22 May 2025
EMA/206317/2025

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 19-22 May 2025

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

Health and safety information

In accordance with the Agency's health and safety policy, delegates were briefed on health, safety and emergency information and procedures prior to the start of the meeting.

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 in-person.

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 19-22 May 2025

The CHMP adopted the agenda for the 19-22 May 2025 meeting.

1.3. Adoption of the minutes

CHMP minutes for 24-27 March 2025.

The CHMP adopted the minutes for the 24-27 March 2025 meeting.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 12 May 2025.

The CHMP adopted the minutes from the PROM meeting held on 12 May 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Deutetrabenazine - EMEA/H/C/006371

treatment of tardive dyskinesia

Scope: Oral explanation

Action: Oral explanation to be held on 20 May 2025 at 16:00

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

An oral explanation was held on 20 May 2025. The presentation by the applicant focused on the quality and clinical data in support of the application.

2.1.2. Kinselby - Resminostat - Orphan - EMEA/H/C/006259

4Sc AG; treatment of patients with advanced stage mycosis fungoides (MF) and Sézary syndrome (SS)

Scope: Oral explanation

Action: Oral explanation to be held on 20 May 2025 at 09:00

Participation of patient representatives

List of Outstanding Issues adopted on 25.04.2025, 27.02.2025. List of Questions adopted on 27.06.2024.

An oral explanation was held on 20 May 2025. The presentation by the applicant focused on the clinical data in support of the application.

See 3.1

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

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

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

Scope: Opinion

Action: For adoption

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

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

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

3.1.2. Aucatzyl - Obecabtagene autoleucel - PRIME - Orphan - ATMP - EMEA/H/C/005907

Autolus GmbH; treatment of patients with relapsed or refractory B cell precursor acute lymphoblastic leukaemia (ALL)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.03.2025. List of Questions adopted on 19.07.2024.

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 obecabtagene autoleucel 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 22 May 2025.

The EMA public health communication was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.3. BLENREP - Belantamab mafodotin - Orphan - EMEA/H/C/006511

Glaxosmithkline Trading Services Limited; treatment of multiple myeloma

Scope: Opinion

Action: For adoption

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

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.

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

The CHMP adopted the similarity assessment report.

3.1.4. Bomyntra - Denosumab - EMEA/H/C/006269

Fresenius Kabi Deutschland GmbH; prevention of skeletal related events in adults with advanced malignancies involving bone

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 27.03.2025. List of Questions adopted on 17.10.2024.

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. Conexxence - Denosumab - EMEA/H/C/006268

Fresenius Kabi Deutschland GmbH; treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 27.03.2025. List of Questions adopted on 17.10.2024.

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

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

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

The summary of opinion was circulated for information.

3.1.6. Emtricitabine/Tenofovir alafenamide Viatris - Emtricitabine / Tenofovir alafenamide - EMEA/H/C/006469

Viatris Limited; for the treatment of human immunodeficiency virus type 1 (HIV-1)

Scope: Opinion

Action: For adoption

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Descovy

List of Outstanding Issues adopted on 27.03.2025. List of Questions adopted on 17.10.2024.

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.

3.1.7. Ezmekly - Mirdametinib - Orphan - EMEA/H/C/006460

Springworks Therapeutics Ireland Limited; treatment of neurofibromatosis type 1

Scope: Opinion

Action: For adoption

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

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

Furthermore, the CHMP considered that mirdametinib 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 22 May 2025.

The CHMP adopted the similarity assessment report.

3.1.8. Itovebi Inavolisib - EMEA/H/C/006353

Roche Registration GmbH; treatment of adult patients with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally

advanced or metastatic breast cancer

Scope: Opinion

Action: For adoption

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

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

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 majority (29 out of 32 votes) together with the CHMP assessment report and translation timetable.

The divergent position (Boje Kvorning Pires Ehmsen, Outi Mäki-Ikola, Peter Mol and Ingrid Wang) was appended to the opinion.

Furthermore, the CHMP considered that inavolisib 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.

3.1.9. Kinselby - Resminostat - Orphan - EMEA/H/C/006259

4Sc AG; treatment of patients with advanced stage mycosis fungoides (MF) and Sézary syndrome (SS)

Scope: Opinion

Action: For adoption

Participation of patient representatives

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

List of Outstanding Issues adopted on 25.04.2025, 27.02.2025. List of Questions adopted on 27.06.2024.

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

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

See 2.1.

3.1.10. MAAPLIV - AMINO ACIDS - Orphan - EMEA/H/C/005557

Recordati Rare Diseases; treatment of decompensation episodes in MSUD patients

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 30.01.2025. List of Questions adopted on

25.01.2024.

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

The Committee adopted a positive opinion recommending the granting of a marketing authorisation under exceptional circumstances 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. RIULVY - Tegomil fumarate - EMEA/H/C/006427

Neuraxpharm Pharmaceuticals S.L.; treatment of multiple sclerosis

Scope: Opinion

Action: For adoption

Hybrid application (Article 10(3) of Directive No 2001/83/EC)

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.

3.1.12. Rolcya - Denosumab - EMEA/H/C/006507

Sandoz GmbH; treatment of osteoporosis and bone loss in postmenopausal women and in men

Scope: Opinion

Action: For adoption

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

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

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

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

The summary of opinion was circulated for information.

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

3.2.1. Lifileucel - ATMP - EMEA/H/C/004741

treatment of unresectable or metastatic melanoma

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 06.12.2024.

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

3.2.2. Sebetralstat - Orphan - EMEA/H/C/006211

Kalvista Pharmaceuticals (Ireland) Limited; treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older

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.

3.2.3. Bifikafusp alfa / Onfekafusp alfa - EMEA/H/C/005651

neoadjuvant treatment of adult patients with locally advanced fully resectable melanoma.

Scope: List of outstanding issues; Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues to be adopted in May 2025.

Action: For adoption

List of Questions adopted on 17.10.2024.

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.

The CHMP did not agree to the request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues adopted in May 2025.

3.2.4. Pridopidine - Orphan - EMEA/H/C/006261

Prilenia Therapeutics B.V.; treatment of Huntington's disease

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. Olezarsen - Orphan - EMEA/H/C/006477

Ionis Ireland Limited; treatment of familial chylomicronemia syndrome

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.

3.2.6. Zuranolone - EMEA/H/C/006488

treatment of postpartum depression (PPD) in adults

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.

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

3.3.1. Nogapendekin alfa inbakicept - EMEA/H/C/006622

treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours

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

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

Scope: 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 May 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 May 2025.

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

Comharsa Life Sciences Limited; Treatment of Rett syndrome in adults and paediatric patients 2 years of age and older

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. Depemokimab - EMEA/H/C/006446

As an add-on maintenance treatment of asthma, and as an add-on treatment of inadequately controlled Chronic rhinosinusitis with nasal polyps (CRSwNP)

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.5. Golimumab - EMEA/H/C/006621

treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis and juvenile idiopathic arthritis

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

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

Scope: 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. Lenacapavir - EMEA/H/C/006658

Accelerated assessment

pre-exposure prophylaxis to prevent HIV-1

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.

3.3.8. Lenacapavir - Article 58 - EMEA/H/W/006659

Accelerated assessment

pre-exposure prophylaxis to prevent HIV-1

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.

3.3.9. Ranibizumab - EMEA/H/C/006502

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

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.

3.3.10. Teplizumab - PRIME - EMEA/H/C/005496

To delay both the onset of Stage 3 type 1 diabetes (T1D) and the progression of Stage 3 T1D

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.

