19 June 2025
EMA/CHMP/221169/2025

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 16-19 June 2025

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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

CHMP agenda for 16-19 June 2025

The CHMP adopted the agenda for the 16-19 June 2025 meeting.

1.3. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 10 June 2025.

The CHMP adopted the minutes from the PROM meeting held on 10 June 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. L-Acetylleucine - Orphan - EMEA/H/C/006327

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

Scope: Oral explanation

Action: Oral explanation to be held on 17 June 2025 at 16:00

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 17.10.2024.

An oral explanation was held on 17 June 2025. The presentation by the applicant focused on the quality, non-clinical and clinical data in support of the application.

2.2. Re-examination procedure oral explanations

2.2.1. Helicobacter Test INFAI - 13C-Urea - EMEA/H/C/000140/II/0028

Infai GmbH

Rapporteur: Christian Gartner

Scope: Oral explanation

Action: Oral explanation to be held on 17 June 2025 at 11:00

Opinion adopted on 30.01.2025.

An oral explanation was held on 17 June 2025. The presentation by the applicant focused on the clinical data in support of the application.

See 9.1

2.3. Post-authorisation procedure oral explanations

2.3.1. CABOMETYX - Cabozantinib - EMEA/H/C/004163/II/0040

Ipsen Pharma

Rapporteur: Ingrid Wang, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Bianca Mulder

Scope: Oral explanation

Action: Oral explanation to be held on 17 June 2025 at 14:00

Request for Supplementary Information adopted on 27.03.2025, 12.12.2024.

An oral explanation was held on 17 June 2025. The presentation by the applicant focused on the clinical data in support of the application.

See 5.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. AFIVEG - Aflibercept - EMEA/H/C/006761

STADA Arzneimittel AG; treatment of age-related macular degeneration (AMD) and visual impairment

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025.

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 18 June 2025.

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

Teva GmbH; treatment of tardive dyskinesia

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 25.07.2024.

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.

Furthermore, the CHMP considered that Deutetrabenazine is not 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.

3.1.3. Eiyzey - Aflibercept - EMEA/H/C/006745

ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.; treatment of age-related macular

degeneration (AMD) and visual impairment

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.03.2025.

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 16 June 2025.

3.1.4. Emtricitabine/Rilpivirine/Tenofovir Alafenamide Viatris - Emtricitabine / Rilpivirine / Tenofovir alafenamide - EMEA/H/C/006491

Viatris Limited; treatment of HIV-1

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025. List of Questions adopted on 14.11.2024.

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 restricted medical prescription.

The summary of opinion was circulated for information.

3.1.5. Imreplys - Sargramostim - EMEA/H/C/006411

Partner Therapeutics Limited; treatment for exposure to myelosuppressive doses of radiation

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.03.2025, 12.12.2024. List of Questions adopted on 23.07.2024.

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 under exceptional circumstances 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 16 June 2025.

3.1.6. MYNZEPLIAflibercept - EMEA/H/C/006438

Advanz Pharma Limited; treatment of age-related macular degeneration (AMD) and visual impairment

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025. List of Questions adopted on 12.12.2024.

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 restricted medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 18 June 2025.

3.1.7. Nintedanib Viatris - Nintedanib - EMEA/H/C/006486

Viatris Limited; treatment of Idiopathic Pulmonary Fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) and systemic sclerosis associated interstitial lung disease (SSc-ILD)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025. List of Questions adopted on 14.11.2024.

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 restricted medical prescription.

The summary of opinion was circulated for information.

3.1.8. Ogsiveo - Nirogacestat - Orphan - EMEA/H/C/006071

Springworks Therapeutics Ireland Limited; treatment of desmoid tumours

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 27.06.2024.

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.

Furthermore, the CHMP considered that Nirogacestat 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.

3.1.9. Rezdiffra - Resmetirom - EMEA/H/C/006220

Madrigal Pharmaceuticals EU Limited; for the treatment of adults with nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.03.2025. List of Questions adopted on 27.06.2024.

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 conditional marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that Resmetirom 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.

The CHMP noted the letter of recommendations dated 19 June 2025.

The EMA public health communication was circulated for information.

3.1.10. Usymro - Ustekinumab - EMEA/H/C/006467

Elc Group s.r.o.; treatment of plaque psoriasis, arthritis psoriatic and Crohn’s Disease

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025. List of Questions adopted on 14.11.2024.

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 restricted medical prescription.

The summary of opinion was circulated for information.

3.1.11. Vgenfli - Aflibercept - EMEA/H/C/006192

Zaklady Farmaceutyczne Polpharma S.A.; treatment of age-related macular degeneration (AMD) and visual impairment

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.03.2025. List of Questions adopted on 25.07.2024.

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 restricted medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 16 June 2025.

3.1.12. Vivlipeg - Pegfilgrastim - EMEA/H/C/006739

Biosimilar Collaborations Ireland Limited; treatment of neutropenia

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 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.

3.1.13. Zemcelpro - Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded - PRIME - Orphan - ATMP - EMEA/H/C/005772

Cordex Biologics International Limited; treatment of adult patients with haematological malignancies

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 21.03.2025. List of Questions adopted on 11.10.2024.

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

Based on the draft opinion prepared by the CAT, 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 Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded 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 13 June 2025.

The EMA public health communication was circulated for information.

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

3.2.1. Denosumab - EMEA/H/C/006722

prevention of skeletal related events in adults with advanced malignancies involving bone

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2025.

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.

3.2.2. Mozafancogene autotemcel - PRIME - Orphan - ATMP - EMEA/H/C/005537

Rocket Pharmaceuticals B.V.; treatment of paediatric patients with Fanconi Anaemia Type A

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 19.07.2024.

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 the list of outstanding issues with a specific timetable, as adopted by CAT.

The CHMP adopted the list of questions to the AHEG.

3.2.3. Golimumab - EMEA/H/C/006560

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis and ulcerative colitis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.02.2025.

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. Hydrocortisone - PUMA - EMEA/H/C/005201

prevention of bronchopulmonary dysplasia in preterm infants born less than 28 weeks of gestation.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2024.

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. Nipocalimab - EMEA/H/C/006379

treatment of generalised Myasthenia Gravis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2025.

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.

3.2.6. Denosumab - EMEA/H/C/006490

treatment of osteoporosis and bone loss in postmenopausal women and in men

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2025.

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.

3.2.7. Denosumab - EMEA/H/C/006734

treatment of osteoporosis and bone loss

Scope: List of outstanding issues

Action: For adoption

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. Denosumab - EMEA/H/C/006238

treatment of osteoporosis and bone loss

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2025.

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. Belumosudil - Orphan - EMEA/H/C/006421

Sanofi Winthrop Industrie; Treatment of chronic graft-versushost disease (cGVHD) after failure of at least two prior lines of systemic therapy.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2025.

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. Denosumab - EMEA/H/C/006552

prevention of skeletal related events in adults and treatment of adults and skeletally mature adolescents with giant cell tumour of bone

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2025.

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.

