25 April 2025
EMA/CHMP/157675/2025

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 22-25 April 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).

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

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

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

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

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

CHMP agenda for 22-25 April 2025

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 24-27 February 2025.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 14 April 2025.

The CHMP adopted the minutes of the 24-27 February 2025 meeting.

The CHMP adopted the minutes from the PROM meeting held on 14 April 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Atropine - PUMA - EMEA/H/C/006385

treatment of myopia in children aged 3 years and older

Scope: Oral explanation

Action: Oral explanation to be held on 23 April 2025 at 16:00

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

An oral explanation was held on 23 April 2025. The presentation by the applicant focused on the clinical data in support of the application.

2.1.2. Inavolisib - EMEA/H/C/006353

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: Oral explanation

Action: Oral explanation to be held on 24 April 2025 at 16:00

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

An oral explanation was held on 24 April 2025. The presentation by the applicant focused on the clinical data in support of the application.

2.1.3. Nirogacestat - Orphan - EMEA/H/C/006071

Springworks Therapeutics Ireland Limited; treatment of desmoid tumours

Scope: Oral explanation

Action: Oral explanation to be held on 22 April 2025 at 16:00

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

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

See 3.2

2.1.4. Teriparatide - EMEA/H/C/005687

treatment of osteoporosis

Scope: Oral explanation

Action: Oral explanation to be held on 23 April 2025 at 09:00

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

An oral explanation was held on 23 April 2025. The presentation by the applicant focused on the clinical data in support of the application.

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. Alyftrek - Deutivacaftor / Tezacaftor / Vanzacaftor - Orphan - EMEA/H/C/006382

Vertex Pharmaceuticals (Ireland) Limited; indicated for the treatment of cystic fibrosis

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 consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that deutivacaftor/tezacaftor/vanzacaftor is a new active substance.

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

The CHMP adopted the similarity assessment report

3.1.2. Attrogy Diflunisal - Orphan - EMEA/H/C/006248

AO Pharma AB; Treatment of ATTR amyloidosis

Scope: Opinion

Action: For adoption

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

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

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 CHMP noted the letter of recommendation dated 25 April 2025.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

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

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

Scope: Opinion

Action: For adoption

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

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

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.

3.1.4. Denbrayce - Denosumab - EMEA/H/C/006199

Mabxience Research S.L.; prevention of skeletal related events in adults with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 27.02.2025. 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 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. Denosumab BBL - Denosumab - EMEA/H/C/006526

Biosimilar Collaborations Ireland Limited; 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 12.12.2024.

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

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

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

The CHMP noted the letter of recommendation dated 15 April 2025.

The summary of opinion was circulated for information.

3.1.6. Duvyzat - Givinostat - Orphan - EMEA/H/C/006079

Italfarmaco S.p.A.; treatment of Duchenne muscular dystrophy (DMD)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 12.12.2024, 19.09.2024. List of Questions adopted on 14.12.2023.

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 majority (19 out of 30 votes) together with the CHMP assessment report and translation timetable.

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

The divergent position (Daniela Phladelphy, Bruno Delafont, Blanka Hirschlerova, Thalia Marie Estrup Blicher, Outi Maki-Ikola, Jean-Michel Race, Jayne Crowe, Elita Poplavska, Peter Mol, Kristina Dunder, Tomas Radimersky) was appended to the opinion.

The CHMP endorsed the EMA press release.

3.1.7. Enwylma - Denosumab - EMEA/H/C/006376

Zentiva k.s.; prevention of skeletal related events in adults with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 27.02.2025. 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 consensus together with the CHMP assessment report and translation timetable.

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

The CHMP noted the letter of recommendation dated 10 April 2025.

The summary of opinion was circulated for information.

3.1.8. Izamby - Denosumab - EMEA/H/C/006152

Mabxience Research S.L.; for the 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 27.02.2025. 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 consensus together with the CHMP assessment report and translation timetable.

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

The CHMP noted the letter of recommendation dated 10 April 2025.

The summary of opinion was circulated for information.

3.1.9. Junod - Denosumab - EMEA/H/C/006436

Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.); 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 Questions adopted on 14.11.2024.

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

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

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

The summary of opinion was circulated for information.

3.1.10. Oczyesa - Octreotide - Orphan - EMEA/H/C/006322

Camurus AB; treatment of acromegaly

Scope: Opinion

Action: For adoption

Hybrid application (Article 10(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 consensus together with the CHMP assessment report and translation timetable.

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.11. Sephience - Sepiapterin - Orphan - EMEA/H/C/006331

PTC Therapeutics International Limited; treatment of hyperphenylalaninemia (HPA) in adult and paediatric patients with phenylketonuria (PKU)

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 consensus together with the CHMP assessment report and translation timetable.

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.12. Tepezza - Teprotumumab - EMEA/H/C/006396

Amgen Europe B.V.; treatment of moderate to severe Thyroid Eye Disease (TED).

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 consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that teprotumumab 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 endorsed the EMA press release.

3.1.13. Vevzuo - Denosumab - EMEA/H/C/006534

Biosimilar Collaborations Ireland Limited; 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 12.12.2024.

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

The Committee adopted a positive opinion recommending the granting of a marketing

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

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

The CHMP noted the letter of recommendation dated 15 April 2025.

The summary of opinion was circulated for information.

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

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

Scope: Opinion

Action: For adoption

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

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

The grounds for refusal were adopted via written procedure on 28.04.2025.

3.1.15. Yaxwer - Denosumab - EMEA/H/C/006437

Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.); 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 Questions adopted on 14.11.2024.

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

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

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

The summary of opinion was circulated for information.

3.1.16. Zadenvi - Denosumab - EMEA/H/C/006377

Zentiva k.s.; for the 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 27.02.2025. 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 consensus together with the CHMP assessment report and translation timetable.

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

The CHMP noted the letter of recommendation dated 10 April 2025.

The summary of opinion was circulated for information.

3.1.17. Ziihera - Zanidatamab - Orphan - EMEA/H/C/006380

Jazz Pharmaceuticals Ireland Limited; Treatment of biliary tract 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 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 conditional marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

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

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

The CHMP noted the letter of recommendation dated 16 April 2025.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

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

3.2.1. Aflibercept - EMEA/H/C/006438

treatment of age-related macular degeneration (AMD) and visual impairment

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.

3.2.2. Aflibercept - EMEA/H/C/006761

treatment of age-related macular degeneration (AMD) and visual impairment

Scope: List of outstanding issues

Action: For adoption

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

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

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

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

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. 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 2nd list of outstanding issues with a specific timetable.

3.2.4. Belantamab mafodotin - Orphan - EMEA/H/C/006511

Glaxosmithkline Trading Services Limited; treatment of multiple myeloma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

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

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

Scope: List of outstanding issues; Letter by the applicant dated 08.04.2023 requesting an

extension to the responses to the list of outstanding issues which will be adopted in October 2024.

Action: For information

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

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

The CHMP did not agree to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in April 2025.

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

3.2.6. Emtricitabine / Rilpivirine / Tenofovir alafenamide - EMEA/H/C/006491

treatment of HIV-1

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

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.

3.2.7. Aflibercept - EMEA/H/C/006282

treatment of age-related macular degeneration (AMD) and visual impairment

Scope: List of outstanding issues; Letter by the applicant dated 11.04.2023 requesting an extension to the responses to the list of outstanding issues which will be adopted in November 2024.

Action: For adoption

List of Questions adopted on 14.11.2024.

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

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 2024.

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

3.2.8. Mirdametinib - Orphan - EMEA/H/C/006460

Springworks Therapeutics Ireland Limited; treatment of neurofibromatosis type 1

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.

3.2.9. 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

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

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.

3.2.10. Macitentan - EMEA/H/C/006524

treatment of pulmonary arterial hypertension (PAH)

Scope: List of outstanding issues; Letter by the applicant dated 22.04.2025 requesting an extension to the responses to the list of outstanding issues which will be adopted in September 2024.

Action: For adoption

List of Questions adopted on 19.09.2024.

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

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 September 2024.

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

3.2.11. Macitentan - EMEA/H/C/006523

treatment of pulmonary arterial hypertension (PAH)

Scope: List of outstanding issues; Letter by the applicant dated 22.04.2025 requesting an extension to the responses to the list of outstanding issues which will be adopted in September 2024.

Action: For adoption

List of Questions adopted on 19.09.2024.

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

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 September 2024.

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

3.2.12. Nintedanib - EMEA/H/C/006486

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

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.

3.2.13. Nirogacestat - Orphan - EMEA/H/C/006071

Springworks Therapeutics Ireland Limited; treatment of desmoid tumours

Scope: List of outstanding issues

Action: For adoption

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

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

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

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

See 2.1

3.2.14. Vimseltinib - Orphan - EMEA/H/C/006363

Deciphera Pharmaceuticals (Netherlands) B.V.; Treatment of adult patients with tenosynovial giant cell tumour (TGCT) who are not amenable to surgery

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

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

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.

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

3.2.15. Ustekinumab - EMEA/H/C/006467

treatment of plaque psoriasis, arthritis psoriatic, Crohn's Disease and ulcerative colitis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.11.2024.

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

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

Scope: List of questions

Action: For information

The CHMP was updated on the discussions at the CAT. The Committee discussed the issues identified in this application.

