1.

3.1.15. Zandoriah - Teriparatide - EMEA/H/C/006688

Cinnagen Co Unipessoal Lda.; treatment of osteoporosis

Scope: Opinion

Action: For adoption

Similar biological application (Article 10(4) of Directive No 2001/83/EC)

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 18 February 2026.

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

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

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

Scope: List of outstanding issues

Action: For adoption

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

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

The CHMP adopted the list of questions to the SAG Oncology.

See 2.1.

3.2.2. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.3. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.4. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

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

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

Scope: List of outstanding issues

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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.6. 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

Third-party interventions

Action: For adoption

List of Questions adopted on 18.09.2025.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

The CHMP noted the third-party interventions.

3.2.7. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.8. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.9. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.10. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.11. 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.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

The CHMP adopted the list of questions to the AHEG.

3.2.12. 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.

The CHMP was updated on discussions at the CAT. The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee endorsed a list of outstanding issues with a specific timetable, as adopted by CAT.

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

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

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

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

3.4.1. Gadoquatrane - EMEA/H/C/006443

For contrast enhancement in magnetic resonance imaging (MRI) used for adults and paediatric patients of all ages.

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

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in December 2025.

3.4.2. 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.

The CHMP did not agree to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in December 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.

The CHMP adopted the re-examination timetable and the list of questions to the SAG Neurology.

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

New active substance (Article 8(3) of Directive No 2001/83/EC)

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

The CHMP adopted the revised opinion.

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

SHINE Europe B.V.; used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with Lutetium (177Lu) chloride

Scope: Revised opinion

Action: For adoption

Well-established use application (Article 10a of Directive No 2001/83/EC)

Opinion adopted on 29.01.2026. List of Outstanding Issues adopted on 16.10.2025. List of Questions adopted on 22.05.2025.

The CHMP adopted the revised opinion.

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.

The CHMP noted the withdrawal of the marketing authorisation application.

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 Lähteenvuo, 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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The summary of opinion was circulated for information.

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The CHMP adopted the similarity assessment report

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The summary of opinion was circulated for information.

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

The Committee discussed the issues identified in this application, relating to quality aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

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

The Committee discussed the issues identified in this application, relating to quality, clinical and data exclusivity/marketing protection aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

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

The Committee discussed the issues identified in this application, relating to quality aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

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

Janssen Cilag International

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

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

line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet.

Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues to be adopted in February 2026.

Action: For adoption

The Committee discussed the issues identified in this application, relating to quality aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in February 2026.

See 2.3

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

The Committee discussed the issues identified in this application, relating to quality and clinical aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

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

The Committee discussed the issues identified in this application, relating to quality and clinical aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions .

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

The Committee discussed the issues identified in this application, relating to clinical and RMP aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The summary of opinion was circulated for information.

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee discussed the issues identified in this application, relating to clinical and RMP aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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 ≥ 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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report .

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee discussed the issues identified in this application, relating to clinical and RMP aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The summary of opinion was circulated for information.

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The summary of opinion was circulated for information.

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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

The Committee discussed the issues identified in this application, relating to clinical aspects.

The Committee adopted a request for supplementary information with a specific timetable.

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. Cobas EGFR Mutation Test v2 - In vitro diagnostic medical device - EMEA/H/D/006931

Roche Diagnostics GmbH; 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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report.

6.3.2. FoundationOne Liquid CDx (F1LCDx-IVD) - In vitro diagnostic medical device - EMEA/H/D/006913

Foundation Medicine Inc.; 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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report.

6.3.3. Ipsogen IDH1 RGQ PCR Kit - In vitro diagnostic medical device - EMEA/H/D/006887

Qiagen GmbH; 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

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report.

6.3.4. TruSight Oncology Comprehensive HRD (DRAGEN) - In vitro diagnostic medical device - EMEA/H/D/006914

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

Scope: Opinion

Action: For adoption

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report.

6.4. Companion diagnostics – follow-up consultation

No items

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

7.1. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.2. Priority Medicines (PRIME)

Information related to priority medicines cannot be released at present time as these contain commercially confidential information

The CHMP adopted the recommendations for PRIME eligibility.

The individual outcomes are listed in the PRIME Monthly Report on the EMA website, in the PRIME homepage, under Outcome of eligibility section.

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Fluad 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

The CHMP noted the withdrawal of the marketing authorisation.