The CHMP adopted the list of questions to the SAG.

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

X4 Pharmaceuticals (Austria) GmbH; Treatment of WHIM syndrome

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

No items

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

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

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

Scope: Adoption of timetable

Restart of the 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 adoption

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

The CHMP adopted the procedural timetable.

3.5.2. Winlevi - Clascoterone - EMEA/H/C/006138

Cassiopea S.p.A.; indicated for the topical treatment of acne vulgaris in adults and adolescents

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

Action: For adoption

Opinion adopted 25.04.2025. List of Outstanding Issues adopted on 27.03.2025, 12.12.2024, 17.10.2024. List of Questions adopted on 22.02.2024.

The CHMP noted the proposed timetable and appointed a re-examination rapporteur and a re-examination co-rapporteur.

3.6. Initial applications in the decision-making phase

3.6.1. Dazublys - Trastuzumab - EMEA/H/C/006219

CuraTeQ Biologics s.r.o.; treatment of metastatic and early breast cancer

Scope: Revised Opinion

Action: For adoption

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

Opinion adopted on 25.04.2025. List of Outstanding Issues adopted on 30.01.2025. List of Questions adopted on 30.05.2024.

The Committee adopted the revised opinion.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Teriparatide - EMEA/H/C/005687

treatment of osteoporosis

Scope: Withdrawal of initial marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 09.11.2023.

The CHMP noted the withdrawal of the initial marketing authorisation application.

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

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

4.1.1. REZOLSTA - Darunavir / Cobicistat - EMEA/H/C/002819/X/0054/G

Janssen-Cilag International N.V.

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension application to introduce a new strength (675 mg/150 mg film-coated tablets) grouped with an extension of indication (C.I.6.a) to include, treatment of HIV-1 infected paediatric patients (aged 6 years and older with body weight at least 25 kg) for REZOLSTA, based on the 48-week ad hoc 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 darunavir in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1,4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.3, 6.5 and 8 of the SmPC and Annex II are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

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

4.1.2. Xofluza - Baloxavir marboxil - EMEA/H/C/004974/X/0022

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Sonja Hrabcik

Scope: "Extension application to add a new pharmaceutical form (granules) associated with three new strengths (10, 30 and 40 mg)"

Action: For adoption

List of Outstanding Issues adopted on 27.03.2025. 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 summary of opinion was circulated for information.

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

4.2.1. Azacitidine Accord - Azacitidine - EMEA/H/C/005147/X/0021

Accord Healthcare S.L.U.

Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to introduce a new pharmaceutical form (film-coated tablet) associated with new strengths (200 and 300 mg) and new route of administration (oral use).
The RMP (version 2.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 12.12.2024.

The Committee discussed the issues identified in this application.

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

4.2.2. 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 Questions adopted on 27.02.2025.

The Committee discussed the issues identified in this application.

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

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. Saphnelo - Anifrolumab - EMEA/H/C/004975/X/0023

AstraZeneca AB

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new route of administration (subcutaneous use) and a new strength (120 mg)."

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.

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

GlaxoSmithKline Biologicals

Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik

Scope: Extension application to introduce a new pharmaceutical form (suspension for injection in pre-filled syringe).

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.

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

4.4.1. Lunsumio - Mosunetuzumab - Orphan - EMEA/H/C/005680/X/0015

Roche Registration GmbH

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with two new strengths (5 mg and 45 mg) and new route of administration (subcutaneous use).
The RMP (version 3.0) is updated in accordance."

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 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.

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. ASPAVELI – Pegcetacoplan - EMA/VR/0000248937

Swedish Orphan Biovitrum AB (publ)

Rapporteur: Alexandre Moreau, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of adults and adolescents aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulopathy (IC-MPGN) for ASPAVELI, based on interim results from study APL2-C3G-310; this is a randomized, placebo-controlled, double-blinded, multicentre study to evaluate the safety and efficacy of twice-weekly s.c. infusions of pegcetacoplan in patients diagnosed with C3G or primary IC-MPGN and results from Phase 2 study APL2-C3G-204, an open-label, randomized, controlled study to evaluate the efficacy and safety of pegcetacoplan in posttransplant recurrence of C3G or primary IC-MPGN. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. 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.

5.1.2. 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 Smoldering Multiple Myeloma. SMM2001 (CENTAURUS) is a Randomized Phase 2 Trial to Evaluate Three Daratumumab Dose Schedules in Smoldering 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 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.

5.1.3. Dovprela – Pretomanid - EMA/VR/0000258124

Mylan IRE Healthcare Limited

Rapporteur: Filip Josephson

Scope: Extension of indication to include in combination with bedaquiline, linezolid and moxifloxacin the treatment of adults with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to rifampicin, with or without resistance to isoniazid, for DOVPRELA and to update the current regimen, based on final results of the TB-PRACTECAL study; this is a randomised, controlled, open-label, phase II-III trial to evaluate the safety and efficacy of regimens containing bedaquiline and pretomanid for the treatment of adult patients with pulmonary multidrug resistant tuberculosis. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to introduce minor 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.

5.1.4. Dupixent – Dupilumab - EMA/VR/0000248778

Sanofi Winthrop Industrie

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of adults with bullous pemphigoid (BP) for DUPIXENT, based on final results from study R668-BP-1902 (LIBERTY-BP ADEPT); this is a phase 2/3, multicentre, randomised, double blind, placebo-controlled, parallel group study to assess the efficacy and safety of dupilumab in adult patients with bullous pemphigoid; As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 12.0 of the RMP has also been submitted.

Action: For adoption

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

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

5.1.5. Imfinzi - Durvalumab - EMEA/H/C/004771/II/0073

AstraZeneca AB

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include IMFINZI in combination with cisplatin-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, for the treatment of adults with muscle invasive bladder cancer (MIBC), based on an ongoing pivotal study D933RC00001 (NIAGARA); this is a phase 3, randomized, open-label, multi-centre, global study to determine the efficacy and safety of durvalumab in combination with gemcitabine+cisplatin for neoadjuvant treatment followed by durvalumab alone for adjuvant treatment in patients with muscle-invasive bladder cancer. As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. The RMP version 13 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and update the PI according to the Excipients Guideline."

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.

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

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

Eli Lilly Nederland B.V.

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of symptomatic chronic heart failure with preserved ejection fraction (HFpEF) in adults with obesity for MOUNJARO, based on results from the Phase 3 trial I8F-MC-GPID (SUMMIT). SUMMIT was a randomized, multicentre, international, placebo-controlled, double-blind, parallel-arm study in participants with HFpEF and obesity. The study was designed to evaluate the effect of tirzepatide compared with placebo on both clinical and symptomatic or functional outcomes. As a consequence, sections 4.1, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

Request by the applicant for an extension to the clock-stop to respond to the request for supplementary information to be adopted in May 2025.

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.

The CHMP agreed to the request by the applicant for an extension to the clock-stop to respond to the request for supplementary information adopted in May 2025.

5.1.7. mRESVIA - Respiratory syncytial virus mRNA vaccine (nucleoside modified) - EMA/VR/0000248175

Moderna Biotech Spain S.L.

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

Scope: To modify the approved therapeutic indication to include active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV for mRESVIA, based on results from Study mRNA-1345-P303 (Part A) - A Phase 3 Study to Evaluate the Immunogenicity and Safety of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus, in High-risk Adults. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC and the corresponding sections of the Package Leaflet are updated accordingly. The updated RMP Version 1.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI. As part of the application, the MAH also requests an extension of the market protection by one additional year.