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

3.3.2. Blarcamesine - EMEA/H/C/006475

treatment of Alzheimer's disease and dementia

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.3. Donidalorsen - Orphan - EMEA/H/C/006554

Otsuka Pharmaceutical Netherlands B.V.; for routine prevention of recurrent attacks of hereditary angioedema (HAE)

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. Iloperidone - EMEA/H/C/006561

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

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. Germanium (68Ge) chloride / Gallium (68Ga) chloride - EMEA/H/C/006639

indicated for in vitro radiolabelling of specific carrier molecules to be used for positron emission tomography (PET) imaging

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

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

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. Imlunestrant - EMEA/H/C/006184

treatment of adult patients with advanced or metastatic breast cancer

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.8. mRNA-1283 - EMEA/H/C/006428

Active immunisation to prevent COVID 19 caused by SARS-CoV-2 in individuals 12 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.

3.3.9. Aficamten - EMEA/H/C/006228

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

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. Denosumab - EMEA/H/C/006492

Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, treatment of bone loss associated with hormone ablation in men with prostate cancer and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients.

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.

3.3.11. Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human Wiskott-Aldrich syndrome protein - Orphan - ATMP - EMEA/H/C/006525

Fondazione Telethon Ets; treatment of patients with Wiskott-Aldrich Syndrome (WAS)

Scope: List of questions; Letter by the applicant dated 22.04.2025 requesting an extension.

Action: For information

The CHMP was updated on the discussions at the CAT. The Committee discussed the issues identified in this application.

The CHMP agreed to the request by the applicant for a clock stop.

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

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

3.4.1. ACELLULAR PERTUSSIS VACCINE - EMEA/H/C/006304

indicated as active booster immunization against pertussis of persons aged 11 years onwards and passive protection against pertussis in early infancy following maternal immunization during pregnancy

Scope: Request by the applicant for an extension to the clock stop to respond to the list of questions adopted in November 2024.

Action: For adoption

List of Questions adopted on 14.11.2024.

The CHMP did not agree to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in November 2024.

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

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

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

Scope: Appointment of re-examination rapporteurs.

Action: For adoption

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

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

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

4.1.1. Adempas - Riociguat - EMEA/H/C/002737/X/0041

Bayer AG;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (0.15 mg/ml granules for oral suspension) for the Pulmonary arterial hypertension (PAH) paediatric indication. As a consequence, update of the indication to include dosing in children with PAH aged 6 to less than 18 years with bodyweight < 50 kg. Furthermore, the film coated tablets presentations are updated to accommodate the new pharmaceutical form. In addition, contact details for local representatives of Belgium, Luxembourg, Greece and Ireland, have also been updated."

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. 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.

The CHMP adopted the similarity assessment report.

4.1.2. Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/X/0033/G

Bayer AG;

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

Scope: "Extension application to add a new strength of Jivi 4000 UI powder and solvent for solution for injection for treatment and prophylaxis of bleeding in previously treated patients ≥ 12 years of age with haemophilia A (congenital factor VIII deficiency).

Version 3.1 of the RMP has also been submitted.

In addition, the MAH has taken the opportunity to align the product information with the pre-specified language from the updated EC Excipient Guideline.

Action: For adoption

List of Questions 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 CHMP adopted the similarity assessment report.

The summary of opinion was circulated for information.

4.1.3. Talzenna - Talazoparib - EMEA/H/C/004674/X/0022

Pfizer Europe MA EEIG

Rapporteur: Filip Josephson

Scope: "Extension application to add new strengths of 0.35 mg and 0.5 mg hard capsules. Furthermore, the PI is being brought in line with the QRD template version 10.4."

Action: For adoption

List of Questions adopted on 27.02.2025.

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

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

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

BeiGene Ireland Ltd;

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

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

Action: For adoption

List of Questions adopted on 14.11.2024.

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

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

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

4.3.1. Koselugo - Selumetinib - Orphan - EMEA/H/C/005244/X/0018/G

AstraZeneca AB;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

Scope: "Extension application to introduce a new pharmaceutical form (Granules in capsules for opening) associated with new strengths (5 mg and 7.5 mg capsule) grouped with a Type II variation (C.I.4) to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to align the SmPC and labelling of Koselugo capsules and Koselugo granules in capsules for opening. The Package Leaflet and Labelling are updated accordingly. The RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

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

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

4.3.2. 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."

Action: For adoption

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

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

4.3.3. Remsima - Infliximab - EMEA/H/C/002576/X/0149

Celltrion Healthcare Hungary Kft.;

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension application to introduce a new pharmaceutical form (concentrate for solution for infusion) associated with a new strength (40 mg/ml)."

Action: For adoption

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

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

4.3.4. Spinraza - Nusinersen - Orphan - EMEA/H/C/004312/X/0038

Biogen Netherlands B.V.;

Rapporteur: Fátima Ventura, PRAC Rapporteur: Karin Bolin

Scope: "Extension application to add a new strength of 28 mg and 50 mg.
The RMP (version 12.x) is updated in accordance (version 12.2 is under assessment in procedure EMEA/H/C/004312/II/0034/G)."

Action: For adoption

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

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

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

No items

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

No items

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

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

5.1.1. ADCETRIS - Brentuximab vedotin - EMEA/H/C/002455/II/0111

Takeda Pharma A/S;

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

Scope: "Extension of indication for ADCETRIS to include treatment for adult patients with previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone (BrECADD), based on final results from phase 3 study HD21 (NCT02661503). This study is

titled Treatment Optimization Trial in the First-Line Treatment of Advanced-Stage Hodgkin Lymphoma; Comparison of 4-6 Cycles of Escalated BEACOPP With 4-6 Cycles of BrECADD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 20.0 of the RMP has also been submitted.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024, 25.07.2024.

The Committee discussed the issues identified in this application.

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

The summary of opinion was circulated for information.

5.1.2. Alhemo – Concizumab - EMA/VR/0000244862

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt; Co-Rapporteur: Daniela Philadelphy

Scope: Extension of indication to include treatment of haemophilia A without inhibitors and haemophilia B without inhibitors for ALHEMO based on final results from study NN7415-4307; this is an interventional study to investigate efficacy and safety of concizumab prophylaxis in patients with haemophilia A or B without inhibitors. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to 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.

5.1.3. Amvuttra - Vutrisiran - Orphan - EMEA/H/C/005852/II/0015

Alnylam Netherlands B.V.;

Rapporteur: Janet Koenig, Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include treatment of wild-type or hereditary transthyretin-mediated amyloidosis in adult patients with cardiomyopathy (ATTR-CM), based on primary analysis results from study HELIOS-B (ALN-TTRSC02-003); a Phase 3, Randomized, Double-blind, Placebo-controlled, Multicentre Study to Evaluate the Efficacy and Safety of Vutrisiran in Patients With Transthyretin Amyloidosis With Cardiomyopathy (ATTR Amyloidosis With Cardiomyopathy). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. An updated version 1.3 of the RMP has also been submitted.", Request for

1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

The Committee discussed the issues identified in this application.

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

5.1.4. BAQSIMI – Glucagon - EMA/VR/0000244909

Amphastar France Pharmaceuticals;

Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Eamon O Murchu

Scope: Extension of indication to include treatment of severe hypoglycaemia in paediatric patients aged 1 and over with diabetes mellitus for BAQSIMI, based on final results from study I8R-MC-IGBO; this is an Open-Label, Multi-Centre, Single-Dose Study to Assess the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of Nasal Glucagon in Paediatric Patients with Type 1 Diabetes Aged 1 to <4 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 1.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce a correction in the Package Leaflet.

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. Calquence - Acalabrutinib - EMEA/H/C/005299/II/0028

AstraZeneca AB;

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension of indication to include CALQUENCE in combination with venetoclax with or without obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL), based on interim results from study AMPLIFY (D8221C00001). This is a randomised, multicentre, open-label, phase 3 study of acalabrutinib in combination with venetoclax with and without obinutuzumab compared to investigator's choice of chemoimmunotherapy in subjects with previously untreated chronic lymphocytic leukaemia without del(17p) or TP53 Mutation (AMPLIFY). As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.2 of the RMP was also submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

The Committee discussed the issues identified in this application.

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.

5.1.6. Clopidogrel Zentiva - Clopidogrel - EMEA/H/C/000975/II/0092

Zentiva k.s.;

Rapporteur: Fátima Ventura, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include, in combination with acetylsalicylic acid (ASA), patients with ST segment elevation acute myocardial infarction (STEMI) who are undergoing percutaneous coronary intervention (PCI) for CLOPIDOGREL ZENTIVA. As a consequence, sections 4.1, 4.2, 4.4 and 5.1 of the SmPC are updated. Version 0.1 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, introduce minor editorial changes to the PI and bring it in line with the latest QRD template version 10.4."

Action: For adoption

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

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

5.1.7. Cystadrops - Mercaptamine - Orphan - EMEA/H/C/003769/II/0032

Recordati Rare Diseases;

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

Scope: "Extension of indication to include treatment of children from 6 months of age for CYSTADROPS, based on final results from study CYT-C2-001. This is an Open-label, Single-arm, Multicentre Study to Assess the Safety of Cystadrops in Paediatric Cystinosis Patients from 6 Months to Less Than 2 Years Old. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II of the PI and the list of local representatives in the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

The Committee discussed the issues identified in this application.

