18 December 2024
EMA/CHMP/376395/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 22-25 July 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

Disclaimers

Some of the information contained in these 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 July 2024

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 24-27 June 2024

The CHMP adopted the minutes for the 24-27 June 2024 plenary.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

No items

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. Anzupgo - Delgocitinib - EMEA/H/C/006109

LEO Pharma A/S; treatment of moderate to severe chronic hand eczema (CHE)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 30.05.2024. 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 marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considers that Delgocitinib is a new active substance, as claimed by the applicant.

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

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendations dated 23 July 2024.

3.1.2. Axitinib Accord - Axitinib - EMEA/H/C/006206

Accord Healthcare S.L.U.; treatment of adult patients with advanced renal cell carcinoma (RCC)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 20.07.2023.

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 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.

3.1.3. EKSUNBI - Ustekinumab - EMEA/H/C/006448

Samsung Bioepis NL B.V.; treatment of Crohn's disease, Ulcerative colitis, Plaque psoriasis, Paediatric plaque psoriasis and Psoriatic arthritis (PsA)

Scope: Opinion

Action: For adoption

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

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

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

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

The summary of opinion was circulated for information.

3.1.4. Fymskina - Ustekinumab - EMEA/H/C/005805

Formycon AG; treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, Crohn's Disease and Ulcerative colitis

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 30.05.2024. List of Questions adopted on 25.01.2024.

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

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

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

The CHMP noted the letter of recommendations dated 22 July 2024.

The summary of opinion was circulated for information.

3.1.5. IQIRVO - Elafibranor - Orphan - EMEA/H/C/006231

Ipsen Pharma; treatment of primary biliary cholangitis (PBC)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 30.05.2024. List of Questions adopted on 22.02.2024.

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 considers that Elafibranor is a new active substance, as claimed by the applicant.

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.6. Ituxredi - Rituximab - EMEA/H/C/006224

Reddy Holding GmbH; treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL), Rheumatoid arthritis, Granulomatosis with polyangiitis and microscopic polyangiitis and Pemphigus vulgaris.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 14.09.2023.

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

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

The summary of opinion was circulated for information.

3.1.7. Kayfanda - Odevixibat - EMEA/H/C/006462

Ipsen Pharma; treatment of cholestatic pruritus in Alagille syndrome (ALGS)

Scope: Opinion

Action: For adoption

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

List of Questions adopted on 25.04.2024.

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.8. LEQEMBI - Lecanemab - EMEA/H/C/005966

Eisai GmbH; a disease modifying treatment in adult patients with Mild Cognitive Impairment due to Alzheimer's disease and Mild Alzheimer's disease (Early Alzheimer's disease)

Scope: Opinion, third-party intervention

Action: For adoption

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

List of Outstanding Issues adopted on 27.06.2024, 21.03.2024, 09.11.2023. List of Questions adopted on 25.05.2023.

The CHMP noted the third-party interventions.

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

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

3.1.9. LOQTORZI - Toripalimab - EMEA/H/C/006120

TMC Pharma (EU) Limited; Combination treatment for metastatic or recurrent locally advanced nasopharyngeal carcinoma and for metastatic or recurrent oesophageal squamous cell carcinoma

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 30.03.2023.

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

The Committee adopted a positive opinion by majority recommending the granting of a marketing authorisation (28 positive out of 29 votes) together with the CHMP assessment

report and translation timetable.

Furthermore, the CHMP considered that Toripalimab is a new active substance, as claimed by the Applicant.

The divergent position (Thalia Marie Estrup Blicher and Hrefna Gudmundsdottir) was appended to the opinion.

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

The summary of opinion was circulated for information.

3.1.10. Otulfi - Ustekinumab - EMEA/H/C/006544

Fresenius Kabi Deutschland GmbH; treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, Crohn's Disease

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues 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 recommendations dated 23 July 2024.

The summary of opinion was circulated for information.

3.1.11. Ranibizumab Midas - Ranibizumab - EMEA/H/C/006528

MIDAS Pharma GmbH; treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to diabetic macular oedema (DME), proliferative diabetic retinopathy (PDR), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) and visual impairment due to choroidal neovascularisation (CNV)

Scope: Opinion

Action: For adoption

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

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

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

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

The CHMP noted the letter of recommendations dated 22 July 2024.