Action: For adoption

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

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

5.1.8. 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 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.

5.1.9. Saxenda - Liraglutide - EMEA/H/C/003780/II/0042

Novo Nordisk A/S

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

Bianca Mulder

Scope: "Extension of indication to include the use of SAXENDA for weight management in children from the age of 6 years to less than 12 years based on results from study NN8022-4392; this is a 56-week, double-blind, randomised, placebo-controlled study investigating safety and efficacy of liraglutide on weight management in children with obesity aged 6 to <12 years. 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 34.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2025, 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 summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 08 May 2025.

The CHMP adopted the similarity assessment report.

5.1.10. SIRTURO – Bedaquiline - EMA/VR/0000249065

Janssen Cilag International

Rapporteur: Filip Josephson, PRAC Rapporteur: Karin Bolin

Scope: Extension of indication to include treatment of paediatric patients (2 years to less than 5 years of age and weighing at least 7 kg) with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to at least rifampicin and isoniazid, for SIRTURO, based on the Week 24 primary analysis from Cohort 3 (≥2 to <5 years of age) of Study TMC207-C211; this is an open-label, multicentre, single-arm study to evaluate pharmacokinetics, safety/tolerability, antimycobacterial activity and dose selection of bedaquiline in children (birth to <18 years) with multidrug-resistant-TB (MDR-TB). Long-term follow-up to Week 120 in participants of Cohort 1 (≥12 to <18 years of age) and Cohort 2 (≥5 to <12 years of age) have also been submitted. 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 11.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and introduce minor 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.

5.1.11. Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0017

BeOne Medicines Ireland Limited

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

Scope: "Extension of indication to include, in combination with gemcitabine and cisplatin, the first-line treatment of adult patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) for TEVIMBRA based on final results from study BGB-A317-309 (study 309). Study 309 was a Phase 3 randomised, double-blind, placebo-controlled, Asia-only study that compared the efficacy and safety of tislelizumab combined with gemcitabine plus cisplatin (GC) versus placebo combined with GC as 1L treatment for recurrent or metastatic NPC. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.6 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial and administrative changes to the PI as well as to update the PI in line with the Excipients Guideline."

Action: For adoption

Request for Supplementary Information 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.

The summary of opinion was circulated for information.

5.1.12. ZYNYZ – Retifanlimab - EMA/VR/0000247788

Incyte Biosciences Distribution B.V.

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

Scope: Extension of indication to include in combination with carboplatin and paclitaxel treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC) for ZYNYZ, based on interim results from study INCMGA 0012-303 (POD1UM-303/InterAACT-2); this is a phase 3 global, multicentre, double-blind randomized study of carboplatin-paclitaxel with retifanlimab or placebo in participants with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal not previously treated with systemic chemotherapy; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

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

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

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. 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.

6.3.2. 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.

6.4. 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. Norucholic acid – H0006515

Treatment of primary sclerosing cholangitis (PSC) in adults

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. Arsenic trioxide Mylan (SRD) - Arsenic trioxide – EMEA/H/C/005235

Mylan Ireland Limited; treatment of relapsed acute promyelocytic leukaemia (APL)

Rapporteur: Daniela Philadelphy

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

9.1.2. Tecovirimat SIGA - Tecovirimat - EMA/S/0000248804

Siga Technologies Netherlands B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber

Scope: Annual reassessment for products authorised under exceptional circumstances

Action: For adoption

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

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

9.1.3. Tremfya – Guselkumab - EMA/VR/0000257541

Janssen Cilag International

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

Scope: Update of sections 4.2, 4.5, 4.8, 5.1, and 5.2 of the SmPC in order to add subcutaneous induction dosing for the ulcerative colitis (UC) indication based on interim results from study CNTO1959UCO3004 listed as a category 3 study in the RMP; this is a phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the efficacy and safety of guselkumab subcutaneous induction therapy in participants with moderately to severely active UC; the Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted. In addition, the MAH took the opportunity to bring 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.

9.1.4. LUTATHERA - Lutetium (177Lu) oxodotreotide - Orphan - EMEA/H/C/004123/II/0052

Advanced Accelerator Applications

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: Withdrawal of Type II extension of indication application

Action: For information

Request for Supplementary Information adopted on 27.02.2025, 19.09.2024.

The CHMP noted the withdrawal of the type II extension of indication application.

9.1.5. SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0052

Clinuvel Europe Limited

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: "Update of section 4.2 of the SmPC in order to update the posology recommendations by removing the current recommendation of a maximum of four implants per year, based on a literature review and analysis of safety data. The Package Leaflet is updated accordingly. The RMP version 9.8 has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial change to the Product Information."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2025, 14.11.2024, 30.05.2024.

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

The Committee adopted a 4th request for supplementary information with a specific timetable.

9.1.6. MINJUVI – Tafasitamab – Orphan - EMA/R/0000256675

Incyte Biosciences Distribution B.V.

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn

Scope: Renewal of conditional marketing authorisation

Action: For adoption

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

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

9.1.7. BEQVEZ - Fidanacogene elaparvovec - PRIME - ATMP - EMEA/H/C/004774

Pfizer Europe MA EEIG; indicated for the treatment of severe and moderately severe haemophilia B

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Silke Dorner

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

10. Referral procedures

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

10.1.1. Oxbryta - Voxelotor - EMEA/H/A-20/1538/C/004869/0014

Pfizer Europe MA EEIG

Referral Rapporteur: Patrick Vrijlandt, Referral Co- Rapporteur: Alexandre Moreau

Scope: List of outstanding issues, timetable

Action: For adoption

The EC initiated a procedure under Article 20 of Regulation (EC) No 726/2004 to assess the benefit-risk balance of Oxbryta in its authorised indication. The initiation of the review follows an imbalance of deaths between voxelotor and placebo observed in clinical trials. The findings from these emerging safety data need to be further reviewed, taking into account all available data, to determine whether there is an impact on the benefit-risk balance of Oxbryta in its authorised indication.

List of outstanding issues adopted on 12.12.2024. List of questions adopted on 29.07.2024

The CHMP adopted a 2nd list of outstanding issues with a specific timetable.

Submission of responses: 15.07.2025

Rapporteur/co-rapporteur joint assessment report(s): 25.08.2025

Ad-hoc expert group meeting (AHEG): tbc

Comments: 04.09.2025

Updated Rapporteur/co-rapporteur joint assessment report(s): 10.09.2025

CHMP LoOI or opinion: 18 September 2025

The CHMP agreed to consult an ad-hoc expert group (AHEG) and adopted the list of questions to the AHEG.

10.2. Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004

10.2.1. Colistimethate sodium (CMS) – EMEA/H/A-5(3)/1524

Various MAHs

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Ewa Balkowiec Iskra

Scope: Revised list of outstanding issues, revised timetable

Action: For adoption

Review of the ratio of polymyxins E1 and E2 in colistin starting material and of the (sulfomethylation) composition profile of CMS finished product.

List of outstanding issues adopted on 21.03.2024, 22.02.2024. List of questions adopted on 22.06.2023.

The CHMP adopted a revised 2nd list of outstanding issues with a revised timetable.

Submission: 20.06.2025

Rapporteur joint assessment report: 11.07.2025

CHMP discussion: 24.07.2025

Submission: 02.04.2026

Re-start of the procedure: 23.04.2026

Rapporteurs' joint assessment report: 02.07.2026

Comments: 09.07.2025

Updated Rapporteur joint assessment report(s): 15.07.2026

CHMP LoOI or opinion: 23 July 2026

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: 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.