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.

5.1.8. Gazyvaro – Obinutuzumab - EMA/VR/0000244907

Roche Registration GmbH;

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

Scope: Extension of indication to include treatment of treatment of adult patients with active lupus nephritis who are receiving standard therapy for GAZYVARO, based on results from study Regency (CA41705). This is an ongoing, Phase III, randomized, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of obinutuzumab administered at standard infusion rates in patients with ISN/RPS 2003 Class III or IV lupus nephritis treated with standard-of-care therapy.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.

Action: For adoption

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

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

5.1.9. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/II/0040

Vanda Pharmaceuticals Netherlands B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of nighttime sleep disturbances in adults with Smith Magenis Syndrome (SMS) for HETLIOZ, based on results from study VP-VEC-162-2401. This is a double-blind, randomized, two-period crossover study evaluating the effects of tasimelteon vs. placebo on sleep disturbances of individuals with Smith-Magenis Syndrome (SMS). As a consequence, sections 4.1, 4.5, 5.1, 5.2 and 5.3 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. The RMP version 5.0 has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

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

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

5.1.10. Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0092

Janssen-Cilag International N.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension of indication to include IMBRUVICA in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone (R-CHOP) for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are eligible for

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

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted a request for supplementary information with a specific timetable, relating to clinical aspects.

5.1.11. Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/II/0034

Bayer AG;

Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment and prophylaxis of bleeding in previously treated patients ≥7 years of age with haemophilia A for JIVI, based on integrated analysis results from Part A of the Alfa-PROTECT study (21824) and PROTECT Kids main study (15912). Alfa-PROTECT is a Phase 3, single-group treatment, open-label study to evaluate the safety of BAY 94-9027 infusions for prophylaxis and treatment of bleeding in previously treated children aged 7 to <12 years with severe haemophilia A. PROTECT Kids is a multi-centre, Phase 3, non-controlled, open-label trial to evaluate the pharmacokinetics, safety, and efficacy of BAY 94-9027 for prophylaxis and treatment of bleeding in previously treated children (age <12 years) with severe haemophilia A. 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 3.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 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 CHMP adopted the similarity assessment report.

The summary of opinion was circulated for information.

5.1.12. Keytruda – Pembrolizumab - EMA/VR/0000245108

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include, KEYTRUDA as monotherapy, for the treatment of resectable locally advanced head and neck squamous cell carcinoma (HNSCC) as neoadjuvant treatment, continued as adjuvant treatment in combination with radiation therapy with or without platinum-containing chemotherapy and then as monotherapy in adults, based on the results of study P689V01MK3475 (KEYNOTE-689); this is a Phase 3, randomised, open-label study evaluating pembrolizumab as neoadjuvant therapy and in combination with standard of care as adjuvant therapy for stage III or IVA, resectable, locoregionally advanced head and neck squamous cell carcinoma. Consequently, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 48.1 has also been submitted. In addition, the MAH took the opportunity to introduce some 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.

5.1.13. Koselugo – Selumetinib - EMA/VR/0000245231

AstraZeneca AB;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication for KOSELUGO to include treatment of adults based on results from study D134BC00001 (KOMET). This is a phase III, multicentre, international study with a parallel, randomised, double-blind, placebo-controlled, 2 arm design that assesses efficacy and safety of selumetinib in adult participants with NF1 who have Symptomatic Inoperable Plexiform Neurofibromas.

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 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC. 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 and RMP aspects.

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

5.1.14. Neuraceq - Florbetaben (18F) - EMA/VR/0000227744

Life Molecular Imaging GmbH;

Rapporteur: Antonio Gomez-Outes; PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include monitoring of the biological treatment response to

pharmacological and non-pharmacological interventions for NEURACEQ, based on supporting literature. As a consequence, sections 4.1, 4.4 and 5.1 of the SmPC are updated. The Package Leaflet (PL) is updated in accordance. Version 6.91 of the RMP has also been submitted. In addition, the MAH took the opportunity to include the proposal to discontinue the inclusion of a paper copy of the SmPC with the product package.

Action: For adoption

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

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

5.1.15. Norvir – Ritonavir - EMA/VR/0000249795

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Patrick Vrijlandt; PRAC Rapporteur: Liana Martirosyan

Scope: Type II (C.I.6.a): To modify the approved therapeutic indication to reflect current clinical use as a pharmacokinetic enhancer of other antiretroviral products only. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.8 and 5.1 of the SmPC. The Package Leaflet is updated accordingly. The updated RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

Action: For adoption

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

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

5.1.16. Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0061/G

Pfizer Europe MA EEIG;

Rapporteur: Jean-Michel Race (FR) (MNAT with DE-BfArM for Quality), Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Martin Huber

Scope: "A grouped application comprised of a Type II Variation and a Type IB Variation, as follows:
Type II (C.I.6.a): Extension of indication to include treatment of coronavirus disease 2019 (COVID-19) in paediatric patients 6 years of age and older weighing at least 20 kg for PAXLOVID, based on the final analysis of Cohorts 1 and 2 from pivotal Study C4671026; this is a Phase 2/3, Interventional Safety, Pharmacokinetics, and Efficacy, Open-Label, Multi-Centre, Single-Arm Study to Investigate Orally Administered PF 07321332 (Nirmatrelvir)/Ritonavir in Nonhospitalized Symptomatic Paediatric Participants With COVID-19 Who Are at Risk of Progression to Severe Disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Type IB (B.II.e.5.a.2): To add a new pack-size specific to paediatric patients 6 years and older weighing 20 kg to less than 40 kg and moderate renal impaired patients (EU/1/22/1625/003); the Package Leaflet and Labelling are updated accordingly."

Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

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

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

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

Novartis Europharm Limited;

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

Scope: "Extension of indication to include second-line treatment of paediatric patients aged 2 years and above with acquired severe aplastic anaemia (SAA) for REVOLADE based on the ETB115E2201 (E2201) study primary analysis results; this is a paediatric phase II, open-label, uncontrolled, intra-patient dose escalation study to characterise the pharmacokinetics after oral administration of eltrombopag in paediatric patients with refractory, relapsed severe aplastic anaemia or recurrent aplastic anaemia. 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 56.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

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

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

5.1.18. Simponi - Golimumab - EMEA/H/C/000992/II/0121

Janssen Biologics B.V.;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Karin Bolin

Scope: "Extension of indication to include treatment of paediatric ulcerative colitis for SIMPONI, based on results from study CNTO148UCO3003; this is a Phase 3 Randomized, Open-label Study to Assess the Efficacy, Safety, and Pharmacokinetics of Golimumab Treatment, a Human anti-TNFα Monoclonal Antibody, Administered Subcutaneously in Paediatric Participants with Moderately to Severely Active Ulcerative Colitis; As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. Version 28.1 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. Furthermore, the PI is updated in accordance with the latest EMA excipients guideline and aligned 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.

5.1.19. TEZSPIRE – Tezepelumab - EMA/VR/0000245013

AstraZeneca AB;

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

Scope: Extension of indication to include treatment of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) for Tezspire, based on results from study WAYPOINT (D5242C00001); this is a global, multicentre, randomised, double-blind, parallel-group, placebo-controlled study that evaluated the efficacy and safety of tezepelumab compared with placebo in the treatment of CRSwNP. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to update the PI and the Package Leaflet in accordance with the latest EMA excipients guideline.

Action: For adoption

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

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

5.1.20. Veklury - Remdesivir - EMEA/H/C/005622/II/0053/G

Gilead Sciences Ireland UC;

Rapporteur: Janet Koenig (DE) (MNAT with AT for Quality), PRAC Rapporteur: Eva Jirsová

Scope: " Extension of indication to include treatment of paediatric patients who are at least 4 weeks of age and weighing at least 3 kg who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19 for Veklury, based on final results from study GS-US-540-5823; this is a Phase 2/3 single-arm, open-label study to evaluate the safety, tolerability, pharmacokinetics, and efficacy of remdesivir in participants from birth to < 18 years of age with COVID-19. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10 of the RMP is approved with this variation."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024, 21.03.2024.

The Committee discussed the issues identified in this application.

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.

5.1.21. Vyvgart - Efgartigimod alfa - Orphan - EMEA/H/C/005849/II/0020

Argenx;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension of indication to include the monotherapy treatment of adult patients with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP)

after prior treatment with corticosteroids or immunoglobulins for Vyvgart, based on final results from study ARGX-113-1802; this is a pivotal study to investigate the efficacy, safety and tolerability of efgartigimod PH20 SC in adult patients CIDP; and based on interim results from study ARGX-113-1902; this is an open-label extension study of the ARGX-113-1802 trial to investigate the long-term safety, tolerability and efficacy of efgartigimod PH20 SC in patients with CIDP. 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. RMP is updated to version 3.0 In addition, the MAH took the opportunity to implement editorial changes to the SmPC and to update the list of local representatives in the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 19.09.2024.

The Committee discussed the issues identified in this application.

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.