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

The CHMP noted the withdrawal of the marketing authorisation.

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

The CHMP noted the withdrawal of the marketing authorisation.

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

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.

The CHMP adopted a list of outstanding issues with a procedural timetable.

Timetable:

(Co-)rapporteurs' preliminary JAR to CHMP: 11 March 2026

Comments: 16 March 2026

(Co-)rapporteurs' updated JAR to CHMP: 19 March 2026

CHMP list of outstanding issues or CHMP opinion: March 2026 CHMP

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

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.

The CHMP adopted a list of outstanding issues with a procedural timetable.

Timetable:

(Co-)rapporteurs' preliminary JAR to CHMP: 04 June 2026

Comments: 11 June 2026

(Co-)rapporteurs' updated JAR to CHMP: 17 June 2026

CHMP list of outstanding issues or CHMP opinion: June 2026 CHMP

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

The CHMP noted the 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

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: Timetable

Action: For adoption

The CHMP adopted the timetable of the EC Request for EMA scientific opinion .

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

Emilia Mavrokordatou (CY) gave a proxy to Carla Torre (Co-opted member) for Monday 23 of February.

Aris Angelis (EL) gave a proxy to Margareta Bego Mernik (HR) for Monday 23 of February.

Jan Mueller-Berghaus (Co-opted member) gave a proxy to Janet Koenig (DE) for Thursday 26 of February.

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

The CHMP adopted the EURD list for February 2026.

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

The CHMP noted the 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

The CHMP adopted the BWP reports.

14.3.2. Name Review Group (NRG)

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

Action: For adoption

The CHMP adopted the Table of Decisions.

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. Table of conclusions.

Action: For information

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

The CHMP noted the report from the SAWP meeting and the table of conclusions.

14.3.4. SAWP composition

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

SAWP composition for re-nomination.

Action: For adoption

The CHMP adopted the SAWP composition for re-nomination.

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

The CHMP noted the information.

16. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 23-26 February 2026 CHMP meeting, which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Bruno Sepodes	Chair	Portugal	No restrictions applicable to this meeting	
Daniela Philadelphy	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No restrictions applicable to this meeting	
Gergana Lazarova	Alternate	Bulgaria	No restrictions applicable to this meeting	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Katerina Savvidou	Alternate	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member (Vice-Chair)	Finland	No interests declared	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Nicolas Beix	Alternate	France	No interests declared	
Janet Koenig	Member	Germany	No interests declared	
Martin Mengel	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
Finbarr Leacy	Member	Ireland	No interests declared	
Ruth Kieran	Alternate	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No restrictions applicable to this meeting	
Maria Grazia Evandri	Alternate	Italy	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Elita Poplavska	Member	Latvia	No restrictions applicable to this meeting	
Vilma Petrikaite	Member	Lithuania	No restrictions applicable to this meeting	
Larisa Gorobets	Alternate	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No restrictions applicable to this meeting	
Peter Mol	Member	Netherlands	No restrictions applicable to this meeting	
Patrick Vrijlandt	Alternate	Netherlands	No restrictions applicable to this meeting	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No restrictions applicable to this meeting	
Ewa Balkowiec Iskra	Member	Poland	No restrictions applicable to this meeting	
Fatima Ventura	Member	Portugal	No restrictions applicable to this meeting	
Paulo Paixão	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No restrictions applicable to this meeting	
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Kristina Nadrah	Member	Slovenia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Carolina Prieto Fernandez	Member	Spain	No interests declared	
Antonio Gomez-Outes	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No interests declared	
Carla Torre	Co-opted member	Portugal	No restrictions applicable to this meeting	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sol Ruiz	Co-opted member	Spain	No interests declared	
Jean Daniel Lelievre	Expert	France	No restrictions against giving the SAG report for Tecovirimat SIGA	
Gerardo Priotto	Expert	WHO	No interests declared	
Janne Komi	Expert	Finland	No interests declared	
Tommi Nurminen	Expert	Finland	No interests declared	
Lidija Prka	Expert	Croatia	No interests declared	
Bojana Divkovic	Expert	Austria	No interests declared	
Sabrina Jenull	Expert	Austria	No interests declared	
Michael Jirout	Expert	Austria	No interests declared	
Tobias Fellinger	Expert	Austria	No restrictions applicable to this meeting	
Melanie Ramberger	Expert	Austria	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No restrictions applicable to this meeting	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Johanna de Groot	Expert	Netherlands	No interests declared	
Nicolas Nyssen	Expert	Belgium	No interests declared	
Valerie Lescrainier	Expert	Belgium	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Marta Romano	Expert	Belgium	No restrictions applicable to this meeting	
Inne Crevecoeur	Expert	Belgium	No restrictions applicable to this meeting	
Nele Alders	Expert	Belgium	No restrictions applicable to this meeting	
Sandra Bright	Expert	Ireland	No interests declared	
Rosemary (Maher) Kane	Expert	Ireland	No participation in discussion, final deliberations and voting on:	2.1.4. EMEA/H/C/006313 3.2.9. EMEA/H/C/006539 3.2.10. EMEA/H/C/006498 4.1.5. EMA/X/0000256688
Olive Smyth	Expert	Ireland	No interests declared	
Catherine Byrne	Expert	Ireland	No interests declared	
Richard Carroll	Expert	Ireland	No interests declared	
Ailise Carleton	Expert	Ireland	No interests declared	
Liam McDonough	Expert	Ireland	No interests declared	
Agnieszka Przybyszewska	Expert	Ireland	No restrictions applicable to this meeting	
Declan Byrnes	Expert	Ireland	No interests declared	
Benita Cullen	Expert	Ireland	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Juan Ignacio Bedoya Ponte	Expert	Spain	No restrictions applicable to this meeting	
Ana Moreno Oliver	Expert	Spain	No interests declared	
Teresa Llacer Delicado	Expert	Spain	No interests declared	
Hilke Zander	Expert	Germany	No interests declared	
Leonardo Kelava	Expert	Croatia	No restrictions applicable to this meeting	
Susanna Hausmann	Expert	Germany	No interests declared	
Anne Isabel Roth	Expert	Germany	No interests declared	
Sofia Kapanadze	Expert	Germany	No interests declared	
Nina Hessvik	Expert	Norway	No interests declared	
Panagiota Tsantili	Expert	Greece	No interests declared	
Mário Miguel Coelho da Silva Rosa	Expert	Portugal	No restrictions applicable to this meeting	
Tiago Machado	Expert	Portugal	No restrictions applicable to this meeting	
Céline Jumeau	Expert	France	No interests declared	
Solène Maitenaz	Expert	France	No interests declared	
Yanna Chevalme	Expert	France	No interests declared	
Jean-Noel Talbot	Expert	France	No interests declared	
Cristina Migali	Expert	Italy	No interests declared	
Simona Russo	Expert	Italy	No interests declared	
Hanneke van der Woude	Expert	Netherlands	No interests declared	
Loes den Otter	Expert	Netherlands	No restrictions applicable to this meeting	
Peter van de Ven	Expert	Netherlands	No restrictions applicable to this meeting	
Bastian Hornung	Expert	Netherlands	No restrictions applicable to this meeting	
Cornelia Huigen	Expert	Netherlands	No restrictions applicable to this meeting	
Emmely de Vries	Expert	Netherlands	No interests declared	
Gerlienke Geurts-Voerman	Expert	Netherlands	No interests declared	
Jens Stegers	Expert	Netherlands	No interests declared	
Nieske Rodenhuis	Expert	Netherlands	No interests declared	
Susanna Uiterwaal	Expert	Netherlands	No interests declared	
Casparus (Jasper) Nooten	Expert	Netherlands	No interests declared	
Rou-Afza Gunput	Expert	Netherlands	No interests declared	
Concepcion Payares Herrera	Expert	Spain	No participation in discussion, final deliberations and voting on:	2.1.3. EMEA/H/C/005927 4.1.3. EMA/X/0000257923 5.1.9. EMA/VR/0000310637 5.1.12.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				EMA/VR/0000288098
Paolo Foggi	Expert	Italy	No interests declared	
Rosalía Ruano Camps	Expert	Spain	No interests declared	
Gabriella Passacquale	Expert	Italy	No interests declared	
Viktoria Starokozhko	Expert	Netherlands	No restrictions applicable to this meeting	
Clemens Mittmann	Expert	Germany	No interests declared	
Sonja Beken	Expert	Belgium	No interests declared	
Carin Bergquist	Expert	Sweden	No interests declared	
Silvijus Abramavicius	Expert	Lithuania	No restrictions applicable to this meeting	
Uta Buckpesch-Heberer	Expert	Germany	No interests declared	
Michal Pirozynski	Expert	Malta	No restrictions applicable to this meeting	
Rowena McMullan	OPEN Expert	TGA	No restrictions applicable to this meeting	
Catalina Carrasco Pozo	OPEN Expert	TGA	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff.				