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

The Committee adopted a positive opinion by consensus recommending that the marketing authorisation for Azithromycin containing medicinal products for systemic use should be

varied.

The CHMP recommends several changes, including amendment and removal of certain indications. These recommendations aim to optimise the use of this common antibiotic and minimise the development of antimicrobial resistance, the ability of microorganisms to become resistant to antimicrobials.

The Committee adopted the CHMP assessment report and translation timetable.

The EMA public health communication was circulated for information.

10.6.2. Ipidacrine – various - EMA/REF/0000271842

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

Scope: Appointment of rapporteurs, list of questions and timetable

Action: For adoption

The HPRA considers that there are serious concerns regarding the benefit-risk balance of ipidacrine-containing medicinal products as a result of the paucity of the data supporting the efficacy in their ill-defined indications and of the emergence of new data casting doubt on the efficacy in neuritis, polyneuritis, polyradiculoneuropathy, as well as raising concerns around their hepatotoxicity potential. Therefore, taking also into account the expected increase in exposure of patients across the Union to ipidacrine (due to the recent approvals of generic medicinal products in over a third of EU/EEA Member States) and the related potential risk to human health, HPRA is of the view that there is a need to reevaluate the benefit-risk balance of ipidacrine-containing products in the authorised indications.

In view of the above, the Irish Competent Authority triggered a referral under Article 31 of Directive 2001/83/EC, based on the interest of the Union, requesting CHMP it gives its opinion as to whether marketing authorisations of these products should be maintained, varied, suspended, or revoked.

The CHMP appointed a referral rapporteur and a referral Co-Rapporteur.

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

Submission of responses: 20.08.2025

Re-start of the procedure: 18.09.2025

Rapporteur/co-rapporteur joint assessment report(s): 25.09.2025

Comments: 02.10.2025

Updated Rapporteur/co-rapporteur joint assessment report(s): 08.10.2025

CHMP LoOI or opinion: 16 October 2025

The EMA public health communication was circulated for information.

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

May 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

Sol Ruiz (Co-opted member) gave a proxy vote to Antonio Gomez Outes (ES) for the entire duration of the meeting.

Simona Badoi (RO) gave a proxy vote to Ewa Bałkowiec-Iskra (PL) for the entire duration of the meeting.

Carla Torre (Co-opted member) gave a proxy vote to Fatima Ventura (PT) for Thursday 22 of May until the end of the meeting.

Robert Porszasz (HU) gave a proxy vote to Outi Mäki-Ikola (FI) for Thursday 22 of May from 11:30 until the end of the meeting.

14.1.2. CHMP co-opted membership

The 3-year co-opted member mandate for Sol Ruiz comes to an end on 21.07.2025. Her area of expertise is Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies).

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

The election is anticipated at the June 2025 plenary meeting.

Action: For endorsement

The CHMP agreed that a co-opted member should be appointed in the following area of expertise: Quality of biologicals.
A call for nomination was launched following the CHMP plenary meeting.

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 May 2025.

Action: For adoption

The CHMP adopted the EURD list for May 2025.

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at May 2025 PDCO

Action: For information

Agenda of the PDCO meeting held on 20-23 May 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. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 05-08 May 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.

14.3.3. Election of second Scientific Advice Working Party (SAWP) Vice-Chair

Election of second SAWP vice-Chair.

Action: For election

Nomination(s) received

The CHMP elected Ewa Balkowiec Iskra (PL) as second SAWP vice-Chair. The mandate starting date is 20 May 2025.

14.3.4. Election of the Cardiovascular Working Party (CVSWP) Vice-Chair

Election of new CVSWP vice-Chair. The mandate of the CVSWP vice-chair Patrick Vrijlandt expires on 19 May 2025.

Action: For election

Nomination(s) received

The CHMP re-elected Patrick Vrijlandt (NL) as Vice-Chair of the CVSWP. The mandate starting date is 20 May 2025.

14.3.5. Election of the Haematology Working Party (HAEMWP) Chair

Election of new HAEMWP Chair. The mandate of the HAEMWP Chair Daniela Philadelphy expires on 12 June 2025.

Action: For election

Nomination(s) received

The CHMP re-elected Daniela Philadelphy (AT) as Chair of the HAEMWP. The mandate starting date is 13 June 2025.

CVSWP response to the CHMP request

Action: For adoption

The CHMP adopted 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

No items

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

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

Action: For discussion

The CHMP noted the information.

16. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 19-22 May 2025 CHMP meeting, which was held in-person.

An asterisk (*) after the role, in the second column, signals that the member/alternate attended remotely. Additional experts participated in (part of) the meeting, either in person or 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	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Katerina Savvidou	Alternate	Cyprus	No interests declared	
Tomas Radimersky	Member*	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
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 restrictions applicable to this meeting	
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:	9.1.7. BEQVEZ - Fidanacogene elaparvovec - PRIME - ATMP - EMEA/H/C/004774; 10.1.1. Oxbryta -

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				Voxelotor - EMEA/H/A-20/1538/C/004869/0014; 4.3.1. Saphnelo - Anifrolumab - EMEA/H/C/004975/X/0023; 5.1.5. Imfinzi - Durvalumab - EMEA/H/C/004771/II/0073; 5.1.8. 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	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Finbarr Leacy	Alternate*	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No restrictions applicable to this meeting	
Elita Poplavska	Member	Latvia	No restrictions applicable to this meeting	
Vilma Petrikaite	Member	Lithuania	No interests declared	
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:	3.3.10. Teplizumab - PRIME - EMEA/H/C/005496; 5.1.4. Dupixent – Dupilumab - EMA/VR/0000248778
John Joseph Borg	Member	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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Fatima Ventura	Member	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	
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	
Pavlína Chladová	Expert	Czech Republic	No interests declared	
Gabriela Burianová	Expert	Czech Republic	No interests declared	
Jeanette McCallion	Expert	Ireland	No interests declared	
Agnieszka Przybyszewska	Expert	Ireland	No restrictions applicable to this meeting	
Doreen Fagan	Expert	Ireland	No interests declared	
Nicole Kavanagh	Expert	Ireland	No interests declared	
Ivona Jukic	Expert	Croatia	No interests declared	
Marija Kristina Josipovic	Expert	Croatia	No interests declared	
Harald Bernsteiner	Expert	Austria	No interests declared	
Maximilian Koblischke	Expert	Austria	No participation in discussion, final deliberations and voting on:	5.1.10. SIRTURO – Bedaquiline - EMA/VR/0000249065; 9.1.3. Tremfya – Guselkumab - EMA/VR/0000257541; 4.1.1. REZOLSTA - Darunavir / Cobicistat - EMEA/H/C/002819/X/0054/G; 5.1.2. Darzalex - Daratumumab -