5.1.22. Xofluza - Baloxavir marboxil - EMEA/H/C/004974/II/0021

Roche Registration GmbH;

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

Scope: "Extension of indication to include treatment of patients aged 3 weeks and above for Xofluza, based on final results from study CP40559 (MiniSTONE-1); this was a global Phase 3, multicentre, single-arm, open-label study to assess the safety, PK, and efficacy of baloxavir marboxil in OwH paediatric patients from birth to < 1 year with influenza-like symptoms. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 27.02.2025, 17.10.2024.

The Committee discussed the issues identified in this application.

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.

5.1.23. Zoonotic Influenza Vaccine Seqirus - Zoonotic influenza vaccine (H5N8) (surface antigen, inactivated, adjuvanted) - EMA/VR/0000249071

Seqirus S.r.l.;

Rapporteur: Maria Grazia Evandri, PRAC Rapporteur: Amelia Cupelli

Scope: Extension of indication to include treatment of individuals 6 months of age and above for Zoonotic Influenza Vaccine Seqirus based on final results from study V87_30. This

is a Phase 2, Randomised, Observer-Blind, Multicentre Study to Evaluate the Immunogenicity and Safety of Several Doses of Antigen and MF59 Adjuvant Content in a Monovalent H5N1 Pandemic Influenza Vaccine in Healthy Paediatric Subjects 6 Months to < 9 Years of Age. As a consequence, sections 4.1, 4.2, 4.6, 4.7, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.1 of the RMP has been approved. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the PI.

The requested variation proposed amendments to the Summary of Product Characteristics, Labelling and Package Leaflet and to the Risk Management Plan (RMP).

Action: For adoption

The Committee discussed the issues identified in this application.

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.

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

6.1.1. Human albumin solution - EMEA/H/D/006540

Ex vivo heart perfusion

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.02.2025. 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.

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

No items

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. Lurbinectedin – H0006673

Lurbinectedin, in combination with atezolizumab, is indicated for the maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) whose disease has not progressed after first-line induction therapy with atezolizumab, carboplatin and etoposide.

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

Action: For adoption

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

8.1.2. Nerandomilast – H0006405

is indicated for the treatment of adult patients with Idiopathic Pulmonary Fibrosis (IPF) and for the treatment of adult patients with Progressive Pulmonary Fibrosis (PPF).

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.

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Extavia (SRD) - Interferon beta-1B – EMEA/H/C/000933

Novartis Europharm Limited; treatment of single demyelinating events and multiple sclerosis

Rapporteur: Janet Koenig, Co-Rapporteur: Elita Poplavska

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of marketing authorisation.

9.1.2. Eylea – Aflibercept - EMA/VR/0000249440

Bayer AG;

Rapporteur: Jean-Michel Race

Scope: Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update the posology recommendations for indications nAMD and DME and update clinical information based on the final week 156 results from studies PULSAR and PHOTON. PULSAR (20968) was a pivotal Phase 3 study to investigate the efficacy and safety of high dose aflibercept in patients with neovascular age-related macular degeneration (nAMD). PHOTON (21091) was a pivotal Phase 2/3 study to investigate the efficacy and safety of high dose aflibercept in patients with Diabetic Macular Edema (DME). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce a minor editorial change 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.

9.1.3. Kymriah – Tisagenlecleucel - EMA/VR/0000248534

Novartis Europharm Limited;

CAT Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Scope: Submission of the interim report from study CCTL019H2301 / BELINDA, including final overall survival results, listed as an obligation in the Annex II of the Product Information. This is an open label, phase III PAES of Kymriah versus standard of care in adult patients with relapsed or refractory aggressive B cell non-Hodgkin lymphoma. The Annex II is updated accordingly.

Action: For adoption

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

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

9.1.4. Livmarli - Maralixibat - Orphan - EMEA/H/C/005857/S/0019

Mirum Pharmaceuticals International B.V.,

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: Annual reassessment for products authorised under exceptional circumstances

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.

9.1.5. Omidria - Phenylephrine / Ketorolac - EMEA/H/C/003702/R/0030

Rayner Surgical (Ireland) Limited

Rapporteur: Jayne Crowe, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Jan Neuhauser

Scope: Renewal of marketing authorisation for unlimited validity

Action: For adoption

Request for Supplementary Information adopted on 27.02.2025.

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

9.1.6. Pemazyre - Pemigatinib – Orphan – EMEA/H/C/005266/R/0019

Incyte Biosciences Distribution B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: Renewal of conditional marketing authorisation

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable.

The CHMP was of the opinion that the renewal for this conditional marketing authorisation can be granted. The marketing authorisation remains conditional.

9.1.7. Regkirona – Regdanvimab – EMEA/H/C/005854

Celltrion Healthcare Hungary Kft.; treatment of Covid 19

Rapporteur: Filip Josephson, Co-Rapporteur: Jan Mueller-Berghaus

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of marketing authorisation.

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

AstraZeneca AB;

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

Scope: Renewal of marketing authorisation for unlimited validity

Action: For adoption

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

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

9.1.9. Zostavax - shingles (herpes zoster) vaccine (live) EMEA/H/C/000674

Merck Sharp & Dohme B.V.; prevention of herpes zoster and herpes zoster-related post-herpetic neuralgia (PHN)

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Outi Mäki-Ikola

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of marketing authorisation.

10. Referral procedures

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

No items

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

No items

10.3. Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004

No items

10.4. Disagreement between Member States on application for medicinal product (potential serious risk to public health) –under Article 29(4) of Directive 2001/83/EC

No items

10.5. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC

No items

10.6. Community Interests - Referral under Article 31 of Directive 2001/83/EC

No items

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

April 2025 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

Information related to GMP inspections will not be published as it undermines the purpose of such inspections.

12.2. GCP inspections

Information related to GCP inspections will not be published as it undermines the purpose of such inspections.

12.3. Pharmacovigilance inspections

Information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections.

12.4. GLP inspections

Information related to GLP inspections will not be published as it undermines the purpose of such inspections.

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

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

No items

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

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

Blanka Hirschlerova (Co-opted member) gave a proxy to Tomas Radimersky (CZ) on Thursday 24 April from 11 to 16h.

Hrefna Gudmundsdottir (IS) gave a proxy to Ingrid Wang (NO) for the entire duration of the meeting.

14.1.2. CHMP membership

No items

14.1.3. Strategic Review and Learning Meeting

Agenda of the upcoming SRLM meeting in Poland.

CHMP: Ewa Balkowiec Iskra

Action: For information

The CHMP noted the agenda of the upcoming SRLM meeting in Poland.

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 April 2025.

Action: For adoption

The CHMP adopted the EURD list for April 2025.

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at April 2025 PDCO

Action: For information

Agenda of the PDCO meeting held on 22-25 April 2025

Action: For information

The CHMP noted the information.

14.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Action: For adoption

The CHMP adopted the BWP reports.

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 08-09 April 2025.

Action: For adoption

The CHMP adopted the Table of Decisions.

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo FoggiReport from the SAWP meeting held on 07-10 April 2025. Table of conclusions

Action: For information

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

The CHMP noted the table of conclusions.

14.3.4. Election of a new Non-Clinical Working Party (NcWP) Chair and Vice-Chair

Election of new NcWP Chair and Vice-Chair. The mandate of the NcWP Chair Susanne Brendler-Schwaab expires on 21 April 2025. The mandate of the NcWP Vice-Chair Karen van Malderen expires on 21 April 2025.

Action: For election

Nomination(s) received for the Chair position

Nomination(s) received for the Vice-Chair position

The CHMP elected Susanne Brendler-Schwaab (DE) as Chair and Karen van Malderen as Vice-Chair of the NcWP.

14.3.5. Election of a new Central Nervous System Working Party (CNSWP) Chair

Election of new CNSWP Chair. The mandate of the CNSWP Chair Andre Elferink will expire on 21 April 2025.

Action: For election

Nomination(s) received

The CHMP elected Ewa Bałkowiec-Iskra (PL) as Chair of the CNSWP.

14.3.6. Election of a new Vaccines Working Party (VWP) Chair

Election of new VWP Chair. The mandate of the VWP Chair Mair Powell will expire on 21 April 2025.

Action: For election

Nomination(s) received

The CHMP elected Sol Ruiz (ES) as Chair of the VWP.

14.3.7. Election of a new Cardiovascular Working Party (CVSWP) Chair

Election of new CVSWP Chair and Vice-Chair. The mandate of the CVSWP Chair Alar Irs will expire on 22 April 2025 and the mandate of the vice-chair Patrick Vrijlandt will expire on 19 May 2025.

Action: For election

Nomination(s) received

The CHMP elected Alar Irs (EE) as Chair of the CVSWP.

14.3.8. Election of a new Infectious Disease Working Party (IDWP) Chair

Election of new IDWP Chair. The mandate of the IDWP Chair Maria Jesus Fernandez Cortizo will expire on 18 May 2025.

Action: For election

Nomination(s) received

The CHMP elected Maja Sommerfelt Grønvold (NO) as Chair of the IDWP.