The summary of opinion was circulated for information.

3.1.12. Tuznue - Trastuzumab - EMEA/H/C/006252

Prestige Biopharma Belgium; is indicated for the treatment of adult patients with HER2 positive metastatic breast cancer (MBC), HER2 positive early breast cancer (EBC) and HER2 positive metastatic gastric cancer (MGC)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 30.05.2024. 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 marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

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

The summary of opinion was circulated for information.

3.1.13. Vevizye - Ciclosporin - EMEA/H/C/006250

Novaliq GmbH; Treatment of dry eye disease in adult patients

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 30.05.2024. 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 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 recommendations dated 22 July 2024.

The summary of opinion was circulated for information.

3.1.14. Vyloy - Zolbetuximab - Orphan - EMEA/H/C/005868

Astellas Pharma Europe B.V.; treatment of locally advanced unresectable or metastatic HER2 negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 09.11.2023.

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

The Committee adopted a positive opinion by majority recommending the granting of a marketing authorisation (28 positive out of 29 votes) together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that Zolbetuximab is a new active substance, as claimed by the Applicant.

The divergent position (Peter Mol) was appended to the opinion.

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

The CHMP noted the letter of recommendations dated 25 July 2024.

The summary of opinion was circulated for information.

3.1.15. YUVANCI - Macitentan / Tadalafil - EMEA/H/C/005001

Janssen - Cilag International; treatment of pulmonary arterial hypertension (PAH) in adult patients

Scope: Opinion

Action: For adoption

Fixed combination application (Article 10b of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 09.11.2023.

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

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

The summary of opinion was circulated for information.

The CHMP adopted 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. Apremilast - EMEA/H/C/006193

treatment of psoriatic arthritis, psoriasis, Behçet's disease

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.02.2024.

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

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

The CHMP agreed to consult the MWP and adopted a list of questions to this expert group.

3.2.2. Levetiracetam - EMEA/H/C/006186

treatment of partial onset seizures

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

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

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

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

3.2.3. Marstacimab - Orphan - EMEA/H/C/006240

Pfizer Europe Ma EEIG; routine prophylaxis of bleeding episodes in patients with haemophilia A or haemophilia B

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.02.2024.

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.

3.2.4. Pomalidomide - EMEA/H/C/006302

in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

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. Vorasidenib - Orphan - EMEA/H/C/006284

Les Laboratoires Servier; treatment of predominantly non-enhancing astrocytoma or oligodendroglioma with a IDH1 R132 mutation or IDH2 R172 mutation

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.04.2024.

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

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

3.2.6. Eplontersen - Orphan - EMEA/H/C/006295

AstraZeneca AB; indicated for the treatment of adult patients with polyneuropathy associated with hereditary transthyretin-mediated amyloidosis (ATTRv).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.02.2024.

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

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

The CHMP agreed to consult a SAG Neurology and adopted a list of questions to these experts.

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

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

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

Scope: List of questions

Action: For information

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

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

3.3.2. Deutetrabenazine - EMEA/H/C/006371

treatment of tardive dyskinesia

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. Ferric citrate coordination complex - EMEA/H/C/006402

treatment of iron deficiency anaemia in adult chronic kidney disease (CKD) patients with elevated serum phosphorus levels

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. Human normal immunoglobulin - EMEA/H/C/006423

replacement therapy (primary immunodeficiency syndromes and secondary hypogammaglobulinemia), immunomodulation (in primary immune thrombocytopenic purpura, Guillain Barré syndrome, Kawasaki disease and Multifocal Motor Neuropathy).

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. Eltrombopag - EMEA/H/C/006459

treatment of primary immune thrombocytopenia (ITP), chronic hepatitis C virus (HCV) and acquired severe aplastic anaemia (SAA)

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

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

Scope: List of questions

Action: For information

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

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

3.3.7. Denosumab - EMEA/H/C/006398

prevention of skeletal related events with advanced malignancies

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

The CHMP noted the change of the timetable.

3.3.8. Denosumab - EMEA/H/C/006424

treatment of osteoporosis and bone loss

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. Denosumab - EMEA/H/C/006157

prevention of skeletal related events with advanced malignancies

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/006399

treatment of osteoporosis and bone loss

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. *Pneumococcal polysaccharide* conjugate vaccine (21-valent) - EMEA/H/C/006267

for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae*

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.