Experts' declared interests were evaluated against the topics or activities they participated in.

Experts from international organisations or regulatory authorities in third countries cannot participate in the adoption of any procedural decision, scientific opinion or recommendation by the Committee at any step of the procedure.

Explanatory notes

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

Oral explanations *(section 2)*

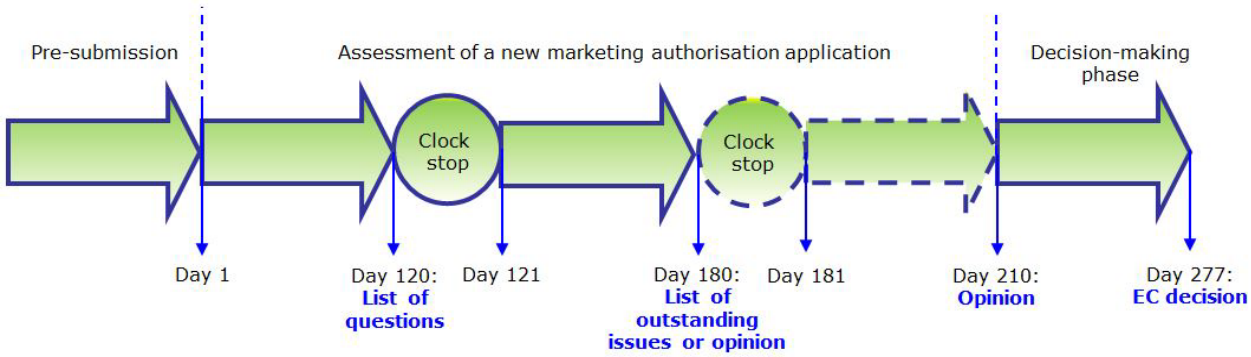
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

Ancillary medicinal substances in medical devices *(section 6)*

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

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 *(section 3.5)*

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

Re-examination procedures *(section5.3)*

This section lists applications for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP.

Withdrawal of application *(section 3.7)*

Applicants may decide to withdraw applications at any stage during the assessment and a CHMP opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Procedure under article 83(1) of regulation (EC) 726/2004 (compassionate use) *(section 7)*

Compassionate use is a way of making available to patients with an unmet medical need a promising medicine which has not yet been authorised (licensed) for their condition. Upon request, the CHMP provides recommendations to all EU Member States on how to administer, distribute and use certain medicines for compassionate use.

Pre-submission issues *(section 8)*

In some cases the CHMP may discuss a medicine before a formal application for marketing authorisation is submitted. These cases generally refer to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation. In case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

Post-authorisation issues *(section 9)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 10)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

This section lists issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines. Feedback is provided by the PRAC. This section also refers to the early notification system, a system used to notify the European regulatory network on proposed EMA communication on safety of medicines.

Inspections Issues *(section 12)*

This section lists inspections that are undertaken for some medicinal products. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Innovation task force *(section 13)*

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes from the last ITF meeting as well as any related issue that requires discussion with the CHMP are listed in this section of the agenda. Further information on the ITF can be found here.

Scientific advice working party (SAWP) *(section 14.3.1)*

This section refers to the monthly report from the CHMP's Scientific Advice Working Party (SAWP) on scientific advice given to companies during the development of medicines. Further general information on SAWP can be found here.

Satellite groups / other committees *(section 14.2)*

This section refers to the reports from groups and committees making decisions relating to human medicines: the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), the Committee for Orphan Medicinal Products (COMP), the Committee for Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmamacovigilance Risk Assessment Committee (PRAC).

Invented name issues *(section 14.3)*

This section list issues related to invented names proposed by applicants for new medicines. The CHMP has established the Name Review Group (NRG) to perform reviews of the invented names. The group's main role is to consider whether the proposed names could create a public-health concern or potential safety risk. Further information can be found here.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2026
EMA/CHMP/49159/2026

Annex to 23-26 February 2026 CHMP Minutes

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**	Adopted

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

Final Outcome of Rapporteurship allocation for February 2026: **For adoption**	Adopted

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 February 2026	None

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.