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 22-25 April 2025 CHMP meeting, which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Bruno Sepodes	Chair	Portugal	No interests declared	
Daniela Philadelphy	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No restrictions applicable to this meeting	
Gergana Lazarova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Emilia Mavrokordatou	Member	Cyprus	No interests declared	
Katerina Savvidou	Alternate	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Boje Kvorning Pires Ehmsen	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member (Vice-Chair)	Finland	No interests declared	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Janet Koenig	Member	Germany	No interests declared	
Aris Angelis	Member	Greece	No participation in discussion, final deliberations and voting on:	4.1.4. - EMEA/H/C/004674/X/0022; 5.1.16. EMEA/H/C/005973/II/0061/G; 9.1.9. EMEA/H/C/000674; 5.1.12. EMA/VR/0000245108; 5.1.13. EMA/VR/0000245231; 5.1.19. EMA/VR/0000245013; 9.1.8. EMA/R/000024513

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
				6; 4.3.1. EMEA/H/C/005244 /X/0018/G; 5.1.5. - EMEA/H/C/005299 /II/0028; 9.1.2. - EMA/VR/0000249440; 4.1.1. EMEA/H/C/002737 /X/0041; 4.1.3. EMEA/H/C/004054 /X/0033/G; 5.1.11. EMEA/H/C/004054 /II/0034
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
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 interests declared	
Elita Poplavska	Member	Latvia	No restrictions applicable to this meeting	
Vilma Petrikaite	Member	Lithuania	No restrictions applicable to this meeting	
Larisa Gorobets	Alternate	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No restrictions applicable to this meeting	
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	
Fatima Ventura	Member	Portugal	No restrictions applicable to this meeting	
Paulo Paixão	Alternate	Portugal	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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 interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Anna Kubandová	Expert	Slovakia	No interests declared	
Jana Schweigertová	Expert	Slovakia	No interests declared	
Agnieszka Przybyszewska	Expert	Ireland	No interests declared	
Olive Smyth	Expert	Ireland	No interests declared	
Rosemary Maher	Expert	Ireland	No interests declared	
Aoife Thornton	Expert	Ireland	No restrictions applicable to this meeting	
Sandra Bright	Expert	Ireland	No interests declared	
Simona De Robertis	Expert	Ireland	No interests declared	
Lauren Vareslija	Expert	Ireland	No interests declared	
Brian Aylward	Expert	Ireland	No interests declared	
Maja Sommerfelt Grønvold	Expert	Norway	No interests declared	
Ilona Reischl	Expert	Austria	No restrictions applicable to this meeting	
Ana Lemos	Expert	Portugal	No restrictions applicable to this meeting	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Karri Penttilä	Expert	Finland	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No restrictions applicable to this meeting	
Karen van Malderen	Expert	Belgium	No interests declared	
Silvijus Abramavicius	Expert	Lithuania	No restrictions applicable to this meeting	
Mário Miguel Coelho da Silva Rosa	Expert	Portugal	No interests declared	
Adriana Ammassari	Expert	Italy	No interests declared	
Anders Lignell	Expert	Sweden	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Lukas Malte Aguirre Davila	Expert	Germany	No interests declared	
Flora Musuamba Tshinanu	Expert	Belgium	No restrictions applicable to this meeting	
Joerg Zinserling	Expert	Germany	No participation in discussion, final deliberations and voting on:	3.2.6. - EMEA/H/C/006491
Carin Bergquist	Expert	Sweden	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Federico De Angelis	Expert	Italy	No interests declared	
Svenja Dierkes	Expert	Germany	No interests declared	
Ulrike Hermes	Expert	Germany	No interests declared	
Jutta Dedorath	Expert	Germany	No interests declared	
Kathrin Bayanga	Expert	Germany	No interests declared	
Tilman Gross	Expert	Germany	No restrictions applicable to this meeting	
Nathalie Dumarcet	Expert	France	No interests declared	
Violaine Closson-Carella	Expert	France	No interests declared	
Solène Maitenaz	Expert	France	No restrictions applicable to this meeting	
Christian Woloch	Expert	France	No interests declared	
Celine Jumeau	Expert	France	No interests declared	
Mona Kassem-Youssef	Expert	France	No interests declared	
Simona Teodosiu	Expert	France	No interests declared	
Cecile Dop	Expert	France	No interests declared	
Stephanie Hueber	Expert	France	No restrictions applicable to this meeting	
Christophe Versini	Expert	France	No interests declared	
Simin Oveisi	Expert	France	No restrictions applicable to this meeting	
Maria Concepcion Payares	Expert	Spain	No participation in discussion, final deliberations and voting on:	3.5.1. - EMEA/H/C/006024
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No restrictions applicable to this meeting	
Irene Bachmann	Expert	Germany	No interests declared	
Ulrike Hermes	Expert	Germany	No interests declared	
Georgios Aislaitner	Expert	Germany	No interests declared	
Marion Haberkamp	Expert	Germany	No interests declared	
Christine Greiner	Expert	Germany	No interests declared	
Sofia Kapanadze	Expert	Germany	No interests declared	
Michael Schramm	Expert	Germany	No interests declared	
Silke Dorner	Expert	Austria	No interests declared	
Melanie Ramberger	Expert	Austria	No interests declared	
Johanna de Groot	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
Hemme Hijma	Expert	Netherlands	No restrictions applicable to this meeting	
Charlotte de Wolf	Expert	Netherlands	No interests declared	
Mark van Bussel	Expert	Netherlands	No interests declared	
Martijn van Gils	Expert	Netherlands	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Fei Fei	Expert	Belgium	No interests declared	
Hinke Johanna van der Woude	Expert	Netherlands	No interests declared	
Anne Torrez Flores-Lexmond	Expert	Netherlands	No interests declared	
Anya Staal	Expert	Germany	No interests declared	
Laurens Verscheijden	Expert	Netherlands	No restrictions applicable to this meeting	
Carolien Versantvoort	Expert	Netherlands	No interests declared	
Elin Lindhagen	Expert	Sweden	No interests declared	
Marina Senek	Expert	Sweden	No interests declared	
Christine Prendergast	Expert	Ireland	No participation in discussion, final deliberations and voting on:	5.1.17. - EMEA/H/C/001110/II/0077; 9.1.1. - EMEA/H/C/00093; 9.1.3. - EMA/VR/0000248534
Joseph De Courcey	Expert	Ireland	No interests declared	
Maja Lusina Kregar	Expert	Croatia	No restrictions applicable to this meeting	
Mirna Galovic	Expert	Croatia	No interests declared	
Mikael Andersson	Expert	Sweden	No interests declared	
Karin Fjordén	Expert	Sweden	No interests declared	
Kristofer Olofsson	Expert	Sweden	No restrictions applicable to this meeting	
Jenny-Maria Jönsson	Expert	Sweden	No participation in discussion, final deliberations and voting on:	5.1.12. - EMA/VR/0000245108
Rune Kjeken	Expert	Norway	No restrictions applicable to this meeting	
Tomas Arroyo Perez	Expert	Spain	No interests declared	
Meeting run with the help of 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)*

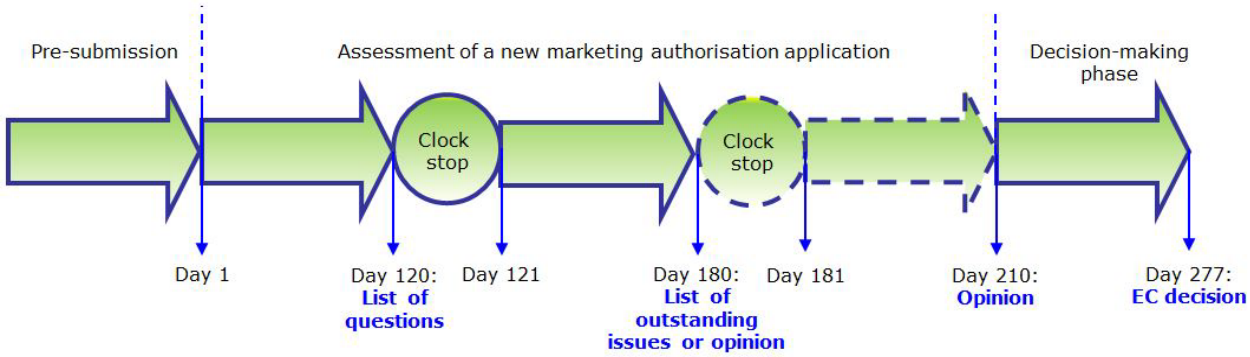
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

25 April 2025
EMA/CHMP/138001/2025

Annex to 22-25 April 2025 CHMP Minutes

Pre-submission and post-authorisations issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

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

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

B.1.1. Annual reassessment for products authorised under exceptional circumstances

Ceplene - Histamine dihydrochloride - EMEA/H/C/000796/S/0049 Laboratoires Delbert, Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances.
Livmarli - Maralixibat - EMEA/H/C/005857/S/0019, Orphan Mirum Pharmaceuticals International B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski	See 9.1 Request for supplementary information adopted with a specific timetable.

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

Aybintio - Bevacizumab - EMEA/H/C/005106/R/0022 Samsung Bioepis NL B.V., Rapporteur: Christian Gartner, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Karin Erneholm Request for Supplementary Information adopted on 27.02.2025.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
Omidria - Phenylephrine / Ketorolac -	See 9.1

EMEA/H/C/003702/R/0030 Rayner Surgical (Ireland) Limited, Rapporteur: Jayne Crowe, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Jan Neuhauser Request for Supplementary Information adopted on 27.02.2025.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
Raxone - Idebenone - EMEA/H/C/003834/R/0043, Orphan Chiesi Farmaceutici S.p.A., Rapporteur: John Joseph Borg, PRAC Rapporteur: Amelia Cupelli	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.