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				Orphan - EMEA/H/C/004077/II/0077
Ilona Reischl	Expert	Austria	No restrictions applicable to this meeting	
Jenny Lund	Expert	Norway	No participation in discussion, final deliberations and voting on:	3.3.2. Influenza and COVID-19 vaccine - EMEA/H/C/006472
Elisabeth Øya	Expert	Norway	No interests declared	
Anna Mari Lone	Expert	Norway	No restrictions applicable to this meeting	
Julia Katharina Maier	Expert	Germany	No interests declared	
Robert Pollmann	Expert	Germany	No interests declared	
Katja Findeisen	Expert	Germany	No participation in discussion, final deliberations and voting on:	3.1.4. Bomyntra - Denosumab - EMEA/H/C/006269; 3.1.5. Conexxence - Denosumab - EMEA/H/C/006268
Claudia Reichmann	Expert	Germany	No interests declared	
Cornelia Arras-Reiter	Expert	Germany	No interests declared	
Hilke Zander	Expert	Germany	No interests declared	
Sara Tognarelli	Expert	Germany	No participation in discussion, final deliberations and voting on:	3.3.10. Teplizumab - PRIME - EMEA/H/C/005496; 5.1.4. Dupixent – Dupilumab - EMA/VR/0000248778
Jörg Engelbergs	Expert	Germany	No interests declared	
Christian Merz	Expert	Germany	No restrictions applicable to this meeting	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Kinga Nowicka-Matus	Expert	Denmark	No restrictions applicable to this meeting	
Berendina Maria van den Hoorn	Expert	Netherlands	No interests declared	
Anne Torrez Flores	Expert	Netherlands	No interests declared	
Hanneke van der Woude	Expert	Netherlands	No interests declared	
Birgitte Tiesjema	Expert	Netherlands	No interests declared	
Viktoriia Starokozhko	Expert	Netherlands	No restrictions applicable to this meeting	
Taina Mattila	Expert	Netherlands	No interests declared	
Christine Siezen	Expert	Netherlands	No restrictions applicable to this meeting	
Ingrid Schellens	Expert	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Leonoor Wijnans	Expert	Netherlands	No interests declared	
Marc Maliepaard	Expert	Netherlands	No interests declared	
Erich Schneider	Expert	Germany	No restrictions applicable to this meeting	
Jo-Birger Schmeing	Expert	Germany	No interests declared	
Bruna Dekic	Expert	Germany	No interests declared	
Nicolas Beix	Expert	France	No interests declared	
Kuberaka Mariampillai	Expert	France	No interests declared	
Elsa Grangier	Expert	France	No interests declared	
Simona Teodosiu	Expert	France	No interests declared	
Cecile Dop	Expert	France	No interests declared	
Olivier Garinot	Expert	France	No interests declared	
Hafedh Marouani	Expert	France	No interests declared	
Ismail Rafik	Expert	France	No interests declared	
Sophie Teng	Expert	France	No interests declared	
Anissa Benlazar	Expert	France	No interests declared	
Oussama El Mokh	Expert	France	No interests declared	
Mona Kassem-Youssef	Expert	France	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Pierre Demolis	Expert	Iceland	No interests declared	
Linda Trauffler	Expert	Austria	No restrictions applicable to this meeting	
Hilke Zander	Expert	Germany	No interests declared	
André Elferink	Expert	Netherlands	No interests declared	
Cristina Migali	Expert	Italy	No interests declared	
Elina Asikanius	Expert	Finland	No restrictions applicable to this meeting	
Maria Grazia Malpezzi	Expert	Italy	No interests declared	
Stefania Bellino	Expert	Italy	No interests declared	
Juha Kolehmainen	Expert	Finland	No interests declared	
Serena Marchetti	Expert	Netherlands	No restrictions applicable to this meeting	
Michal Zwiewka	Expert	Germany	No interests declared	
Torsten Holm Nielsen	Expert	Denmark	No restrictions applicable to this meeting	
Joerg Zinserling	Expert	Germany	No restrictions applicable to this meeting	
Christoph Furtmann	Expert	Germany	No restrictions applicable to this meeting	
Mário Miguel Coelho da Silva Rosa	Expert	Portugal	No restrictions applicable to this meeting	
Adrien Inoubli	Expert	WHO	No interests declared	
Mateo Prochazka Nunez	Expert	WHO	No interests declared	
Sakeni Hadebe	Expert	Zambia	No interests declared	
Libert Chirinda	Expert	Zimbabwe	No interests declared	
Priscilla Nyambayo	Expert	Zimbabwe	No interests declared	
Bezalel Dumisani Kanhukamwe	Expert	Zimbabwe	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martha Mandale	Expert	Kenya	No interests declared	
Thanathon Promwong	Expert	Thailand	No interests declared	
Victoria Sekiti	Expert	South Africa	No interests declared	
Audrey Chigome	Expert	South Africa	No restrictions applicable to this meeting	
Madira Litedu	Expert	South Africa	No interests declared	
Gladys Zanele Xaba	Expert	South Africa	No restrictions applicable to this meeting	
Mitarya Solomon Louis	Expert	Nigeria	No interests declared	
Adarki Pongri	Expert	Nigeria	No interests declared	
Clemens Mittmann	Expert	Germany	No interests declared	
Sissela Liljeqvist	Expert	Sweden	No restrictions applicable to this meeting	
Kristina Magnusson Lundqvist	Expert	Sweden	No interests declared	
Karin Mathold	Expert	Sweden	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Ana Rita Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Johanna de Groot	Expert	Netherlands	No interests declared	
Ana Maria Imedio	Expert	Spain	No interests declared	
Line Præst Lauridsen	Expert	Denmark	No restrictions applicable to this meeting	
Jens Stegers	Expert	Netherlands	No interests declared	
Robine Donken	Expert	Netherlands	No restrictions applicable to this meeting	
Esther Broekman	Expert	Netherlands	No restrictions applicable to this meeting	
Veera van Wijnen	Expert	Netherlands	No restrictions applicable to this meeting	
A representative from the European Commission attended the meeting				
An observer from Health Canada (Canada) 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)*

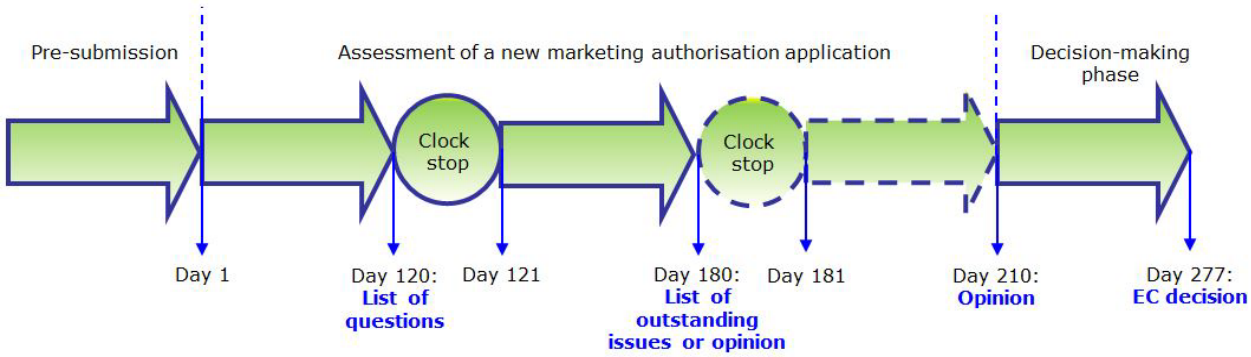
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

22 May 2025
EMA/CHMP/177109/2025

Annex to 19-22 May 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 May 2025: **For adoption**	Adopted

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

Final Outcome of Rapporteurship allocation for May 2025: **For adoption**	Adopted

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

Arsenic trioxide medac - Arsenic trioxide - EMEA/H/C/005218/R/0006 medac Gesellschaft fur klinische Spezialpraparate mbH, Generic of TRISENOX, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Tiphaine Vaillant Opinion adopted on 22.05.2025. Request for Supplementary Information adopted on 27.03.2025.	Positive Opinion adopted by consensus together with the CHMP assessment report. 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.