3.3.12. Denosumab - EMEA/H/C/006156

treatment of osteoporosis and bone loss

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.

3.3.13. Atropine - EMEA/H/C/006324

treatment of progression of myopia in children aged 3 to 18 years

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.

3.3.14. Sargramostim - EMEA/H/C/006411

treatment for exposure to myelosuppressive doses of radiation

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.

3.3.15. Aflibercept - EMEA/H/C/006192

treatment of age-related macular degeneration (AMD) and visual impairment, treatment of age-related macular degeneration (AMD), visual impairment and retinopathy of prematurity (ROP)

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.

3.3.16. Denosumab - EMEA/H/C/006468

prevention of skeletal related events with advanced malignancies and treatment of giant cell tumour of bone

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.

3.3.17. Tegomil fumarate - EMEA/H/C/006427

treatment of multiple sclerosis

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

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

3.4.1. Liquid ethanolic extract 30 per cent (W/W) of Allium cepa fresh bulb and Citrus limon fresh fruit / Dry aqueous extract of paullinia cupana seed / Dry hydroethanolic extract of theobroma cacao seed - EMEA/H/C/004155

treatment of alopecia areata in children and adolescents

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in June 2024.

Action: For adoption

List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 12.10.2023.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in June 2024.

3.4.2. Bimatoprost - EMEA/H/C/005916

indicated for the reduction of intraocular pressure (IOP) in adults with open angle glaucoma (OAG) or ocular hypertension (OHT) who are unsuitable for topical IOP-lowering medications

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in June 2024.

Action: For adoption

List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 20.07.2023.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in June 2024.

3.4.3. Temozolomide - Orphan - EMEA/H/C/006169

Orphelia Pharma; treatment of neuroblastoma

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in June 2024.

Action: For adoption

List of Outstanding Issues adopted on 27.06.2024 List of Questions adopted on 14.12.2023.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in June 2024.

3.4.4. Donanemab - EMEA/H/C/006024

to slow disease progression in adult patients with Alzheimer’s disease (AD).

Scope: Third-party intervention

Action: For information

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 14.12.2023

The CHMP noted the third-party intervention.

3.4.5. Trastuzumab - EMEA/H/C/006219

treatment of metastatic and early breast cancer

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of questions adopted in May 2024.

Action: For adoption

List of Questions adopted on 30.05.2024.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in May 2024.

3.4.6. Resmetirom - EMEA/H/C/006220

for the treatment of adults with nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of questions adopted in June 2024.

Action: For adoption

List of Questions adopted on 27.06.2024.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in June 2024.

3.4.7. Avacincaptad pegol - EMEA/H/C/006153/0000

treatment of adults with geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of outstanding issues adopted in May 2024.

Action: For adoption

List of Outstanding Issues adopted on 30.05.2024. List of Questions adopted on 14.12.2023.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in May 2024.

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

3.5.1. Masitinib AB Science - Masitinib - Orphan - EMEA/H/C/005897

AB Science; in combination with riluzole for the treatment of adult patients with amyotrophic lateral sclerosis (ALS)

Scope: Re-examination rapporteurs appointment

Action: For adoption

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

Opinion adopted on 27.06.2024. List of Outstanding Issues adopted on 30.05.2024, 25.01.2024, 25.05.2023. List of Questions adopted on 15.12.2022.

The CHMP noted the re-examination request.

3.5.2. Syfovre - Pegcetacoplan - EMEA/H/C/005954

Apellis Europe B.V.; Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Scope: Re-examination rapporteurs were appointed in the July CHMP PROM meeting.

Action: For adoption

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

Opinion adopted on 27.06.2024. List of Outstanding Issues adopted on 25.04.2024, 12.10.2023. List of Questions adopted on 25.05.2023.

The CHMP noted the re-examination request.

3.6. Initial applications in the decision-making phase

3.6.1. AKANTIOR - Polihexanide - Orphan - EMEA/H/C/005858

SIFI SPA; treatment of acanthamoeba keratitis

Scope: Request from the European Commission for clarification in relation to the Opinion adopted by the CHMP for Akantior at its May meeting, revision of the CHMP assessment report

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024, 09.11.2023. List of Questions adopted on 15.09.2022.

The CHMP adopted the revised 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.