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

3.3.1. Tolebrutinib - EMEA/H/C/006386

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

3.3.2. Estetrol - EMEA/H/C/006213

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

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. Midazolam - EMEA/H/C/005657

conscious sedation before and during diagnostic or therapeutic procedures with or without local anaesthesia and premedication before induction of anaesthesia

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

treatment of motor fluctuations in patients with Parkinson’s disease

Scope: List of questions; Request by the applicant for an extension to the clock stop to respond to the list of questions to be adopted in June 2025.

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.

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 June 2025.

3.3.5. Teriparatide - EMEA/H/C/006688

treatment of osteoporosis

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

Accelerated assessment

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

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. Midazolam - EMEA/H/C/005658

treatment of prolonged, acute, convulsive seizures in adults, adolescents, children and toddlers (from 2 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.

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

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

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

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

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

Action: For information

List of Questions adopted on 25.04.2025.

The CHMP noted the timetable adopted by CAT.

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

3.4.2. Delandistrogene moxeparvovec - Orphan - ATMP - EMEA/H/C/005293

Roche Registration GmbH; treatment of ambulatory patients aged 3 to 7 years old with Duchenne muscular dystrophy

Scope: Update on the procedure

Action: For information

List of Outstanding Issues adopted on 16.04.2025. List of Questions adopted on 11.10.2024.

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 the list of outstanding issues with a specific timetable, as adopted by CAT.

3.4.3. Autologous cartilage-derived articular chondrocytes, in-vitro expanded - ATMP - EMEA/H/C/004594

repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV

Scope: Update on the procedure

Action: For information

List of Outstanding Issues adopted on 21.03.2025. List of Questions adopted on 19.04.2024.

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 the list of outstanding issues with a specific timetable, as adopted by CAT.

3.4.4. Blarcamesine - EMEA/H/C/006475

treatment of Alzheimer's disease and dementia

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

Action: For adoption

List of Questions adopted on 25.04.2025.

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 April 2025.

3.4.5. Eflornithine - Orphan - EMEA/H/C/006067

Norgine B.V.; treatment of high-risk neuroblastoma responsive to prior multiagent, multimodality therapy

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

Action: For adoption

List of Questions adopted on 25.04.2025.

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 April 2025.

3.4.6. Aficamten - EMEA/H/C/006228

treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) in adult patients

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

Action: For adoption

List of Questions adopted on 25.04.2025.

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 April 2025.

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

3.5.1. Atropine sulfate FGK - Atropine - PUMA - EMEA/H/C/006385

FGK Representative Service GmbH; treatment of myopia in children aged 3 years and older

Scope: Request for re-examination, appointment of re-examination rapporteurs

Action: For adoption

Opinion adopted on 22.05.2025. List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 19.09.2024.

The CHMP appointed a re-examination rapporteur and a re-examination co-rapporteur.

3.5.2. Aplidin - plitidepsin - Orphan - EMEA/H/C/004354

Pharma Mar, S.A.; treatment of multiple myeloma

Scope: Update on the procedure

Restart the 2018 re-examination procedure relating to the initial marketing authorisation application for Aplidin following the adoption of Commission Implementing Decision C(2024) 4469 final of 28 June 2024 which revoked Commission Implementing Decision C(2018) 4831 final of 17 July 2018 refusing marketing authorisation for 'Aplidin – plitidepsin'. That decision was revoked following the judgment of 14 March 2024 in D & A Pharma v Commission and EMA, C 291/22 P.

Action: For information

The CHMP noted the update on the procedure.

3.5.3. Kisunla - Donanemab - EMEA/H/C/006024

Eli Lilly Nederland B.V.; to slow disease progression in adult patients with Alzheimer's disease (AD).

Scope: Adoption of timetable

Action: For adoption

Opinion adopted on 27.03.2025. List of Outstanding Issues adopted on 12.12.2024, 25.04.2024. List of Questions adopted on 14.12.2023.

The CHMP adopted the timetable.

3.6. Initial applications in the decision-making phase

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

4.1.1. Brukinsa - Zanubrutinib - EMEA/H/C/004978/X/0023

Beone Medicines Ireland Limited

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (160 mg film-coated tablets)."

Action: For adoption

List of Outstanding Issues adopted on 25.04.2025. List of Questions adopted on 14.11.2024.

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

4.1.2. Pyzchiva - Ustekinumab - EMEA/H/C/006183/X/0006

Samsung Bioepis NL B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new strength (45 mg solution for injection in a vial) for partial use in paediatric patients."

Action: For adoption

List of Outstanding Issues adopted on 22.05.2025. List of Questions adopted on 27.02.2025.

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.

4.1.3. Spevigo - Spesolimab - EMEA/H/C/005874/X/0011

Boehringer Ingelheim International GmbH

Rapporteur: Kristina Dunder, PRAC Rapporteur: Zoubida Amimour

Scope: "Extension application to add a new strength of 300 mg (150 mg/ml) for solution for

injection in a pre-filled syringe.
The RMP (version 3.0) is updated in accordance.
In addition, the applicant has updated SmPC (Annex I) and Package Leaflet (Annex IIIB) for both 450 mg concentrate for solution for infusion and 150 mg and 300 mg solution for injection in line with the new excipient guideline."

Action: For adoption

List of Questions adopted on 27.02.2025.

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.

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

No items

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

4.3.1. EURneffy – Epinephrine - EMA/X/0000248440

Alk-Abello A/S

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

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

Action: For adoption

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.

4.3.2. Kerendia – Finerenone - EMA/X/0000248026

Bayer AG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Bianca Mulder

Scope: Extension application to introduce a new strength 40 mg for film-coated tablets, packed in blisters of 14 tablets, 28 tablets, 98 tablets and 100 x 1 tablets (unit dose) grouped with a type II variations C.I.6: Extension of indication to include the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in adults for KERENDIA, based on final results from the phase 3 study FINEARTS-HF (20103);

this is a randomized, double-blind, placebo-controlled phase 3 study evaluating the efficacy and safety of finerenone on morbidity and mortality in participants with symptomatic heart failure with left ventricular ejection fraction (LVEF) ≥40%.; Type II variation C.I.13: Submission of the final report from non-clinical study T105281-7, R-14405 - Juvenile toxicology study in rats; Type IB variation C.I.z: Minor correction of numbers in the currently approved SmPC due to a previously communicated GCP violation affecting the FIDELIO-DKD and FIGARO-DKD trials.

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

Action: For adoption

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. Keytruda – Pembrolizumab - EMA/X/0000248795

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Extension application to introduce a new pharmaceutical form (solution for injection) associated with two new strengths (790 mg and 395 mg) and new route of administration (subcutaneous use).

The RMP (version 49.1) is updated in accordance.

Action: For adoption

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

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

4.3.4. Omlyclo – Omalizumab - EMA/X/0000248400

Celltrion Healthcare Hungary Kft.

Rapporteur: Finbarr Leacy

Scope: Extension application to introduce a new strength of 300 mg for Omlyclo solution for injection. The new strength is indicated for the treatment of asthma (adults, adolescents and children), chronic rhinosinusitis with nasal polyps (adults) and chronic spontaneous urticaria (adult and adolescents).

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 questions.

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

Janssen Cilag International

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

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

Action: For adoption

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 questions.