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 05-08 May 2025 PRAC:	
PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its May 2025 meeting:	
EMEA/H/C/PSUSA/00000954/202409 (denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation

prostate cancer)) CAPS: **Jubbonti** (EMEA/H/C/005964) (Denosumab), Sandoz GmbH, Rapporteur: Christian Gartner **Prolia** (EMEA/H/C/001120) (Denosumab), Amgen Europe B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, "25/09/2021 To: 25/09/2024"	and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to add a warning regarding a reduction in bone mineral density following denosumab discontinuation
EMEA/H/C/PSUSA/00010311/202409 (dulaglutide) CAPS: **Trulicity** (EMEA/H/C/002825) (Dulaglutide), Eli Lilly Nederland B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Amelia Cupelli, "19/09/2021 To: 18/09/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the new ADR "dysgeusia" with frequency uncommon. The Package Leaflet has been updated accordingly.
EMEA/H/C/PSUSA/00010590/202410 (chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosi - centrally authorised products only)) CAPS: **Chenodeoxycholic acid Leadiant** (EMEA/H/C/004061) (Chenodeoxycholic acid), Leadiant GmbH, Rapporteur: Anastasia Mountaki, PRAC Rapporteur: Adam Przybylkowski, "09/10/2023 To: 09/10/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add new adverse reactions jaundice and increased transaminases with frequency unknown. The Package leaflet is updated accordingly
EMEA/H/C/PSUSA/00010703/202410 (axicabtagene ciloleucel) CAPS: **Yescarta** (EMEA/H/C/004480) (Axicabtagene ciloleucel), Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Erneholm, "18/10/2023 To: 17/10/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add haemorrhage with a frequency common. Update of section 4.4 of the SmPC to add a warning/precaution regarding secondary malignancy of myeloid origin. Update of section 4.8 of the SmPC to amend the adverse reaction secondary malignancy of T-cell

	origin with a frequency rare to uncommon. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010724/202409 (abemaciclib) CAPS: **Verzenios** (EMEA/H/C/004302) (Abemaciclib), Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Carla Torre, "29/09/2023 To: 28/09/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section(s) 4.8 of the SmPC to add the adverse reaction Keratitis with a frequency category of uncommon. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010780/202409 (cemiplimab) CAPS: **LIBTAYO** (EMEA/H/C/004844) (Cemiplimab), Regeneron Ireland Designated Activity Company, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Bianca Mulder, "26/09/2022 To: 26/09/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section(s) 4.4 of the SmPC to add a warning / precaution regarding imAEs in patients with pre-existing autoimmune disease. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010868/202410 (ivacaftor / tezacaftor / elexacaftor) CAPS: **Kaftrio** (EMEA/H/C/005269) (Ivacaftor / Tezacaftor / Elexacaftor), Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, "21/04/2024 To: 20/10/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.4 and 4.8 of the SmPC to amend the warning regarding elevated transaminases and hepatic injury and to amend the explanation regarding liver injury under the table of adverse reactions. The Package leaflet is updated accordingly. Update of sections 4.4 and 4.8 of the SmPC to amend the warning regarding depression, to add a warning regarding behavioural changes in paediatric patients and to add the adverse reaction behavioural changes with a frequency not known. The Package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00011027/202410 (loncastuximab tesirine) CAPS: **Zynlonta** (EMEA/H/C/005685) (Loncastuximab tesirine), Swedish Orphan Biovitrum AB (publ), Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Eva Jirsová, "23/04/2024 To: 22/10/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.4 and 4.8 of the SmPC to add sepsis with a frequency common. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00011038/202410 (tremelimumab) CAPS: **IMJUDO** (EMEA/H/C/006016) (Tremelimumab), AstraZeneca AB, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: David Olsen, "21/04/2024 To: 20/10/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.2, 4.4 and 4.8 of the SmPC to add the adverse reaction polymyalgia rheumatica, amend a warning/precaution and a footnote regarding "Other immune-mediated adverse reactions". The Package Leaflet is updated accordingly.

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

EVRA - Ethinylestradiol / Norelgestromin - EMEA/H/C/000410/II/0054 Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt Opinion adopted on 22.05.2025. Request for Supplementary Information adopted on 13.02.2025.	Positive Opinion adopted by consensus on 22.05.2025.
Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0034 Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson Request for Supplementary Information adopted on 22.05.2025, 23.01.2025, 19.09.2024.	Request for supplementary information adopted with a specific timetable.
Recarbrio - Imipenem / Cilastatin / Relebactam -	Positive Opinion adopted by consensus on

EMEA/H/C/004808/II/0035/G Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson Opinion adopted on 22.05.2025. Request for Supplementary Information adopted on 23.01.2025, 19.09.2024.	22.05.2025.
Roclanda - Latanoprost / Netarsudil - EMEA/H/C/005107/II/0031/G Santen Oy, Rapporteur: Jayne Crowe Opinion adopted on 15.05.2025. Request for Supplementary Information adopted on 03.04.2025, 13.02.2025.	Positive Opinion adopted by consensus on 15.05.2025.
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0054/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy Opinion adopted on 22.05.2025. Request for Supplementary Information adopted on 13.03.2025.	Positive Opinion adopted by consensus on 22.05.2025.
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0056/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 22.05.2025, 27.03.2025.	Request for supplementary information adopted with a specific timetable.
VEYVONDI - Vonicog alfa - EMEA/H/C/004454/II/0036/G Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 15.05.2025, 05.12.2024.	Request for supplementary information adopted with a specific timetable.
WS2780 **Riltrava Aerosphere- EMEA/H/C/005311/WS2780/0017** **Trixeo Aerosphere- EMEA/H/C/004983/WS2780/0024** AstraZeneca AB, Lead Rapporteur: Finbarr Leacy, Lead PRAC Rapporteur: Jan Neuhauser Request for Supplementary Information adopted on 22.05.2025, 30.01.2025.	Request for supplementary information adopted with a specific timetable.
WS2789 **Ervebo-EMEA/H/C/004554/WS2789/0039** **Gardasil- EMEA/H/C/000703/WS2789/0109** **Gardasil 9- EMEA/H/C/003852/WS2789/0078** **HBVAXPRO-**	Positive Opinion adopted by consensus on 08.05.2025.

EMEA/H/C/000373/WS2789/0082 **M-M-RvaxPro-** **EMEA/H/C/000604/WS2789/0130** **ProQuad-** **EMEA/H/C/000622/WS2789/0171** **Vaxneuvance-** **EMEA/H/C/005477/WS2789/0028** Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 06.02.2025.	
WS2805/G **Celldemic-** **EMEA/H/C/006052/WS2805/0003/G** **Incellipan-** **EMEA/H/C/006051/WS2805/0003/G** Seqirus Netherlands B.V., Lead Rapporteur: Daniela Philadelphy Opinion adopted on 15.05.2025. Request for Supplementary Information adopted on 20.02.2025.	Positive Opinion adopted by consensus on 15.05.2025.