B.2.3. Renewals of Conditional Marketing Authorisations

Pemazyre - Pemigatinib - EMEA/H/C/005266/R/0019, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder Request for Supplementary Information adopted on 12.12.2024.	See 9.1 Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection PRAC recommendations on signals adopted at the PRAC meeting held on 07-10 April 2025 PRAC:	
Signal of hyperammonaemia, hyperammonaemic encephalopathy Regorafenib – STIVARGA (CAP) Rapporteur: Peter Mol, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder PRAC recommendation for variation **Action:** For adoption	The CHMP adopted the PRAC recommendation.
Post-authorisation safety studies PRAC recommendations on PASS results adopted at the PRAC meeting held on 22-25 April 2025	

Lemtrada (CAP) – EMEA/H/C/PSR/S/0050 (alemtuzumab) PRAC Rapporteur: Karin Erneholm, Scope: Provision of the final study results of the cat.1 PASS study A non-interventional post-authorisation safety study to investigate drug utilisation and safety monitoring patterns for LEMTRADA (alemtuzumab). PRAC recommendation to CHMP **Action:** For adoption	Adopted
Lemtrada (CAP) – EMEA/H/C/PSR/S/0051 (alemtuzumab) PRAC Rapporteur: Karin Erneholm, Scope: Provision of the final study results of the cat.1 PASS study A Non-Interventional Post-Authorisation Safety Study to Investigate the Risk of Mortality in Multiple Sclerosis Patients Treated with Alemtuzumab (LEMTRADA®) Relative to Comparable Multiple Sclerosis Patients Using Other Disease Modifying Therapies: A Cohort Study. PRAC recommendation to CHMP **Action:** For adoption	Adopted
PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its April 2025 meeting:	
EMEA/H/C/PSUSA/00000107/202409 (epcoritamab) CAPS: **Tepkinly** (EMEA/H/C/005985) (Epcoritamab), AbbVie Deutschland GmbH & Co. KG, Rapporteur: Peter Mol, PRAC Rapporteur: Monica Martinez Redondo, "22/03/2024 To: 21/09/2024"	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 for the above-mentioned medicinal product, concerning the following change: Update of section 4.4 of the SmPC to add a warning/precaution regarding HLH. The Package leaflet should be updated accordingly.
EMEA/H/C/PSUSA/00001936/202409 (measles / mumps / rubella / varicella vaccines (live)) CAPS: **ProQuad** (EMEA/H/C/000622) (Measles, mumps, rubella and varicella vaccine (live)), Merck Sharp & Dohme B.V., Rapporteur: Jan Mueller-Berghaus NAPS: **NAPS** - Europa	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC 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 medicinal products containing the above referred active substance(s), concerning the following

PRAC Rapporteur: Gabriele Maurer, "05/09/2021 To: 05/09/2024"	change(s): Centrally authorised medicinal product (ProQuad) Update of section 4.6 of the SmPC to update the recommendations for use in pregnancy. Nationally authorised medicinal product (Priorix Tetra) Update of section 4.3 of the SmPC to amend the definition of contraindication in the presence of immunosuppression and update of section 4.6 of the SmPC to update the recommendations for use in pregnancy. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010113/202408 (loxapine (pre-dispensed inhalation powder)) CAPS: **Adasuve** (EMEA/H/C/002400) (Loxapine), Ferrer Internacional s.a., Rapporteur: Peter Mol, PRAC Rapporteur: Liana Martirosyan, "20/08/2021 To: 20/08/2024"	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 4.4 of the SmPC to add a warning/precaution regarding drug rash with eosinophilia and systemic symptoms (DRESS). The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010366/202409 (naltrexone / bupropion) CAPS: **Mysimba** (EMEA/H/C/003687) (Naltrexone hydrochloride / Bupropion hydrochloride), Orexigen Therapeutics Ireland Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber, "09/09/2023 To: 09/09/2024"	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 4.4 of the SmPC to add information on the availability of the patient card. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010403/202409 (pembrolizumab) CAPS: **Keytruda** (EMEA/H/C/003820) (Pembrolizumab), Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder, "03/09/2023 To: 03/09/2024"	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/00010426/202409 (isavuconazole) CAPS: **Cresemba** (EMEA/H/C/002734) (Isavuconazole), Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski, "06/09/2021 To: 06/09/2024"	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 adverse reaction hyponatremia with a frequency uncommon. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010920/202408 (somapacitan) CAPS: **Sogroya** (EMEA/H/C/005030) (Somapacitan), Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "01/09/2023 To: 31/08/2024"	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 4.4 of the SmPC to add a warning/precaution regarding the risk of SCFE. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010976/202409 (abrocitinib) CAPS: **Cibinqo** (EMEA/H/C/005452) (Abrocitinib), Pfizer Europe MA EEIG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas, "08/03/2024 To: 07/09/2024"	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 for the above mentioned medicinal product, concerning the following changes: Update of section 4.8 of the SmPC to add the adverse reaction of neutropenia with a frequency uncommon. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00011018/202409 (nivolumab / relatlimab) CAPS: **Opdualag** (EMEA/H/C/005481) (Nivolumab / Relatlimab), Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, PRAC Rapporteur: Gabriele Maurer, "18/03/2024 To: 17/09/2024"	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 sections 4.8 and 4.4 of the SmPC to add the adverse reaction Myasthenia gravis with a frequency uncommon, to amend a warning

	regarding the risk of autoimmune reactions and to amend a warning regarding other immune-related 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

Advate - Octocog alfa - EMEA/H/C/000520/II/0124 Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.04.2025. Request for Supplementary Information adopted on 13.02.2025.	Positive Opinion adopted by consensus on 03.04.2025.
Alprolix - Eftrenonacog alfa - EMEA/H/C/004142/II/0048, Orphan Swedish Orphan Biovitrum AB (publ), Rapporteur: Daniela Philadelphy Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 23.01.2025.	Positive Opinion adopted by consensus on 25.04.2025.
CooperSurgical Inc ART Media - Human albumin solution - EMEA/H/D/002307/II/0012 Coopersurgical Inc., Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 25.04.2025, 20.02.2025.	Request for supplementary information adopted with a specific timetable.
GONAL-f - Follitropin alfa - EMEA/H/C/000071/II/0177/G Merck Europe B.V., Rapporteur: Patrick Vrijlandt Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 20.02.2025.	Positive Opinion adopted by consensus on 25.04.2025.
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0163 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 13.02.2025.	Positive Opinion adopted by consensus on 25.04.2025.
HyQvia - Human normal immunoglobulin - EMEA/H/C/002491/II/0101	Positive Opinion adopted by consensus on

Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.04.2025. Request for Supplementary Information adopted on 10.10.2024.	03.04.2025.
KIMMTRAK - Tebentafusp - EMEA/H/C/004929/II/0009/G, Orphan Immunocore Ireland Limited, Rapporteur: Boje Kvorning Pires Ehmsen Opinion adopted on 03.04.2025. Request for Supplementary Information adopted on 19.12.2024.	Positive Opinion adopted by consensus on 03.04.2025.
Lamzede - Velmanase alfa - EMEA/H/C/003922/II/0040/G, Orphan Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 20.02.2025.	Positive Opinion adopted by consensus on 10.04.2025.
LifeGlobal Media - Human albumin solution - EMEA/H/D/004287/II/0009 Coopersurgical Inc., Rapporteur: Maria Grazia Evandri Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 20.02.2025.	Positive Opinion adopted by consensus on 25.04.2025.
Origio - Human albumin solution - EMEA/H/D/000830/II/0021 Coopersurgical Inc., Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 25.04.2025, 20.02.2025.	Request for supplementary information adopted with a specific timetable.
Otulfi - Ustekinumab - EMEA/H/C/006544/II/0001/G Fresenius Kabi Deutschland GmbH, Duplicate of Fymskina, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 10.04.2025.
Ozempic - Semaglutide - EMEA/H/C/004174/II/0051 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 13.02.2025.	Positive Opinion adopted by consensus on 10.04.2025.
Pombiliti - Cipaglucosidase alfa - EMEA/H/C/005703/II/0019	Request for supplementary information adopted with a specific timetable.

Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 25.04.2025.	
Prevenar 20 - Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0031/G Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphy Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 25.04.2025.
Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0213 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 13.02.2025.	Positive Opinion adopted by consensus on 25.04.2025.
Roclanda - Latanoprost / Netarsudil - EMEA/H/C/005107/II/0031/G Santen Oy, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 03.04.2025, 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0052/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 30.01.2025.	Positive Opinion adopted by consensus on 25.04.2025.
Sondelbay - Teriparatide - EMEA/H/C/005827/II/0008 Accord Healthcare S.L.U., Rapporteur: Finbarr Leacy Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 13.02.2025.	Positive Opinion adopted by consensus on 10.04.2025.
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0148/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.04.2025. Request for Supplementary Information adopted on 23.01.2025.	Positive Opinion adopted by consensus on 03.04.2025.
Tevimbra - Tislelizumab -	Positive Opinion adopted by consensus on

EMEA/H/C/005919/II/0019/G Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 10.04.2025.	10.04.2025.
Vazkepa - Icosapent ethyl - EMEA/H/C/005398/II/0028/G Amarin Pharmaceuticals Ireland Limited, Rapporteur: Janet Koenig Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 30.01.2025.	Positive Opinion adopted by consensus on 25.04.2025.
Wegovy - Semaglutide - EMEA/H/C/005422/II/0027 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 13.02.2025.	Positive Opinion adopted by consensus on 10.04.2025.
WS2747/G **Nuwiq-EMEA/H/C/002813/WS2747/0063/G** **Vihuma-EMEA/H/C/004459/WS2747/0045/G** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 23.01.2025, 31.10.2024.	Positive Opinion adopted by consensus on 25.04.2025.
WS2756 **Hexacima-EMEA/H/C/002702/WS2756/0160** **Hexyon-EMEA/H/C/002796/WS2756/0164** Sanofi Winthrop Industrie, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 05.12.2024.	Positive Opinion adopted by consensus on 10.04.2025.