4.3.6. Tremfya – Guselkumab - EMA/X/0000248626

Janssen Cilag International

Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Gabriele Maurer

Scope: Extension application to add a new strength of 45 mg (100 mg/ml) in a pre-filled syringe (glass) in pre-filled pen (VarioJect) grouped with an extension of indication (C.I.6.a) to include treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years who are candidates for systemic therapy based on results from study CNTO1959PSO3011. This is a Phase 3, Multicentre, Randomized, Placebo- and Active Comparator-Controlled Study Evaluating the Efficacy, Safety, and Pharmacokinetics of Subcutaneously Administered Guselkumab for the Treatment of Chronic Plaque Psoriasis in Paediatric Participants (≥6 To <18 Years of Age). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 10.3 of the RMP 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.

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

4.4.1. Shingrix - Herpes zoster vaccine (recombinant, adjuvanted) - EMA/X/0000243671

GlaxoSmithKline Biologicals

Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik

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

Action: For adoption

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 May 2025.

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. Benlysta - Belimumab - EMEA/H/C/002015/II/0133

GlaxoSmithKline (Ireland) Limited

Rapporteur: Kristina Dunder, PRAC Rapporteur: Karin Bolin

Scope: "Extension of indication to include treatment of paediatric patients from 5 years of age with active, autoantibody-positive systemic lupus erythematosus (SLE) for BENLYSTA, based on final results from study 200908; this is a worldwide population pharmacokinetic analysis of subcutaneous administered belimumab plus standard therapy to paediatric patients aged 5-17 years with systematic lupus erythematous (SLE), which was aimed to describe the pharmacokinetic (PK) analysis of belimumab to support an appropriate weight-based dosing regimen for subcutaneous administration in paediatric patients aged 5-17 years with SLE. 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 46.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 27.03.2025, 17.10.2024.

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.

5.1.2. BIMERVAX - COVID-19 vaccine (recombinant, adjuvanted) - EMA/VR/0000257408

Hipra Human Health S.L.

Rapporteur: Beata Maria Jakline Ullrich, Co-Rapporteur: Daniela Philadelphy

Scope: Extension of indication to include the use of BIMERVAX in adolescents aged 12 years and above, based on interim results from the ongoing study HIPRA-HH-3. HIPRA-HH-3 is an open-label, multi-centre, non-inferiority study to assess the safety and immunogenicity of BIMERVAX as heterologous booster for the prevention of COVID-19 in adolescents from 12 years of age to less than 18 years of age. 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. 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.

5.1.3. CABOMETYX - Cabozantinib - EMEA/H/C/004163/II/0040

Ipsen Pharma

Rapporteur: Ingrid Wang, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include the treatment of adult patients with progressive extra-pancreatic (epNET) and pancreatic (pNET) neuroendocrine tumours after prior systemic therapy for CABOMETYX based on final results from study CABINET (A021602). This is a multicentre, two-arm, randomised, double-blind, placebo-controlled phase 3 study investigating cabozantinib versus placebo in patients with advanced Neuroendocrine Tumours (NET). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP has also been submitted.

Action: For adoption

Request for Supplementary Information adopted on 27.03.2025, 12.12.2024.

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

See 2.3

5.1.4. Dapivirine Vaginal Ring 25 mg - Dapivirine - EMEA/H/W/002168/II/0027

International Partnership for Microbicides Belgium AISBL

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include reducing the risk of HIV-1 infection via vaginal intercourse in HIV-uninfected women 16 years and older for Dapivirine Vaginal Ring 25 mg, based on final results from study MTN-034 (REACH) listed as a category 3 study in the RMP; this is a Phase 2a crossover trial evaluating the safety of and adherence to a vaginal matrix ring containing dapivirine and oral emtricitabine/tenofovir disoproxil fumarate in an adolescent and young adult female population. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 1.5 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

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.

5.1.5. Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0077

Janssen-Cilag International N.V.

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include daratumumab for the treatment of adult patients with smouldering multiple myeloma (SMM) at high risk of developing multiple myeloma based on results from studies 54767414SMM3001 (AQUILA) and 54767414SMM2001 (CENTAURUS). SMM3001 (AQUILA) is a Phase 3 Randomized, Multicentre Study of Subcutaneous Daratumumab Versus Active Monitoring in Subjects with High-risk Smouldering Multiple Myeloma. SMM2001 (CENTAURUS) is a Randomized Phase 2 Trial to Evaluate Three Daratumumab Dose Schedules in Smouldering Multiple Myeloma.
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 11.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the PI in accordance with the latest EMA excipients guideline."

Action: For adoption

Request for Supplementary Information adopted on 22.05.2025, 27.02.2025.

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.

5.1.6. Dupixent – Dupilumab - EMA/VR/0000257461

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 in adults and adolescents 12 years and older, whose disease is inadequately controlled by H1 antihistamines and who are naive to anti-IgE therapy for CSU for DUPIXENT, based on final results from 2 studies: EFC16461 (CUPID) study A and study C; both of them were phase 3, randomized, double-blind, placebo-controlled, multi-centre, parallel-group study of dupilumab in patients with CSU who remain symptomatic despite the use of H1 antihistamine treatment in patients naïve to omalizumab. 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 13.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial 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. Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0092

Janssen-Cilag International N.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension of indication to include IMBRUVICA in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone (R-CHOP) for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are eligible for autologous stem cell transplantation (ASCT), based on results from study MCL3003. This is a randomized, 3-arm, parallel-group, open-label, international, multicenter Phase 3 study. The purpose of Study MCL3003 is to compare 3 alternating courses of R CHOP/R-DHAP followed by ASCT (control Arm A), versus the combination with ibrutinib in induction and maintenance (experimental Arm A+I), or the experimental arm without ASCT (experimental Arm I) in participants with previously untreated MCL who are eligible for ASCT. Consequently, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Version 23.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.04.2025.

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

Advanced Accelerator Applications

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of unresectable or metastatic, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adolescents aged 12 years and older for LUTATHERA based on primary analysis results from study CAAA601A32201 (also referred to as NETTER-P) as well as results from modelling and simulation analysis of PK and dosimetry data of Lutathera in adolescents. NETTER-P study is a Phase II, multicentre open-label study which evaluated the safety and dosimetry of Lutathera in adolescent patients with somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) and pheochromocytoma and paragangliomas (PPGLs). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 11 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 27.03.2025.

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

The Committee adopted a 2nd request for supplementary information with a specific timetable.

5.1.9. MINJUVI – Tafasitamab - EMA/VR/0000255975

Incyte Biosciences Distribution B.V.

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

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

part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

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. NUBEQA - Darolutamide - EMEA/H/C/004790/II/0024

Bayer AG

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include in combination with androgen deprivation therapy (ADT) the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) for NUBEQA, based on final results from study 21140 (ARANOTE); this is a randomized, double-blind, placebo-controlled Phase 3 study of darolutamide to demonstrate the superiority of darolutamide in addition to ADT over placebo plus ADT in patients with mHSPC. 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 5.1 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 update the Package Leaflet to more patient friendly wording based on patient council feedback."