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. Edurant - Rilpivirine - EMEA/H/C/002264/X/0042/G

Janssen-Cilag International N.V.

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (2.5 mg dispersible tablets). The new presentation ,in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV 1) infection in paediatric patients 2 to less than 18 years of age and weighing at least 14 kg to less than 25 kg without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, and with a viral load ≤ 100,000 HIV 1 RNA copies/ml (see sections 4.4 and 5.1). Genotypic resistance testing should guide the use of EDURANT (see sections 4.4 and 5.1).The PI and RMP have been updated in accordance.

Type II variation (C.I.6.a) to modify the approved therapeutic indication of the already authorised 25 mg film-coated tablets presentation for the treatment of human immunodeficiency virus type 1 (HIV 1) infection in adults and paediatric patients weighing at least 25 kg without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, and with a viral load ≤ 100,000 HIV 1 RNA copies/ml in combination with other antiretroviral medicinal products. (see sections 4.4 and 5.1). Genotypic resistance testing should guide the use of EDURANT (see sections 4.4 and 5.1). This is based on final results from study studies TMC278-TiDP38-C213 Cohort 2. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3 and 6.4 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. The updated RMP version 10.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes including Annex II and the list of local representatives in the Package Leaflet."

Action: For adoption

List of Outstanding Issues adopted on 30.05.2024. 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 by consensus together with the CHMP Assessment Report and translation timetable.

The summary of opinion was circulated for information.

4.1.2. Opsumit - Macitentan - EMEA/H/C/002697/X/0051/G

Janssen-Cilag International N.V.

Rapporteur: Antonio Gomez-Outes, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (2.5 mg dispersible tablet) grouped with an extension of indication (C.I.6.a) to include, as monotherapy or in combination, the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged 2 years to less than 18 years of age of WHO Functional Class (FC) II to III for OPSUMIT. In addition, the indication of the 10 mg coated tablet is extended, as monotherapy or in combination, for the long-term treatment of PAH in paediatric patients aged less than 18 years and bodyweight ⩾ 40 kg with WHO Functional Class (FC) II to III. This is based on an extrapolation exercise with exposure matching to the adult efficacious dose range given the similarity of the disease in children and adults, as well as on supportive efficacy and safety data from the phase 3 AC-055-312 study (TOMORROW). TOMORROW is a multicenter, open-label, randomized study with single-arm extension period to assess the pharmacokinetics, safety, and efficacy of macitentan versus standard of care in children with pulmonary arterial hypertension.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC for the film-coated tablets are updated. The Package Leaflet and Labelling are updated in accordance. Version 14.4 of the RMP has also been submitted."

Action: For adoption

List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 22.02.2024.

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

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

The CHMP adopted the similarity assessment report

The summary of opinion was circulated for information.

4.1.3. Rybelsus - Semaglutide - EMEA/H/C/004953/X/0039

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: "Extension application to add two new strengths (25 mg and 50 mg) tablets."

Action: For adoption

List of Outstanding Issues adopted on 30.05.2024. List of Questions adopted on 22.02.2024.

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.

4.1.4. Spevigo - Spesolimab - EMEA/H/C/005874/X/0006/G

Boehringer Ingelheim International GmbH

Rapporteur: Kristina Dunder, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Nathalie Gault

Scope: "Extension of indication for 150 mg solution for injection in PFS to include the prevention of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age based on the results from Effisayil 2 (1368-0027), a randomised, double-blind, placebo-controlled phase II b study of spesolimab for subcutaneous administration in adult and adolescent patients with a history of GPP. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.2, 6.3, 6.4, 6.5, 6.6 and 7 have been updated. The PL is updated accordingly.
Extension of indication for 450 mg concentrate for solution for infusion to include the treatment of generalised pustular psoriasis (GPP) flares in adolescents from 12 years of age as monotherapy. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.6 have been updated. Minor editorial changes have been introduced throughout the PI. The PL is updated accordingly.
In addition, the details of the local representative for Norway have been updated. The RMP version 2.2 has also been submitted."

Action: For adoption

List of Outstanding Issues adopted on 30.05.2024, 21.03.2024. List of Questions adopted on 09.11.2023.

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. Cerdelga - Eliglustat - Orphan - EMEA/H/C/003724/X/0036/G

Sanofi B.V.