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

AQUIPTA - Atogepant - **EMEA/H/C/005871/II/0008** AbbVie Deutschland GmbH & Co. KG, Rapporteur: Janet Koenig, "Update of section 4.6 and 5.2 of the SmPC in order to amend information on pregnancy and lactation based on data from study M22-394; this is a phase 1 lactation study to evaluate the pharmacokinetics and safety of ubrogepant and atogepant in healthy adult lactating female subjects one to six months post-partum. The Package Leaflet is updated accordingly." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 13.03.2025.	Positive Opinion adopted by consensus on 08.05.2025.
Dovprela - Pretomanid - **EMEA/H/C/005167/II/0022, Orphan** Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson, "Update of section 4.2 of the SmPC in order to add clarifications on administration instructions based on post marketing data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement an editorial correction to section 5.1	Request for supplementary information adopted with a specific timetable.

of the SmPC." Request for Supplementary Information adopted on 22.05.2025, 14.11.2024.	
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0059/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "A grouped application consisting of: C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information with albendazole based on the post-marketing data and literature and to update information on drug-drug interactions with methadone and ethinyl estradiol based on the literature; the Package Leaflet is updated accordingly. C.I.4: Update of section 4.5 of the SmPC in order to update information on drug-drug interactions with calcium channel antagonists based on the cumulative safety data and literature." Request for Supplementary Information adopted on 15.05.2025, 23.01.2025.	Request for supplementary information adopted with a specific timetable.
Skytrofa - Lonapegsomatropin - EMEA/H/C/005367/II/0036, Orphan Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt, "Update of section 5.1 of the SmPC in order to update efficacy and safety information following the request by CHMP in the outcome for procedure EMEA/H/C/005367/P46/003.1 based on final results from the paediatric study CT-301EXT (enliGHten). In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4." Opinion adopted on 22.05.2025. Request for Supplementary Information adopted on 13.03.2025.	Positive Opinion adopted by consensus on 22.05.2025.
WS2758 Vfend-EMEA/H/C/000387/WS2758/0155 Pfizer Europe MA EEIG, Lead Rapporteur: Patrick Vrijlandt, "Update of section 4.3 and 4.5 of the SmPC in order to add a contraindication for concomitant use with finerenone. The Package Leaflet is updated accordingly. In addition, changes to section 4.5 of the SmPC and other editorial changes to the PI were implemented, as well as updates to the list of local representatives in the Package Leaflet." Opinion adopted on 22.05.2025. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 22.05.2025.

on 30.01.2025.	
WS2793 **Braftovi-** **EMEA/H/C/004580/WS2793/0042** **Mektovi-** **EMEA/H/C/004579/WS2793/0036** Pierre Fabre Medicament, Lead Rapporteur: Janet Koenig, "Submission of the final report from study C4221004, aiming at investigating the potential associations between baseline tumour biomarkers and treatment outcome in the 2-part Phase III Randomized, Open Label, Multicentre Study of LGX818 Plus MEK162 Versus Vemurafenib and LGX818 Monotherapy in Patients with Unresectable or Metastatic BRAF V600 Mutant Melanoma (COLUMBUS study)." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 13.03.2025.	Positive Opinion adopted by consensus on 08.05.2025.
WS2818 **PecFent-** **EMEA/H/C/001164/WS2818/0062** Gruenenthal GmbH, Lead Rapporteur: Janet Koenig, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information between opioids and anticholinergics; the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 15.05.2025, 13.03.2025.	Request for supplementary information adopted with a specific timetable.

B.5.3. CHMP-PRAC assessed procedures

ASPAVELI - Pegcetacoplan - **EMEA/H/C/005553/II/0028, Orphan** Swedish Orphan Biovitrum AB (publ), Rapporteur: Alexandre Moreau, PRAC Rapporteur: Kimmo Jaakkola, "Update of section 4.8 of the SmPC in order to add urticaria/hives to the list of adverse drug reactions (ADRs) with frequency "common" based on post-marketing data and literature; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 08.05.2025.
Cufence - Trientine - **EMEA/H/C/004111/II/0020** Univar Solutions BV, Rapporteur: Daniela	Positive Opinion adopted by consensus on 08.05.2025.

Philadelphy, PRAC Rapporteur: Ana Sofia Diniz Martins, "Update of section 4.2 of the SmPC, Annex II and the RMP based on the submission of the PK/PD sub-study report for study UNV-TR-004 (UNITED) listed as a PAES in the Annex II of the Product Information. This is an open label, prospective study to characterize the pharmacokinetics and pharmacodynamics of Cufence and to investigate the efficacy and safety in Wilson's disease." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 28.11.2024.	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0096/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Gabriele Maurer Opinion adopted on 22.05.2025. Request for Supplementary Information adopted on 25.04.2025, 13.02.2025.	Positive Opinion adopted by consensus on 22.05.2025.
Pluvicto - Lutetium (177Lu) vipivotide tetraxetan - EMEA/H/C/005483/II/0022 Novartis Europharm Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: John Joseph Borg, "Update of section 4.8 of the SmPC in order to update safety information based on final results from study PSMA-617-01 (CAAA617A12301 – VISION) listed as a category 3 study in the RMP; this is an international, prospective, open-label, multicenter, randomized Phase 3 study of 177Lu-PSMA-617 in the treatment of patients with progressive PSMA-positive metastatic castration-resistant prostate cancer. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 08.05.2025.
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	Request for supplementary information adopted with a specific timetable.

updated accordingly. An updated RMP version 18 was provided as part of the application." Request for Supplementary Information adopted on 08.05.2025, 16.01.2025.	
Rozlytrek - Entrectinib - EMEA/H/C/004936/II/0025 Roche Registration GmbH, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder, "Submission of the final integrated analysis report for bone biomarkers based on GO40782 [STARTRK-2], CO40778 [STARTRK-NG], and BO41932 [TAPISTRY] studies (PAESs). The RMP version 6 has also been submitted." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 13.03.2025.	Positive Opinion adopted by consensus on 08.05.2025.
SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0052 Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of section 4.2 of the SmPC in order to update the posology recommendations by removing the current recommendation of a maximum of four implants per year, based on a literature review and analysis of safety data. The Package Leaflet is updated accordingly. The RMP version 9.8 has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial change to the Product Information." Request for Supplementary Information adopted on 22.05.2025, 27.02.2025, 14.11.2024, 30.05.2024.	Request for supplementary information adopted with a specific timetable. See 9.1
Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0022/G Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, PRAC Rapporteur: Ana Sofia Diniz Martins, "Grouping of two type II variations: - Update of section 5.1 of the SmPC to include efficacy and resistance data based on Week 156 interim data from Study GS-US-200-4625; a phase 2/3 study to evaluate the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with an optimized background regimen in heavily treatment experienced people living with HIV-1 infection with multidrug resistance (category 3 study in the RMP). Additionally, upon request by the	Positive Opinion adopted by consensus on 08.05.2025.

CHMP following the assessment of II/0013, the MAH proposes to update section 4.8 of the SmPC to include information related to injection site nodules and induration that were non-resolved at the end of follow-up. Section 4.4 of the SmPC and the patient information leaflet were also updated to include a warning about the potential for slow or non-resolving injection site nodules and indurations. - Provision of the final study report of Study GS-US-200-4334: a phase 2 randomized, open label, active controlled study evaluating the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with other antiretroviral agents in people living with HIV (category 3 study in the RMP). The MAH submitted an updated RMP (version 2.2) which included removal of two Category 3 studies (GS-US-200-4625 and GS-US-200-4334) from the Pharmacovigilance Plan and removal of "Long-term safety information" as a safety concern (missing information). " Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 10.04.2025, 13.03.2025, 16.01.2025.	
Sunosi - Solriamfetol - EMEA/H/C/004893/II/0026 Atnahs Pharma Netherlands B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Julia Pallos, "Update of sections 4.6 and 5.2 of the SmPC in order to update information on lactation and breast-feeding based on results from the post-marketing lactation study JZP110-401 listed as a category 3 study in the RMP. This was a Phase 4, open-label, single-dose study to evaluate the PK of solriamfetol in the breast milk and plasma of healthy postpartum women following oral administration of a 150 mg solriamfetol tablet. The Package Leaflet is updated accordingly. The RMP version 1.3 has also been submitted." Request for Supplementary Information adopted on 08.05.2025.	Request for supplementary information adopted with a specific timetable.
Tysabri - Natalizumab - EMEA/H/C/000603/II/0150 Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2 and 4.4 of the SmPC in order to modify administration instructions to add the option for self-administration or administration by a caregiver	Positive Opinion adopted by consensus on 22.05.2025.