Action: For adoption

Request for Supplementary Information adopted on 22.05.2025, 30.01.2025.

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

The Committee adopted a positive opinion by majority (19 out of 31 votes) together with the CHMP assessment report and translation timetable.

The divergent position (Bruno Delafont, Jan Mueller-Berghaus, Blanka Hirschlerova, Emilia Mavrokordatou, Tomas Radimersky, Thalia Marie Estrup Blicher, Alexandre Moreau, Janet Koenig, Hrefna Gudmundsdottir, Peter Mol, Frantisek Drafi, Kristina Nadrah and Aris Angelis) was appended to the opinion.

The summary of opinion was circulated for information.

5.1.11. Nucala – Mepolizumab - EMA/VR/0000257645

GlaxoSmithKline Trading Services Limited

Rapporteur: Finbarr Leacy, Co-Rapporteur: Petr Vrbata, PRAC Rapporteur: Gabriele Maurer

Scope: Extension of indication for NUCALA to include treatment of Chronic Obstructive Pulmonary Disease (COPD) based on final results from study 208657 (MATINEE). This is a randomized, double-blind, parallel-group, placebo-controlled study of mepolizumab 100 mg SC as add-on treatment in participants with COPD experiencing frequent exacerbations and characterized by eosinophil levels. 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 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, to bring the PI in line with the latest QRD

template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI.

Action: For adoption

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. Revolade - Eltrombopag - EMEA/H/C/001110/II/0077

Novartis Europharm Limited

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update pharmacokinetics, based on the ETB115E2201 (E2201) study primary analysis results; this is a paediatric phase II, open-label, uncontrolled, intra-patient dose escalation study to characterise the pharmacokinetics after oral administration of eltrombopag in paediatric patients with refractory, relapsed severe aplastic anaemia or recurrent aplastic anaemia. The Package Leaflet is updated in accordance. Version 56.2 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

Request for Supplementary Information adopted on 25.04.2025, 12.12.2024.

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 question-and-answer document was circulated for information.

The CHMP noted the letter of recommendation dated 17 June 2025.

5.1.13. SARCLISA - Isatuximab - EMEA/H/C/004977/II/0035

Sanofi Winthrop Industrie

Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau

Scope: "Extension of indication to include, in combination with bortezomib, lenalidomide and dexamethasone, the induction treatment of adult patients with newly diagnosed multiple myeloma (NDMM) who are eligible for autologous stem cell transplant (ASCT) for SARCLISA, based on the results from study IIT15403 (GMMG-HD7); this is a randomized phase III study designed to assess the efficacy and safety of Sarclisa for the induction and maintenance treatment of NDMM. 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 accordingly. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 27.03.2025.

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 noted the letter of recommendations dated 19 June 2025.

The CHMP adopted the similarity assessment report.

5.1.14. Uplizna - Inebilizumab - EMEA/H/C/005818/II/0012

Amgen Europe B.V.

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include treatment of adult patients with Immunoglobulin G4-Related Disease (IgG4-RD) for UPLIZNA, based on primary analysis results from study MITIGATE (VIB0551.P3.S2) for all subjects from the completed 52-week randomised-controlled period. This is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adult subjects with IgG4-RD. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to bring it in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 27.02.2025.

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

The Committee adopted a 2nd request for supplementary information with a specific timetable.

5.1.15. Uplizna - Inebilizumab - EMA/VR/0000257358

Amgen Europe B.V.

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Amelia Cupelli

Scope: A grouped application consisting of:

C.I.6 (Extension of indication): Extension of indication to include add-on to standard therapy for the treatment of adult patients with generalised myasthenia gravis (gMG) for Uplizna, based on primary analysis results from Study MINT (VIB0551.P3.S1); this is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adults subjects with myasthenia gravis. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1, 5.2, and 7 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity

to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

A.6: Update of the ATC code of inebilizumab to L04AG10 in line with the 2024 ATC INDEX.

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

6.1.1. Human serum albumin - EMEA/H/D/006611

use in Assisted Reproductive Technologies (ART)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.01.2025.

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.

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006723

to determine HER2 gene status by enumeration of the ratio of the HER2 gene to

Chromosome 17 by light microscopy

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted a list of questions with a specific timetable.

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006724

semi-quantitative detection of HER2 antigen by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin-embedded breast carcinoma, gastric carcinoma, and biliary tract cancer

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted a list of questions with a specific timetable.

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. MIN-102 - H0006693

Treatment of male adrenoleukodystrophy patients 2 years and older with brain lesions to delay progression of cerebral ALD (cALD).

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

The CHMP did not agree to the request for accelerated assessment and adopted the briefing

note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

8.1.2. FBT-002 – H0006746

Corrective measure in case of clinical signs of ricin intoxication in addition to symptomatic treatment, or alone as ricin post-exposure prophylaxis.

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

The CHMP agreed to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

8.1.3. Trilaciclib – H0006709

indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients in small cell lung cancer (SCLC)

Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

The CHMP did not agree to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

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. Helicobacter Test INFAI - 13C-Urea - EMEA/H/C/000140/II/0028

Infai GmbH

Scope: "Update of sections 4.2, 4.3 and 5.1 of the SmPC in order to modify administration instructions and to add a new contraindication based on final results from study HPT30/J/17; this is a single-group, observer-blind, multi-centre study to quantify the sensitivity and specificity of the 13C-UBT using the new test meal for Hp in patients with dyspepsia and GERD taking PPI. The Package Leaflet is updated accordingly. In addition,

the MAH took the opportunity to update section 6.6 of the SmPC."

Action: For adoption

Opinion adopted on 30.01.2025.

The Committee adopted a negative opinion by majority recommending the refusal of the variation to the terms of the marketing authorisation. The CHMP assessment report was adopted.

The divergent position was appended to the opinion.

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

See 2.2

9.1.2. Sixmo – Buprenorphine – EMEA/H/C/004743

L. Molteni & C. dei Fratelli Alitti Societa di Esercizio S.p.A.; Substitution treatment for opioid drug dependence

Rapporteur: Finbarr Leacy, Co-Rapporteur: Petr Vrbata

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of marketing authorisation.

9.1.3. Trixeo Aerosphere - Formoterol / Glycopyrronium bromide / Budesonide - EMA/R/0000245136

AstraZeneca AB

Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra

Scope: Renewal of marketing authorisation for unlimited validity

Action: For adoption

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

Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.

9.1.4. Xarelto – Rivaroxaban - EMEA/H/C/000944/II/0113

Bayer AG; treatment of venous thromboembolism (VTE) and prevention of VTE recurrence

Rapporteur: Kristina Dunder, Co-Rapporteur: Janet Koenig

Scope: Update of section 4.8 of the SmPC in order to add ´splenic rupture´ to the list of adverse drug reactions (ADRs) with frequency 'very rare' based on the data from the clinical trials, post-marketing data sources and literature; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity introduce editorial updates as agreed with QRD group.

Withdrawal of Type II variation application

Action: For information

Request for Supplementary Information adopted on 13.02.2025.

The CHMP noted the withdrawal of Type II variation application.

9.1.5. Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0044

AstraZeneca AB

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

Scope: "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2025, 19.09.2024, 21.03.2024.