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension application to introduce a new strength (21 mg capsule, hard) grouped with an extension of indication (C.I.6.a) to include treatment of paediatric patients with GD1 who are 6 years and older with a minimum body weight of 15 kg, who have been previously treated with enzyme replacement therapy (ERT), and who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs) or extensive metabolisers (EMs) for

Cerdelga, based on interim results from study EFC13738 (Open label, two cohort (with and without imiglucerase), multicentre study to evaluate pharmacokinetics, safety, and efficacy of eliglustat in paediatric patients with Gaucher disease type 1 and type 3). 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. The RMP version 8.0 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

Action: For adoption

List of Questions adopted on 25.04.2024.

The Committee discussed the issues identified in this application and its remaining outstanding issues relating to quality aspects.

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

4.2.2. Menveo - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/001095/X/0119

GSK Vaccines S.r.l

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection). The RMP (version 11.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 12.10.2023.

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

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

4.2.3. Ofev - Nintedanib - EMEA/H/C/003821/X/0057/G

Boehringer Ingelheim International GmbH

Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension application to add a new strength of 25 mg hard capsules, grouped with an extension of indication (C.I.6.a) to include treatment of fibrosing Interstitial Lung Diseases (ILDs) in children and adolescents from 6 to 17 years of age for Ofev, following the assessment of procedure X/0052/G, based on final results from study 1199-0337 (A Double Blind, Randomised, Placebo-controlled Trial to Evaluate the Dose-exposure and Safety of Nintedanib Per os on Top of Standard of Care for 24 Weeks, Followed by Open Label Treatment With Nintedanib of Variable Duration, in Children and Adolescents (6 to 17 Year-old) With Clinically Significant Fibrosing Interstitial Lung Disease), which is supplemented by the currently ongoing prospective Phase III extension trial 1199-0378 (An Open-label Trial of the Long-term Safety and Tolerability of Nintedanib Per os, on Top of Standard of Care, Over at Least 2 Years, in Children and Adolescents With Clinically Significant Fibrosing Interstitial Lung Disease). The main objective of the study 1199-0337

was to evaluate dose-exposure and safety of nintedanib in children and adolescents with fibrosing Interstitial Lung Disease (ILD). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 12.0 of the RMP has also been submitted."

Action: For adoption

List of Questions adopted on 22.02.2024.

The Committee discussed the issues identified in this application and its remaining outstanding issues relating to quality and clinical 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. Bosulif - Bosutinib - EMEA/H/C/002373/X/0058/G

Pfizer Europe MA EEIG

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: "Extension application to introduce a new pharmaceutical form (hard capsules) associated with two new strengths (50 mg and 100 mg) grouped with an extension of indication (C.I.6.a) to include treatment of paediatric patients greater than or equal to 1 year of age with newly-diagnosed (ND) chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukaemia (Ph+ CML) for BOSULIF, based on interim results from study ITCC-054/AAML1921 (BCHILD); this is a phase 1/2, multicentre, international, single-arm, open-label study of bosutinib in paediatric patients with newly diagnosed chronic phase or resistant/intolerant Ph+ chronic myeloid leukaemia. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 7.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

Action: For adoption

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

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

4.3.2. PREVYMIS - Letermovir - Orphan - EMEA/H/C/004536/X/0037/G

Merck Sharp & Dohme B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Kirsti Villikka

Scope: "Extension applications to introduce a new pharmaceutical form (granules in sachet) associated with new strengths (20 and 120 mg) grouped with a type II variation (C.I.6.a) to include treatment of paediatric patients from birth up to 18 years old based on the final results from studies P030 and P031.
Study P030 was a Phase 2b, open-label, single-arm study to evaluate PK, efficacy, safety,

and tolerability of LET when used for CMV prophylaxis in paediatric participants from birth to <18 years of age who are at risk of developing CS-CMVi following an allogeneic HSCT. Study P031 was an open-label, single-dose, four-period, seven-treatment, crossover study designed to evaluate the bioavailability of 2 paediatric formulations of MK-8228 (Formulations A and B) administered alone or in soft food (applesauce and vanilla pudding) compared to a currently marketed tablet formulation.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes."

Action: For adoption

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

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

4.3.3. Retsevmo - Selpercatinib - EMEA/H/C/005375/X/0031

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to introduce a new pharmaceutical form (film-coated tablets) associated with new strengths (40 mg, 80 mg, 120 mg and 160 mg).
The RMP (version 7.1) is updated in accordance."