and to update educational guidance, based on supportive data including final results from study 101MS330; this is a Single-Arm, Open-Label, Phase 3 Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Multiple Doses of Natalizumab Administered to Japanese Participants With Relapsing-Remitting Multiple Sclerosis via a Subcutaneous Route of Administration. The Annex II, Labelling and Package Leaflet are updated accordingly. The RMP version 32.1 has also been submitted." Opinion adopted on 22.05.2025. Request for Supplementary Information adopted on 27.03.2025.	
Vabysmo - Faricimab - EMEA/H/C/005642/II/0016 Roche Registration GmbH, Rapporteur: Jayne Crowe, PRAC Rapporteur: Carla Torre, "Update of section 5.1 of the Summary of Product Characteristics (SmPC) to reflect the long-term safety profile of faricimab in patients with diabetic macular oedema (DME) based on the final results from study GR41987 (Rhone-X), listed as category 3 study in the Risk Management Plan (RMP). Rhone-X was a phase III interventional, multicentre, open-label extension study to evaluate the long-term safety and tolerability of faricimab in patients with DME. In addition, SmPC section 4.4 and the package leaflet (PL) were updated to highlight information about the educational material (a guide to ensure awareness of signs and symptoms of intraocular inflammation and endophthalmitis and actions to take) provided to the patient / career by the prescriber. The MAH took also the opportunity to introduce other minor (administrative) changes, in both SmPC and PL. The RMP version 7.1 was also approved." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 08.05.2025.
Xenpozyme - Olipudase alfa - EMEA/H/C/004850/II/0012/G, Orphan Sanofi B.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "A grouped application consisting of: C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information	Positive Opinion adopted by consensus on 08.05.2025.

based on final results from study DFI12712 ASCEND, listed as a category 3 study in the RMP; this is a Phase 2/3, multicentre, randomised, double-blinded, placebo-controlled, repeat-dose study to evaluate the efficacy, safety, pharmacodynamics and pharmacokinetics of olipudase alfa in patients with AMSD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the SmPC. C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study LTS13632 listed as a category 3 study in the RMP; this is a long-term study the ongoing safety and efficacy of olipudase alfa in patients with ASMD. The Package Leaflet is updated accordingly. The RMP version 3.3 has also been submitted." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 10.04.2025, 16.01.2025, 31.10.2024.	
WS2798 **Nilemdo-** **EMEA/H/C/004958/WS2798/0045** **Nustendi-** **EMEA/H/C/004959/WS2798/0050** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Patrick Vrijlandt, Lead PRAC Rapporteur: Kimmo Jaakkola, "Update of sections 4.2, 4.4, and 5.2 of the SmPC in order to amend information concerning renal impairment based on the final results from Study 1002-071 listed as a category 3 study in the RMP; this is a phase 1, open-label, single-dose study to evaluate the pharmacokinetics of bempedoic acid in healthy subjects with normal renal function and subjects with end-stage renal disease receiving HD; the Package Leaflet is updated accordingly. The RMP version 7.0 has also been submitted." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 13.02.2025.	Positive Opinion adopted by consensus on 08.05.2025.

B.5.4. PRAC assessed procedures

PRAC Led **Cinryze - C1 ESTERASE INHIBITOR**	Positive Opinion adopted by consensus on

(HUMAN) - EMEA/H/C/001207/II/0104 Takeda Manufacturing Austria AG, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of sections 4.6, 5.1 and 5.3 of the SmPC based on final results from the Icatibant Outcome Survey (IOS), listed as an imposed PASS in the Annex II. This is a prospective, observational disease registry. The Package Leaflet is updated accordingly. The RMP version 11.2 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 product information in line with the latest QRD template version 10.4 and to update Annex II of the PI." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 13.02.2025.	08.05.2025.
PRAC Led **EXJADE - Deferasirox - EMEA/H/C/000670/II/0090** Novartis Europharm Limited, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Update of section 4.2 of the SmPC in order to update information on posology based on the non-interventional study CICL670A2429 listed as a category 3 study in the RMP. This is a survey to assess physicians' knowledge of Exjade posology and biological monitoring recommendations as described in the Educational Materials (EMs)." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 10.04.2025, 28.11.2024.	Positive Opinion adopted by consensus on 08.05.2025.
PRAC Led **Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/II/0055, Orphan** Vertex Pharmaceuticals (Ireland) Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of section 4.6 of the SmPC in order to amend the existing wording on exposure during pregnancy following PSUR procedure (EMEA/H/C/PSUSA/00010868/202310)." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 16.01.2025, 31.10.2024.	Positive Opinion adopted by consensus on 08.05.2025.

PRAC Led **TachoSil - Human thrombin / Human fibrinogen - EMEA/H/C/000505/II/0131** Corza Medical GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 4.2 of the SmPC to emphasise correct product handling and section 4.8 of the SmPC to reflect the fact that cases of product non-adhesion issues have been reported, upon request by PRAC following the outcome of the PSUR procedure EMEA/H/C/PSUSA/00010297/202306. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 28.11.2024.	Positive Opinion adopted by consensus on 08.05.2025.
PRAC Led **Zometa - Zoledronic acid - EMEA/H/C/000336/II/0104** Phoenix Labs Unlimited Company, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of an updated RMP version 12.2 in order to update the list of safety concerns and missing information as per the guidance provided in the GVP V–Rev.2 and PSUSA/3149/202308." Opinion adopted on 08.05.2025. Request for Supplementary Information adopted on 10.04.2025.	Positive Opinion adopted by consensus on 08.05.2025.

B.5.5. CHMP-CAT assessed procedures

Yescarta - Axicabtagene ciloleucel - EMEA/H/C/004480/II/0085, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, "Submission of the final report from study KT-US-482-0147 (ZUMA-26). This is a Prospective, Noninterventional, Clinical Efficacy Study Investigating and Analyzing the Impact of Tumor Cd19 Antigen Expression and Density on Response to Axicabtagene Ciloleucel Treatment Using a Quantitative Flow Cytometry Method." Opinion adopted on 22.05.2025, 16.05.2025. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 22.05.2025.

on 21.02.2025.

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

PRAC Led **WS2771** **Tecartus-** **EMEA/H/C/005102/WS2771/0054** **Yescarta-** **EMEA/H/C/004480/WS2771/0084** Kite Pharma EU B.V., Lead PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Boje Kvorning Pires Ehmsen, "Submission of an updated RMP version 4.3 for Tecartus and version 11.1 for Yescarta following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040), and of a PASS protocol for a framework for the sampling and testing of secondary malignancies of T-cell origin." Request for Supplementary Information adopted on 16.05.2025, 24.01.2025.	Request for supplementary information adopted with a specific timetable.

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

The information on Marketing authorisation applications under review including a summary of the therapeutic indication applied for by the applicant, will continue be published on the EMA website (under this page). As of February, The EMA will also start publishing on the same EMA webpage information on the start of the procedures for extension applications and for Type II variation that propose an extension of the authorised indication, which have been submitted and started in IRIS in 2025. This information will be published the week following the CHMP plenary.

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.