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.

9.1.6. Xofluza - Baloxavir marboxil - EMA/VR/0000246160

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher

Scope: Update of sections 4.8, and 5.1 of the SmPC in order to update clinical efficacy and safety information based on final results from study MV40618 (Centerstone); this is a phase 3b, multicentre, randomized, double-blind, placebo-controlled, clinical efficacy study of baloxavir marboxil for the reduction of direct transmission of influenza from otherwise healthy patients to household contacts. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and introduce editorial changes in the PI.

Action: For adoption

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

The Committee adopted a 2nd request for supplementary information with a specific timetable.

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

Chiesi Farmaceutici S.p.A.,

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

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

The Committee adopted a 2nd request for supplementary information with a specific timetable.

9.1.8. BroPair Spiromax - Salmeterol/Fluticasone propionate - EMEA/H/C/005591

Teva B.V.; treatment of asthma;

Rapporteur: John Joseph Borg, Co-Rapporteur: Ewa Balkowiec Iskra

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of marketing authorisation.

10. Referral procedures

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

No items

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. Azithromycin containing medicinal products for systemic use – various – EMEA/H/A-31/1532

MAH various (NAPs only)

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Antonio Gómez Outes

Scope: Update on the procedure; revised Opinion

Action: For adoption

Need to re-evaluate the benefit-risk ratio of the approved indications considering the current scientific knowledge, the increasing resistance rate, the consumption data suggesting overuse and the different indications in the EU Member States. Furthermore, the appropriate dose and duration of administration for both oral and intravenous formulations need to be discussed as well as the adequacy of safety relevant information, information on pregnancy and breastfeeding and pharmacological properties.
The German National Competent Authority triggered a referral under Article 31 of Directive 2001/83 based on interest of the Union, requesting an opinion to CHMP on the benefit-risk of azithromycin-containing products and whether marketing authorisations of azithromycin-containing products for systemic use should be maintained, varied, suspended, or revoked.

Opinion adopted on 22.05.2025. List of outstanding issues adopted on 27.02.2025, 17.10.2024, 25.04.2024. List of Questions adopted on 09.11.2023.

The CHMP adopted a revised opinion.

10.6.2. Sodium oxybate syrup and oral solution used in alcohol dependence - EMA/REF/0000278933

MAHs: various

Scope: Rapporteur appointment, List of questions (LoQ), timetable

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 appointed John-Joseph Borg as a referral rapporteur and Jean Michel Race as a referral Co-Rapporteur.

The CHMP adopted a list of questions with a procedural timetable.

CHMP List of questions: 19 June 2025
Submission of responses: 18 August 2025
Re-start of the procedure: 08 September 2025
Rapporteur/co-rapporteur assessment reports: 23 September 2025
Comments: 30 September 2025
Updated Rapporteur/co-rapporteur assessment reports: 06 October 2025
CHMP list of outstanding issues or CHMP opinion: October 2025 CHMP

The CHMP endorsed the EMA start of procedure communication.

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

June 2025 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

Information related to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to contain commercially confidential information.

13.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by Proxy

No items

14.1.2. CHMP co-opted membership

Election of CHMP co-opted member in light of the expiry of mandate of co-opted member Sol Ruiz on 21.07.2025.

Agreed areas of expertise: Quality of biologicals

Nomination(s) received

Action: For election

The CHMP re-elected Sol Ruiz as CHMP co-opted member on Quality of biologicals.

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 June 2025.

Action: For adoption

The CHMP adopted the EURD list for June 2025.

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 in June 2025 PDCO.

Action: For information

Agenda of the PDCO meeting held on 17-20 June 2025.

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 11-12 June 2025.

Action: For adoption

The CHMP adopted the Table of Decisions.

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 02-05 June 2025. Table of conclusions.

Action: For information

Scientific advice letters

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

The CHMP noted the table of conclusions.

14.3.4. Election of Infectious Diseases Working Party vice-chair

The position of vice-chair of the IDWP is currently available.

Action: For election

Nomination(s) received

Due to the lack of nominations received, the elections were postponed and the deadline of the call for Infectious Diseases Working Party vice-chair was extended.

14.3.5. CVSWP Response to the CHMP request

Action: For discussion

The CHMP noted the CVSWP Response to the CHMP request.

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

14.8.1. Update of the Business Pipeline report for the human scientific committees

Business Pipeline Report - Forecast for Q2-2025

Action: For information

The CHMP noted the update of the Business Pipeline Report - Forecast for Q2-2025.

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.

15.1.2. ICH E20 Draft Guideline on Adaptive Designs for Clinical Trials – Step 2b

The ICH E20 Expert Working Group has completed a draft guideline that provides guidance on confirmatory clinical trials with an adaptive design 2 intended to evaluate a treatment for a given medical condition within the context of its overall 3 development program. The

document is presented for adoption for a 6-month public consultation.

Action: For adoption

The CHMP adopted the ICH E20 Draft Guideline on Adaptive Designs for Clinical Trials – Step 2b for a 6-month public consultation.

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 16-19 June 2025 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	
Emilia Mavrokordatou	Member	Cyprus	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	
Boje Kvorning Pires Ehmsen	Alternate	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	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No restrictions applicable to this meeting	
Janet Koenig	Member	Germany	No interests declared	
Martin Mengel	Alternate	Germany	No interests declared	
Aris Angelis	Member	Greece	No participation in discussion, final deliberations and voting on:	4.3.3. Keytruda – Pembrolizumab - EMA/X/000024879 5; 9.1.3. Trixeo Aerosphere - Formoterol / Glycopyrronium

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				bromide / Budesonide - EMA/R/0000245136; 9.1.5. Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0044; 4.3.2. Kerendia – Finerenone - EMA/X/0000248026; 9.1.4. Xarelto – Rivaroxaban - EMEA/H/C/000944/II/0113; 5.1.10. NUBEQA - Darolutamide - EMEA/H/C/004790/II/0024
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	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Finbarr Leacy	Alternate	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No restrictions applicable to this meeting	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
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 participation in discussion, final deliberations and voting on:	5.1.13. SARCLISA - Isatuximab - EMEA/H/C/004977/II/0035; 3.2.9. Belumosudil - Orphan - EMEA/H/C/00642; 3.3.1 Tolebrutinib - EMEA/H/C/006386; 5.1.6. Dupixent – Dupilumab - EMA/VR/0000257461