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

Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0012 Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe, "Update of section 5.1 of the SmPC in order to update information based on end-of-season 2 data from clinical study C3671013.	Positive Opinion adopted by consensus on 10.04.2025.

This is an ongoing Phase 3, randomised, double-blind, placebo-controlled study to evaluate safety, immunogenicity and efficacy of Abrysvo in prevention of lower respiratory tract disease in adults 60 years of age and older during the first respiratory syncytial virus (RSV) season and the immunogenicity and efficacy of Abrysvo in the second RSV season and across 2 RSV seasons. In addition, the MAH took the opportunity to introduce minor changes to the PI based on the final clinical study report C3671008, which was already submitted under Article 46, and to update the list of local representatives in the Package Leaflet." Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 27.02.2025, 21.11.2024.	
Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0028 Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher, "Update of sections 4.8 and 5.1 based on primary analysis and first-year analysis results from study VAS00006 (HARMONIE). This is an ongoing phase IIIb randomized open-label study of nirsevimab (versus no intervention) in preventing hospitalizations due to respiratory syncytial virus in infants (under 12 months) in order to determine the efficacy and safety of a single intramuscular (IM) dose of nirsevimab. In addition, the MAH took the opportunity to introduce minor formatting changes." Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 30.01.2025.	Positive Opinion adopted by consensus on 25.04.2025.
Braftovi - Encorafenib - EMEA/H/C/004580/II/0041 Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Submission of results of a modelling and simulation study in patients with moderate and severe hepatic impairment, and post-marketing data collection for the important potential risk "overexposure in patients with moderate to severe hepatic impairment"." Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 12.12.2024.	Positive Opinion adopted by consensus on 25.04.2025.
Enhertu - Trastuzumab deruxtecan -	Positive Opinion adopted by consensus on

EMEA/H/C/005124/II/0054 Daiichi Sankyo Europe GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, "Submission of the final report from study DS8201-A-U201 listed as a Recommendation (REC). This is a phase 2 multicenter, open-label efficacy and safety study of DS-8201a, an Anti-HER2-Antibody Drug Conjugate (ADC) for HER2- positive, unresectable and/or metastatic breast cancer subjects previously treated with T-DM1." Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 13.02.2025.	25.04.2025.
Fexinidazole Winthrop - Fexinidazole - EMEA/H/W/002320/II/0021 Sanofi Winthrop Industrie, Rapporteur: Fátima Ventura, "Submission of the final report for study DNDi-FEX-09-HAT. This is a phase 3b, open-label study assessing effectiveness, safety and compliance with fexinidazole in patients with human African trypanosomiasis due to T.b. gambiense at any stage. Section 4.2 of the SmPC is updated to allow for the possibility of treatment at home with supervision by an informed caregiver. SmPC section 4.4 is also revised, to remove the stipulation that children with a body weight <35 kg had to be treated in the hospital under strict supervision of trained health staff. The corresponding Package Leaflet section 3 and section 2, respectively, are also revised accordingly." Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 27.02.2025.	Positive Opinion adopted by consensus on 25.04.2025.
IMCIVREE - Setmelanotide - EMEA/H/C/005089/II/0034, Orphan Rhythm Pharmaceuticals Netherlands B.V., Rapporteur: Karin Janssen van Doorn, "Update of section 4.8 of the SmPC in order to update the list of adverse drug reactions (ADRs) based on the availability of new safety data. The Package Leaflet is updated accordingly." Opinion adopted on 03.04.2025. Request for Supplementary Information adopted on 27.02.2025.	Positive Opinion adopted by consensus on 03.04.2025.
Inrebic - Fedratinib - EMEA/H/C/005026/II/0026, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update of sections 4.4 and 4.8 of	Request for supplementary information adopted with a specific timetable.

the SmPC in order to add 'Uveitis' to the list of adverse drug reactions (ADRs) with frequency 'common' based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI." Request for Supplementary Information adopted on 25.04.2025, 23.01.2025.	
JEMPERLI - Dostarlimab - EMEA/H/C/005204/II/0040 GlaxoSmithKline (Ireland) Limited, Rapporteur: Carolina Prieto Fernandez, "Update of section 4.8 of the SmPC in order to add 'Guillain-Barre syndrome' to the list of adverse drug reactions (ADRs) in patients treated with dostarlimab in combination with chemotherapy with frequency 'uncommon' based on new safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the PI in accordance with the latest EMA excipients guideline. Also, the MAH has taken the opportunity to update the list of local representatives in the Package Leaflet and introduce editorial changes to the PI." Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 06.02.2025.	Positive Opinion adopted by consensus on 25.04.2025.
LYFNUA - Gefapixant - EMEA/H/C/005476/II/0003/G Merck Sharp & Dohme B.V., Rapporteur: Peter Mol, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information from the multicentre randomised study MK-7264-043 in patients with refractory or unexplained chronic cough and add 'headache' to the list of adverse drug reactions (ADRs) with frequency common. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and introduce minor editorial changes to the PI." Opinion adopted on 03.04.2025. Request for Supplementary Information adopted on 20.02.2025, 05.12.2024, 12.09.2024.	Positive Opinion adopted by consensus on 03.04.2025.
Mektovi - Binimetinib - EMEA/H/C/004579/II/0034 Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Submission of results of a modelling and simulation study in patients with moderate and severe hepatic impairment, and post-	Positive Opinion adopted by consensus on 25.04.2025.

marketing data collection for the important potential risk "overexposure in patients with moderate to severe hepatic impairment"." Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 12.12.2024.	
Phesgo - Pertuzumab / Trastuzumab - EMEA/H/C/005386/II/0027 Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, "Update of sections 4.2 and 4.4 of the SmPC in order to update administration instructions based on the final results from studies AL42478 and WP42873. AL42478 is an US expanded access, single-arm, multicentre study to provide at home subcutaneous administration of pertuzumab and trastuzumab fixed-dose combination (PH FDC SC) for patients with HER2-positive breast cancer during the COVID-19 pandemic. WP42873 is a randomized, open-label, 2-arm, parallel group, single dose, multi-centre study in healthy male subjects to investigate the comparability of pharmacokinetics of the fixed-dose combination of pertuzumab and trastuzumab administered subcutaneously using a handheld syringe or using the on-body delivery system. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 2 and 4.4 of the SmPC, the Labelling and section 2 of the Package Leaflet in line with the Annex to the guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (EMA/CHMP/190743/2016) with regard to polysorbates, to bring the PI in line with version 10.4 of the QRD template and to update the list of local representatives in the Package Leaflet." Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 30.01.2025.	Positive Opinion adopted by consensus on 25.04.2025.
Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0210 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.4 of the SmPC in order to strengthen the existing warning on 'Aseptic Meningitis Syndrome (AMS)' by the addition of monitoring precautions for recurrent AMS, associated with IVIg treatment, potentially progressing to brain oedema (cerebral oedema),	Positive Opinion adopted by consensus on 25.04.2025.

based on post-marketing data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet" Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 16.01.2025.	
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0147 Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, "Submission of the final report from study mRNA-1273-P205 listed as a category 3 study in the RMP. This is a Phase 2/3 study to evaluate the immunogenicity and safety of Spikevax vaccine boosters for SARS-CoV-2 Variants." Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 10.04.2025.
Trodelvy - Sacituzumab govitecan - EMEA/H/C/005182/II/0037 Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2 and 4.4 the SmPC in order to add information on the timing of fatal infections as well as recommendations on the use of primary prophylaxis with G-CSF in patients who are at high risk for neutropenia, based on clinical trials data, post-marketing data and the literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 6.6 of the SmPC to remove the requirement to calculate the required dose at the beginning of each treatment cycle or more frequently if the patient's body weight changed by more than 10% since the previous administration as well as the requirement to warm the vials to room temperature." Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 30.01.2025.	Positive Opinion adopted by consensus on 25.04.2025.

B.5.3. CHMP-PRAC assessed procedures

Epruvy - Ranibizumab - EMEA/H/C/006528/II/0002/G MIDAS Pharma GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Bolin Opinion adopted on 10.04.2025.	Positive Opinion adopted by consensus on 10.04.2025.