Action: For adoption

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

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

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

4.4.1. Lyrica - Pregabalin - EMEA/H/C/000546/X/0127

Upjohn EESV

Rapporteur: Peter Mol, PRAC Rapporteur: Liana Martirosyan

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the list of questions adopted in May 2024.

Action: For adoption

List of Questions adopted on 30.05.2024.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in May 2024.

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 - Orphan - EMEA/H/C/002455/II/0111

Takeda Pharma A/S

PRAC Rapporteur: Bianca Mulder, PRAC Co-Rapporteur: Jan Mueller-Berghaus, PRAC-CHMP liaison: Peter Mol

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

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

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

5.1.2. Aflunov - Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - EMEA/H/C/002094/II/0086

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 older for AFLUNOV, based on final results from study V87_30. This is a Phase 2, Randomized, 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, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 5.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC."

Action: For adoption

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

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

5.1.3. AREXVY - Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMEA/H/C/006054/II/0008

GlaxoSmithkline Biologicals S.A.

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include treatment of adults 50-59 years of age who are at increased risk for RSV disease for AREXVY, based on results from study 219238 (RSV OA=ADJ-018); this is a phase 3, observer-blind, placebo-controlled, randomized, multi-country, multi-center, non-inferiority study with 2 cohorts to evaluate immunogenicity, reactogenicity and safety of a single dose of RSVPreF3 OA in adults 50-59 years of age. As a consequence, sections 4.1, 4.6, 4.8, 5.1 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 2.0 of the RMP is acceptable. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI, to bring it in line with the latest QRD template version 10.3, and to update the list of local representatives in the Package Leaflet. As part of the application, the MAH requested 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 25.04.2024.

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

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

The summary of opinion was circulated for information.

5.1.4. CellCept - Mycophenolate mofetil - EMEA/H/C/000082/II/0170/G

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher

Scope: "C.I.6.a: Extension of indication to include paediatric patients (3 months to 18 years of age) for hepatic and cardiac transplants and to extend the indication for renal transplants for paediatric patients starting from 3 months, based on pharmacokinetic data, published literature and the Roche Global Safety Database. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly.
Type IB (C.I.z): To update section 4.2 of the SmPC for the CellCept 500 mg tablets

formulation in order to be in line with the other three CellCept formulations. And for alignment with the current QRD guidance, the Package Leaflet was updated to cross reference section 2 in section 6 for sodium content.
In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and bring the PI in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024, 14.09.2023.

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

The Committee adopted a 3rd request for supplementary information with a specific timetable.

5.1.5. Dupixent - Dupilumab - EMEA/H/C/004390/II/0081

Sanofi Winthrop Industrie

Rapporteur: Jan Mueller-Berghaus

Scope: "Extension of indication to include treatment of children aged 1 year and older to the already approved eosinophilic esophagitis (EoE) indication for Dupixent based on final results from study R668-EE-1877 (Part A, Part B, and Part A Addendum) - A Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Dupilumab in Paediatric Patients with Active Eosinophilic Esophagitis. 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."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

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

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

5.1.6. EVKEEZA - Evinacumab - EMEA/H/C/005449/II/0015

Ultragenyx Germany GmbH

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Mari Thorn

Scope: "Extension of indication for EVKEEZA to include the treatment of paediatric patients with homozygous familial hypercholesterolaemia aged 6 months to less than 5 years, based on the results of population PK and population PK/PD model-based extrapolation reports (R1500-PM-23202-SR-01V2 and R1500-PM-23089-SR-01V2). 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 Marketing authorisation holder (MAH) took the opportunity to implement minor changes to sections 4.2, 4.4, and 4.7 of the SmPC, along with editorial changes to the SmPC."

Action: For adoption

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

and RMP aspects.

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

5.1.7. Kevzara - Sarilumab - EMEA/H/C/004254/II/0044

Sanofi Winthrop Industrie

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Extension of indication to include treatment of Polymyalgia Rheumatica (PMR) in adult patients who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper for Kevzara, based on results from study EFC15160; this is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of sarilumab in patients with polymyalgia rheumatica; 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 4.0 of the RMP is also submitted. 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 21.03.2024.