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
John Joseph Borg	Member	Malta	No restrictions applicable to this meeting	
Helen Vella	Alternate	Malta	No interests declared	
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	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Anna Kubandová	Expert	Slovakia	No interests declared	
Jana Schweigertová	Expert	Slovakia	No interests declared	
Christine Monier	Expert	France	No interests declared	
Justina Creppy	Expert	France	No interests declared	
Cécile Dop	Expert	France	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Stephanie Hueber	Expert	France	No restrictions applicable to this meeting	
Céline Jumeau	Expert	France	No interests declared	
Yseult Brun	Expert	France	No interests declared	
Sophie Teng	Expert	France	No interests declared	
Nicolas Beix	Expert	France	No interests declared	
Anissa Benlazar	Expert	France	No interests declared	
Maria Grünewald	Expert	Sweden	No interests declared	
Agnieszka Przybyszewska	Expert	Ireland	No restrictions applicable to this meeting	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Christoph Furtmann	Expert	Germany	No restrictions applicable to this meeting	
Ilona Reischl	Expert	Austria	No restrictions applicable to this meeting	
Philippe Vella	Expert	France	No restrictions applicable to this meeting	
Claire Brotons	Expert	France	No interests declared	
Augusto Fernandez	Expert	France	No interests declared	
Sonia Corosine	Expert	France	No interests declared	
Florian Klinglmüller	Expert	Austria	No restrictions applicable to this meeting	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Mats Økvist	Expert	Norway	No interests declared	
Lena Eroukhmanoff	Expert	Norway	No interests declared	
Luca Fancsalszky	Expert	Hungary	No interests declared	
Cristina Migali	Expert	Italy	No interests declared	
Cinzia Ciceroni	Expert	Italy	No interests declared	
Simona Russo	Expert	Italy	No interests declared	
Elmer Schabel	Expert	Germany	No restrictions applicable to this meeting	
Karoline Buhre	Expert	Germany	No interests declared	
Gabriele Schlosser-Weber	Expert	Germany	No interests declared	
Denna Tabari	Expert	Germany	No restrictions applicable to this meeting	
Norbert Benda	Expert	Germany	No restrictions applicable to this meeting	
Marion Haberkamp	Expert	Germany	No interests declared	
Riitta Niittyvuopio	Expert	Finland	No interests declared	
Elina Asikanius	Expert	Finland	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Robert Pollmann	Expert	Germany	No interests declared	
Sara Tognarelli	Expert	Germany	No participation in discussion, final deliberations and voting on:	5.1.13. SARCLISA - Isatuximab - EMEA/H/C/004977/II/0035; 3.2.9. Belumosudil - Orphan - EMEA/H/C/006421 3.3.1. Tolebrutinib - EMEA/H/C/006386; 5.1.6. Dupixent – Dupilumab - EMA/VR/0000257461
Jörg Engelbergs	Expert	Germany	No interests declared	
Hilke Zander	Expert	Germany	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Berendina Maria (Tineke) Van den Hoorn	Expert	Netherlands	No interests declared	
Emmely de Vries	Expert	Netherlands	No interests declared	
Bastian Hornung	Expert	Netherlands	No restrictions applicable to this meeting	
Viktoriia Starokozhko	Expert	Netherlands	No restrictions applicable to this meeting	
Lies van Vlijmen	Expert	Netherlands	No interests declared	
Cornelia (Marleen) Huigen	Expert	Netherlands	No restrictions applicable to this meeting	
Carlijn Litjens	Expert	Netherlands	No restrictions applicable to this meeting	
Laura Rodwell	Expert	Netherlands	No restrictions applicable to this meeting	
Martijn van Gils	Expert	Netherlands	No interests declared	
Esther Broekman	Expert	Netherlands	No restrictions applicable to this meeting	
Illiana Meurs	Expert	Netherlands	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	
Hugo Tavares	Expert	Portugal	No restrictions applicable to this meeting	
Catarina Santos	Expert	Portugal	No restrictions applicable to this meeting	
Anna Vikerfors	Expert	Sweden	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Hilke Zander	Expert	Germany	No interests declared	
Torsten Holm Nielsen	Expert	Denmark	No restrictions applicable to this meeting	
Kristina Magnusson Lundqvist	Expert	Sweden	No interests declared	
Anders Lignell	Expert	Sweden	No interests declared	
Louisa Braun Exner	Expert	Sweden	No interests declared	
Florian Koban	Expert	Austria	No interests declared	
Klaudia Hettinger	Expert	Austria	No interests declared	
Christian Woloch	Expert	France	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff.				

Experts were evaluated against the agenda topics or activities they participated in.

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)*

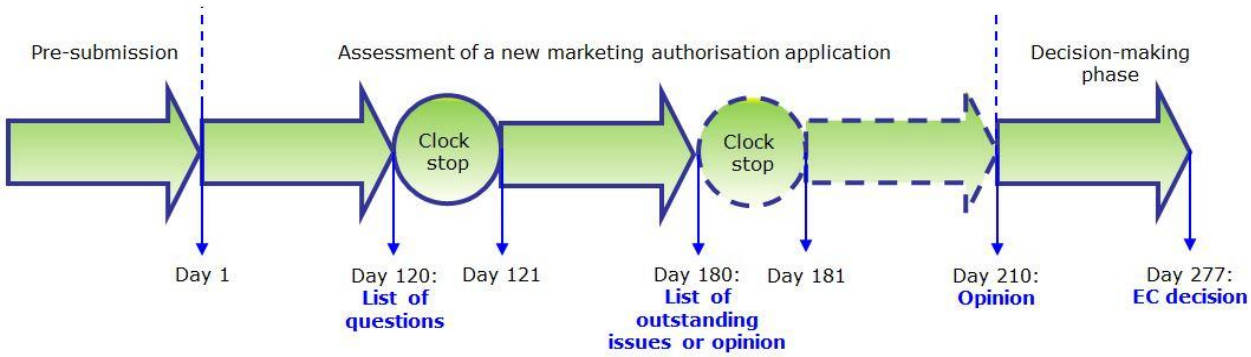
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

19 June 2025
EMA/CHMP/209339/2025

Annex to 16-19 June 2025 CHMP Minutes

Pre-submission and post-authorisations issues

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for June 2025: **For adoption**	Adopted

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

Final Outcome of Rapporteurship allocation for June 2025: **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 02-05 June 2025 PRAC:	
Signal of immune-mediated enterocolitis / immune effector cell-associated enteritis with CAR T-cell products Abecma, Breyanzi, Carvykti, Kymriah, Tecartus, Yescarta (CAP) Rapporteur: various, Co-Rapporteur: various, PRAC Rapporteur: various PRAC recommendation on a variation **Action:** For adoption	The CHMP adopted the PRAC recommendation

Signal of pyoderma gangrenosum Brodalumab - KYNTHEUM (CAP) Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Monica Martinez Redondo PRAC recommendation on a variation **Action:** For adoption	The CHMP adopted the PRAC recommendation
Signal of laboratory test interference leading to falsely elevated digoxin plasma levels with enzalutamide Enzalutamide, digoxin – XTANDI, ENZALUTAMIDE VIATRIS (CAP & NAP) Rapporteur: various, Co-Rapporteur: various, PRAC Rapporteur: Maria del Pilar Rayon PRAC recommendation on a variation **Action:** For adoption	The CHMP adopted the PRAC recommendation
Signal of hallucinations, not related to serotoninergic syndrome Vortioxetine - BRINTELLIX (CAP) Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Jo Robays PRAC recommendation on a variation **Action:** For adoption	The CHMP adopted the PRAC recommendation

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

CEVENFACTA - Eptacog beta (activated) - EMEA/H/C/005655/II/0012 Laboratoire Francais du Fractionnement et des Biotechnologies, Rapporteur: Daniela Philadelphy Opinion adopted on 05.06.2025. Request for Supplementary Information adopted on 06.02.2025.	Positive Opinion adopted by consensus on 05.06.2025.
CooperSurgical Inc ART Media - Human albumin solution - EMEA/H/D/002307/II/0012	Positive Opinion adopted by consensus on 19.06.2025.