Request for Supplementary Information adopted on 16.01.2025.	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0096/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Gabriele Maurer Request for Supplementary Information adopted on 25.04.2025, 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Nyxoid - Naloxone - EMEA/H/C/004325/II/0019 Mundipharma Corporation (Ireland) Limited, Rapporteur: Paulo Paixão, PRAC Rapporteur: Liana Martirosyan, "Update of Annex II.D (conditions or restrictions with regard to the safe and effective use of the medicinal product), based on the submission of the final study results of the imposed post-authorisation efficacy study MR903-9501; removal of this PAES from Annex II.D. Study MR903-9501 is a non-interventional multi-national, prospective, mixed methods study on the effectiveness of naloxone (including intranasal Nyxoid) administration by lay people in reversing opioid overdose. This update is also supported by Real World Evidence (RWE) from literature and European Take-Home Naloxone (THN) programs demonstrating the effectiveness of Nyxoid in a real-world setting. The labelling and Package Leaflet are amended accordingly. The Risk Management Plan (RMP) is also revised to version 3.2." Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 12.12.2024, 25.07.2024.	Positive Opinion adopted by consensus on 25.04.2025.
Ranivisio - Ranibizumab - EMEA/H/C/005019/II/0017/G Midas Pharma GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Bolin Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 10.04.2025.
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	Request for supplementary information adopted with a specific timetable.

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 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. - 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). An updated RMP version 2.1 was included as part of the application." Request for Supplementary Information adopted on 10.04.2025, 13.03.2025, 16.01.2025.	
TAKHZYRO - Lanadelumab - EMEA/H/C/004806/II/0040, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder, PRAC Rapporteur: Terhi Lehtinen, Opinion adopted on 25.04.2025. Request for Supplementary Information adopted on 27.02.2025, 17.10.2024, 11.04.2024.	Positive Opinion adopted by consensus on 25.04.2025.
XALKORI - Crizotinib - EMEA/H/C/002489/II/0084 Pfizer Europe MA EEIG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "Submission of the final report from study CRZ-NBALCL listed as a category 3 study in the RMP. This is a phase I/II study to evaluate the adverse effects of ocular toxicity and bone toxicity and impaired bone growth associated with crizotinib in paediatric and young adult patients with recurrent/refractory anaplastic lymphoma kinase-positive anaplastic large cell lymphoma or neuroblastoma. The RMP version 9.2 is updated accordingly." Request for Supplementary Information adopted on 10.04.2025, 16.01.2025.	Request for supplementary information adopted with a specific timetable.

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 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 3.0 has also been submitted." Request for Supplementary Information adopted on 10.04.2025, 16.01.2025, 31.10.2024.	Request for supplementary information adopted with a specific timetable.

B.5.4. PRAC assessed procedures

PRAC Led **Enbrel - Etanercept - EMEA/H/C/000262/II/0255** Pfizer Europe MA EEIG, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gomez-Outes, "Update of sections 4.2 and 4.4 of the SmPC in order to remove information regarding the Patient Card, based on final results from study B1801309 (BSR Register of Anti-TNF Treated Patients and Prospective Surveillance Study for Adverse Events: Enbrel). This is a non-interventional PASS study listed as a category 3 study in the RMP. The Annex II and Package Leaflet are updated accordingly. The RMP version 7.7 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and	Request for supplementary information adopted with a specific timetable.

formatting changes to the PI as well as to update the list of local representatives in the Package Leaflet and align the PI with the QRD version 10.4." Request for Supplementary Information adopted on 10.04.2025, 16.01.2025.	
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)." Request for Supplementary Information adopted on 10.04.2025, 28.11.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Fintepla - Fenfluramine - EMEA/H/C/003933/II/0028, Orphan** UCB Pharma SA, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of a revised protocol for study EP0218 listed as an obligation in the Annex II of the Product Information. This is a Long-term Registry in approved indications for fenfluramine, with a specific focus on cardiovascular events and growth retardation. The RMP version 4.0 is updated accordingly. In addition, the MAH introduced minor amendments in the targeted follow-up questionnaire for cardiovascular adverse events." Request for Supplementary Information adopted on 25.04.2025, 30.01.2025.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Mosquirix - Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0085/G** GlaxoSmithkline Biologicals SA, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "A grouped application comprised of two type II variations, as follows:	Positive Opinion adopted by consensus on 10.04.2025.

C.I.4: Update of sections 4.4 and 5.1 of the SmPC in order to remove a warning and precaution regarding meningitis and to add effectiveness data based on EPI-MAL-003 study, listed as a category 3 study in the RMP. This is a prospective study to evaluate the safety, effectiveness and impact of the RTS,S/AS01E vaccine in young children in sub-Saharan Africa countries. The Package Leaflet is updated accordingly. The RMP version 6.1 has been agreed. C.I.13: Submission of the final report from study MVPE (Malaria Vaccine Pilot Evaluation) listed as a category 3 study in the RMP. This is a observational study in the context of a cluster-randomized pilot implementation in order to assess the feasibility of delivery, safety, and impact on mortality of the RTS,S/AS01E malaria vaccine delivered through the routine immunization services in Kenya, Malawi, and Ghana over 4 years." Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 13.03.2025, 28.11.2024.	
PRAC Led **Nucala - Mepolizumab - EMEA/H/C/003860/II/0071** GlaxoSmithKline Trading Services Limited, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report of the Mepolizumab (Nucala) Pregnancy Exposure Study 200870: a "Vaccines and Medications in Pregnancy Safety Studies" (VAMPSS) post marketing surveillance study of Mepolizumab safety in pregnancy, listed as a category 3 study in the RMP. This is a non-interventional study to monitor planned and unplanned pregnancies exposed to mepolizumab and to evaluate the possible teratogenic effect of this medication relative to the pregnancy outcomes of major birth defects, preterm delivery, small for gestational age infants and spontaneous abortion or stillbirth. The RMP version 13.0 has been approved." Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 28.11.2024.	Positive Opinion adopted by consensus on 10.04.2025.
PRAC Led	Positive Opinion adopted by consensus on

POTELIGEO - Mogamulizumab - EMEA/H/C/004232/II/0026, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Peter Mol, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Boje Kvorning Pires Ehmsen, "Update of section 4.8 of the SmPC in order to add 'granuloma' to the list of adverse drug reactions (ADRs) with frequency 'unknown', based on post marketing data; the Package Leaflet is updated accordingly." Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 16.01.2025.	10.04.2025.
PRAC Led **Supemtek Tetra - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0020** Sanofi Winthrop Industrie, PRAC Rapporteur: Zoubida Amimour, PRAC-CHMP liaison: Alexandre Moreau, "Update of section 4.6 of the SmPC in order to update pregnancy information based on final results from study VAP00007 (non-interventional PASS); this is a Phase IV, observational retrospective post-authorisation, descriptive, safety surveillance study to evaluate the safety of Supemtek Tetra in pregnant women and their offspring exposed during pregnancy or up to 28 days preceding the estimated date of conception and birth and neonatal/infant outcomes in their infants." Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 10.04.2025.
PRAC Led **Trulicity - Dulaglutide - EMEA/H/C/002825/II/0071** Eli Lilly Nederland B.V., PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, "Submission of an updated RMP version 8.2 in order to add a medullary thyroid cancer (MTC) database linkage study (Study I8F-MC-B014) as an additional pharmacovigilance activity to evaluate the important potential risk of MTC in patients exposed to long-acting glucagon-like peptide-1 receptor agonist (GLP-1 RA) therapies. In addition, the MAH took the opportunity to include an amendment to Study H9X-MC-B013 due to the removal of the United States data source."	Positive Opinion adopted by consensus on 10.04.2025.

Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 05.09.2024.	
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 12.1 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." Request for Supplementary Information adopted on 10.04.2025.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2125 Soliris-EMEA/H/C/000791/WS2125/0133 Ultomiris-EMEA/H/C/004954/WS2125/0047** Alexion Europe SAS, Lead PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gomez-Outes, "Submission of an updated RMP version 21.2 for SOLIRIS and RMP version 9.2 for ULTOMIRIS in order to revise the controlled distribution additional risk minimisation measures, following the PRAC outcome for PSUSA/00001198/202310 for SOLIRIS. The Annex II is updated accordingly. In addition, the MAH introduced minor updates to the SmPC to align the wording with the updated Annex II." Opinion adopted on 10.04.2025. Request for Supplementary Information adopted on 28.11.2024.	Positive Opinion adopted by consensus on 10.04.2025.

B.5.5. CHMP-CAT assessed procedures

Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0055/G, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini Opinion adopted on 25.04.2025, 16.04.2025. Request for Supplementary Information adopted on 21.02.2025.	Positive Opinion adopted by consensus on 25.04.2025.

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

PRAC Led **CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0034, Orphan, ATMP** Janssen-Cilag International NV, PRAC Rapporteur: Jo Robays, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of an updated RMP version 6.1 in order to add a new important identified risk of "Secondary malignancy of T-cell origin", to change the important potential risk of "Second primary malignancies" to "Second primary malignancy except secondary malignancy of T-cell origin", and to include an additional pharmacovigilance activity for testing of secondary malignancies of T-cell origin, following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040). The final version of the RMP (v6.1) includes consolidation of recent approved parallel RMP version 5.6 in procedure EMEA/H/C/005095/II/0036 and further updates the important potential risk of "Second primary malignancy except secondary malignancy of T-cell origin" to "Secondary malignancy except those of T cell and myeloid origin" as matter of combination of the two RMP versions." Opinion adopted on 25.04.2025, 16.04.2025. Request for Supplementary Information adopted on 24.01.2025.	Positive Opinion adopted by consensus on 25.04.2025.

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.