Coopersurgical Inc., Rapporteur: Kristina Dunder Opinion adopted on 19.06.2025. Request for Supplementary Information adopted on 25.04.2025, 20.02.2025.	
Ledaga - Chlormethine - EMEA/H/C/002826/II/0035/G, Orphan Helsinn Birex Pharmaceuticals Limited, Rapporteur: Boje Kvorning Pires Ehmsen Opinion adopted on 19.06.2025. Request for Supplementary Information adopted on 21.03.2024, 06.07.2023.	Positive Opinion adopted by consensus on 19.06.2025.
Origio - Human albumin solution - EMEA/H/D/000830/II/0021 Coopersurgical Inc., Rapporteur: Jayne Crowe Opinion adopted on 19.06.2025. Request for Supplementary Information adopted on 25.04.2025, 20.02.2025.	Positive Opinion adopted by consensus on 19.06.2025.
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0056/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy Opinion adopted on 19.06.2025. Request for Supplementary Information adopted on 22.05.2025, 27.03.2025.	Positive Opinion adopted by consensus on 19.06.2025.

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

Cerezyme - Imiglucerase - EMEA/H/C/000157/II/0136 Sanofi B.V., Rapporteur: Patrick Vrijlandt, "Update of sections 4.4 and 4.8 of the SmPC in order to add 'Transient hypertension' to the list of adverse drug reactions (ADRs) with frequency not known as well as to reflect the warning on Infusion-associated reactions (IARs), based on a safety review. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 19.06.2025, 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Helicobacter Test INFAI - 13C-Urea - EMEA/H/C/000140/II/0028 Infai GmbH, Re-examination Rapporteur: Filip Josephson, "Update of sections 4.2, 4.3 and 5.1 of the SmPC in order to modify administration instructions and to add a new contraindication based on final results from study HPT30/J/17; this is a single-group, observer-blind, multi-	Negative Opinion adopted by majority on 19.06.2025. See 9.1

centre study to quantify the sensitivity and specificity of the 13C-UBT using the new test meal for Hp in patients with dyspepsia and GERD taking PPI. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 6.6 of the SmPC." Re-examination Opinion adopted on 19.06.2025. Opinion adopted on 30.01.2025. Request for Supplementary Information adopted on 17.10.2024, 30.05.2024.	
Inrebic - Fedratinib - EMEA/H/C/005026/II/0026, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update of sections 4.4 and 4.8 of the SmPC in order to add a warning regarding 'Uveitis' and to add this to the list of adverse drug reactions (ADRs) with frequency 'common' based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI." Opinion adopted on 05.06.2025. Request for Supplementary Information adopted on 25.04.2025, 23.01.2025.	Positive Opinion adopted by consensus on 05.06.2025.
Inrebic - Fedratinib - EMEA/H/C/005026/II/0027, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update of sections 4.2 and 5.2 of the SmPC in order to add administration option based on results from clinical trial FEDR-CP-005. This is a phase 1, open-label, single-centre, 2-part crossover study to evaluate the relative bioavailability of fedratinib when administered as contents of capsules dispersed in a nutritional supplement orally or via nasogastric tube or administered orally as divided doses of intact capsules with a nutritional supplement in healthy adult subjects. The Package Leaflet is being updated accordingly. In addition, the MAH took the opportunity to add editorial changes to the PI." Request for Supplementary Information adopted on 19.06.2025, 27.02.2025.	Request for supplementary information adopted with a specific timetable.
Metalyse - Tenecteplase - EMEA/H/C/000306/II/0075/G Boehringer Ingelheim International GmbH, Rapporteur: Janet Koenig, "A grouped	Positive Opinion adopted by consensus on 19.06.2025.

application comprised of 4 Type II Variations, as follows: C.I.4: Update of sections 4.3 and 4.4 of the SmPC in order to update the safety information pertaining to the prevention of bleeding risk related to thrombolytic treatment based on a dataset consisting of literature review including published clinical study outcomes. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.2 and 4.4 of the SmPC in order to update the safety information for patients with body weight < 50 kg based on the dataset consisting of reanalysis of existing clinical data and literature review. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.3 and 4.4 of the SmPC related to the medical recommendations for prior stroke patients based on a dataset consisting of reanalysis of existing clinical data and literature review. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.2 and 4.4 of the SmPC in order to revise the medical recommendation in line with the most current medical knowledge in treatment guidelines. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce minor editorial changes to the PI, as well as to update the excipient information according to the latest EU Excipients Guideline. Furthermore, the PI is being brought in line with the latest QRD template (version 10.4)." Opinion adopted on 19.06.2025. Request for Supplementary Information adopted on 27.02.2025.	
OZAWADE - Pitolisant - EMEA/H/C/005117/II/0012 Bioprojet Pharma, Rapporteur: Peter Mol, "Submission of the study note PH24048. This is an update of the final PopPK model (PH20043) submitted at initial Marketing Authorization Approval integrating the results of study 15-03 (HAROSA III). In addition, the results of re-	Request for supplementary information adopted with a specific timetable.

estimated model parameters and covariates are provided." Request for Supplementary Information adopted on 05.06.2025, 13.02.2025.	
Taltz - Ixekizumab - EMEA/H/C/003943/II/0054 Eli Lilly and Co (Ireland) Limited, Rapporteur: Kristina Dunder, "Update section 4.8 of the SmPC to add eczematous eruptions (dyshidrotic eczema and exfoliative dermatitis) to the list of adverse drug reactions (ADRs) with frequency uncommon and rare, respectively, following a review of all associated data. The package leaflet is updated in accordance." Opinion adopted on 12.06.2025. Request for Supplementary Information adopted on 13.03.2025.	Positive Opinion adopted by consensus on 12.06.2025.
Vyloy - Zolbetuximab - EMEA/H/C/005868/II/0005, Orphan Astellas Pharma Europe B.V., Rapporteur: Jan Mueller-Berghaus, "Update of section 5.1 of the SmPC in order to update immunogenicity data based on the validation report for the new method (8951-ME-0016) to replace the method originally used to test ADA samples from the pivotal studies SPOTLIGHT and GLOW. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI." Opinion adopted on 19.06.2025. Request for Supplementary Information adopted on 27.02.2025.	Positive Opinion adopted by consensus on 19.06.2025.
Zejula - Niraparib - EMEA/H/C/004249/II/0057/G, Orphan GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang, "C.I.4: Update of section 4.5 of the SmPC in order to update information on pharmacokinetic drug-drug interactions based on Physiologically based on results from pharmacokinetic (PBPK) modelling; this is Evaluation of GSK3985771 (Niraparib) Drug-Drug Interaction (DDI) Risk Assessment as a Perpetrator using PBPK Modelling; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and introduce editorial changes to the PI. C.I.4: Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on results from Refined PRIMA Model;	Positive Opinion adopted by consensus on 19.06.2025.

this is an amendment to addendum to population pharmacokinetic and exposure-response modelling of niraparib in PRIMA study; the Package Leaflet is updated accordingly." Opinion adopted on 19.06.2025. Request for Supplementary Information adopted on 27.02.2025.	

B.5.3. CHMP-PRAC assessed procedures

Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0007 Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan, "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC in order to introduce an alternative posology regimen based on results from study PB-102-F50 (BRIGHT) and interim results from its extension study CLI-06657AA1-03 (formerly presented as PB-102-F51), as well as results of the observational patient reporting outcome study CLI-06657AA1-05. CLI-06657AA1-03 is an Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Pegunigalsidase Alfa (PRX-102)2 mg/kg Administered by Intravenous Infusion Every 4 Weeks in Patients with Fabry Disease. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4." Request for Supplementary Information adopted on 19.06.2025, 30.01.2025.	Request for supplementary information adopted with a specific timetable. See 9.1
Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0044 AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a	Positive Opinion adopted by consensus on 19.06.2025. See 9.1

switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3." Opinion adopted on 19.06.2025. Request for Supplementary Information adopted on 27.02.2025, 19.09.2024, 21.03.2024.	
PONVORY - Ponesimod - EMEA/H/C/005163/II/0018/G Laboratoires Juvise Pharmaceuticals, Rapporteur: Peter Mol, PRAC Rapporteur: Karin Erneholm, "Grouped application comprised of two Type II Variations, as follows: C.I.13: Submission of the final report from study AC-058B202; this is a Multicentre, Randomized, Double-blind, Parallel-group Extension to Study AC-058B201 to Investigate the Long-term Safety, Tolerability, and Efficacy of 10, 20, and 40 mg/day Ponesimod, an Oral S1P1 Receptor Agonist, in Patients with Relapsing-remitting Multiple Sclerosis. C.I.13: Submission of the final report from study AC-058B303 (OPTIMUM-LT); this is a Multicentre, Non-Comparative Extension to Study AC-058B301, to Investigate the Long-Term Safety, Tolerability, and Control of Disease of Ponesimod 20 mg in Subjects with Relapsing Multiple Sclerosis. The RMP version 4.1 has also been submitted." Request for Supplementary Information adopted on 05.06.2025, 13.03.2025.	Request for supplementary information adopted with a specific timetable.
Pyramax - Pyronaridine / Artesunate - EMEA/H/W/002319/II/0036 Shin Poong Pharmaceutical Co., Ltd., Rapporteur: Jean-Michel Race, PRAC Rapporteur: Zoubida Amimour, "Update of sections 4.4 and 4.6 of the SmPC with revised recommendations for treatment during pregnancy. The Package Leaflet has been updated accordingly. An updated RMP version 18.2 was agreed." Opinion adopted on 05.06.2025. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 05.06.2025.

on 08.05.2025, 16.01.2025.	
XALKORI - Crizotinib - EMEA/H/C/002489/II/0084 Pfizer Europe MA EEIG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "Submission of the final report from study CRZ-NBALCL listed as a category 3 study in the RMP. This is a phase I/II study to evaluate the adverse effects of ocular toxicity and bone toxicity, and impaired bone growth associated with crizotinib in paediatric and young adult patients with recurrent/refractory anaplastic lymphoma kinase-positive anaplastic large cell lymphoma or neuroblastoma. The RMP version 9.2 is updated accordingly." Opinion adopted on 05.06.2025. Request for Supplementary Information adopted on 10.04.2025, 16.01.2025.	Positive Opinion adopted by consensus on 05.06.2025.

B.5.4. PRAC assessed procedures

PRAC Led **Fintepla - Fenfluramine - EMEA/H/C/003933/II/0028, Orphan** UCB Pharma SA, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of a revised protocol for study EP0218 listed as an obligation in the Annex II of the Product Information. This is a Long-term Registry in approved indications for fenfluramine, with a specific focus on cardiovascular events and growth retardation. The RMP version 4.3 is updated accordingly. In addition, the MAH introduced minor amendments in the targeted follow-up questionnaire for cardiovascular adverse events." Opinion adopted on 19.06.2025. Request for Supplementary Information adopted on 25.04.2025, 30.01.2025.	Positive Opinion adopted by consensus on 19.06.2025.
PRAC Led **Firazyr - Icatibant - EMEA/H/C/000899/II/0061** Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Update of section 4.6 based on final results from the Icatibant Outcome Survey (IOS) registry listed as a category 3 study in the RMP; this is a	Request for supplementary information adopted with a specific timetable.

prospective, observational disease registry. The RMP version 8 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.4." Request for Supplementary Information adopted on 05.06.2025, 13.02.2025.	
PRAC Led **Revlimid - Lenalidomide - EMEA/H/C/000717/II/0130** Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from study CC-5013-MCL-005 listed as a category 3 study in the RMP. This is a non-interventional, post-authorization safety study of patients with relapsed or refractory mantle cell lymphoma to further investigate and characterize the association of lenalidomide with tumor flare reaction and high tumor burden. The RMP version 42.0 has also been submitted." Opinion adopted on 05.06.2025. Request for Supplementary Information adopted on 13.02.2025.	Positive Opinion adopted by consensus on 05.06.2025.

B.5.5. CHMP-CAT assessed procedures

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

PRAC Led **Tecartus - Brexucabtagene autoleucel - EMEA/H/C/005102/II/0051, Orphan, ATMP** Kite Pharma EU B.V., PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Peter Mol, "Submission of the final study report for the non-interventional study KT-EU-472-5966 titled "Quantitative Testing of Health Care Professional Knowledge About Tecartus Risk Minimisation Measures'' listed as a category 3 study in the RMP." Request for Supplementary Information adopted on 13.06.2025, 06.12.2024.	Request for supplementary information adopted with a specific timetable.

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

B.5.9. Information on withdrawn type II variation / WS procedure

Xarelto - Rivaroxaban - EMEA/H/C/000944/II/0113 Bayer AG, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add splenic rupture´ to the list of adverse drug reactions (ADRs) with frequency 'very rare' based on the data from the clinical trials, post-marketing data sources and literature; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity introduce editorial updates as agreed with QRD group." Request for Supplementary Information adopted on 13.02.2025. Withdrawal request submitted on 06.06.2025.	The MAH withdrew the procedure on 06.06.2025.

B.5.10. Information on type II variation / WS procedure with revised timetable

D. Annex D - Post-Authorisation Measures (PAMs), (Details on PAMs including description and conclusion, for adoption by CHMP in that given month, or finalised ones with PRAC recommendation and no adoption by CHMP needed)

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

Information related to plasma master files cannot be released at the present time as these contain commercially confidential information.

E.1. PMF Certification Dossiers

E.2. Time Tables – starting & ongoing procedures: For information

PMF timetables starting and ongoing procedures	Tabled in MMD and sent by post mail (folder E).

F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver

G. ANNEX G

G.1. Final Scientific Advice (Reports and Scientific Advice letters):

Information related to Scientific Advice cannot be released at the present time as these contain commercially confidential information.

G.2. PRIME

Some information related to PRIME cannot be released at the present time as these contain commercially confidential information.