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

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

5.1.8. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0150

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include Keytruda in combination with enfortumab vedotin for the first-line treatment of unresectable or metastatic urothelial carcinoma in adults, based on the final results from KEYNOTE-A39/EV-302: "An open label, randomized, controlled phase 3 study of enfortumab vedotin in combination with pembrolizumab versus chemotherapy alone in previously untreated locally advanced (LA) or metastatic urothelial cancer (mUC)". 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 45.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024.

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

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

The summary of opinion was circulated for information.

5.1.9. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0154

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include in combination with pemetrexed and platinum chemotherapy the first-line treatment of adults and adolescents aged 12 years and older with unresectable advanced or metastatic malignant pleural mesothelioma for Keytruda, based on final results from study KEYNOTE-483; this is a multicentre, open-label, Phase 2/3 randomized study to evaluate the efficacy and safety of pembrolizumab in combination with pemetrexed/platinum chemotherapy in participants with unresectable advanced or metastatic malignant pleural mesothelioma (MPM). As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 47.1 of the RMP has also been submitted."

Action: For adoption

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

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

5.1.10. Kisqali - Ribociclib - EMEA/H/C/004213/II/0045

Novartis Europharm Limited

Rapporteur: Filip Josephson, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Extension of indication to include the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, Stage II or Stage III early breast cancer, irrespective of nodal status, in combination with an AI for Kisqali based on study CLEE011O12301C (NATALEE); This is a global, Phase III, multicentre, randomized, open-label trial to evaluate efficacy and safety of ribociclib with ET versus ET alone as adjuvant treatment in patients with HR-positive, HER2-negative, early breast cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024, 14.12.2023.

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

The Committee adopted a 3rd request for supplementary information with a specific timetable.

5.1.11. OPDIVO - Nivolumab - EMEA/H/C/003985/II/0140

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include OPDIVO for the treatment of patients with

resectable stage II-IIIB non-small cell lung cancer, based on results from study CA209977T; a phase 3, randomised, double-blind study of neoadjuvant chemotherapy plus nivolumab versus neoadjuvant chemotherapy plus placebo, followed by surgical resection and adjuvant treatment with nivolumab or placebo for participants with resectable stage II-IIIB non-small cell lung cancer. 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 36.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024.

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

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

5.1.12. Otezla - Apremilast - EMEA/H/C/003746/II/0044/G

Amgen Europe B.V.

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Monica Martinez Redondo

Scope: "A grouped application of a Type II Variation with two Type IA Variations, as follows: Type II (C.I.6.a): Extension of indication to include the treatment of moderate to severe chronic plaque psoriasis in children and adolescents from the age of 6 years who have a contraindication, have an inadequate response, or are intolerant to at least one other systemic therapy or phototherapy for OTEZLA, based on final results from study CC-10004-PPSO-003 as well as results from studies CC-10004-PPSO-001 and CC-10004-PPSO-004. CC-10004-PPSO-003 is a phase 3, multi-centre, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of apremilast (CC-10004) in paediatric subjects from 6 through 17 years of age with moderate to severe plaque psoriasis. As a consequence, sections 4.1, 4.2, 4.4 ,4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 15.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial and formatting changes to the PI and to update the list of local representatives in the Package Leaflet.
2 Type IA (B.II.e.5.a.1): Update of sections 6.5 and 8 of the SmPC to introduce two new pack sizes within approved range as a result of the indication update ."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

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

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

5.1.13. Padcev - Enfortumab vedotin - EMEA/H/C/005392/II/0013

Astellas Pharma Europe B.V.

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Eva

Jirsová

Scope: "Extension of indication to include PADCEV in combination with pembrolizumab, the first-line treatment of adult patients with locally advanced or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy, based on the final results from study KEYNOTE-A39/EV-302. This was an open label, randomized, controlled phase 3 study of enfortumab vedotin in combination with pembrolizumab versus chemotherapy alone in previously untreated locally advanced (LA) or metastatic urothelial cancer (mUC)". As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. 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 25.04.2024.

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

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

The summary of opinion was circulated for information.

5.1.14. Pemazyre - Pemigatinib - Orphan - EMEA/H/C/005266/II/0015

Incyte Biosciences Distribution B.V.

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

Scope: "Extension of indication to include treatment of adults with myeloid/lymphoid neoplasms (MLNs) with Fibroblast Growth Factor Receptor1 (FGFR1) rearrangement for PEMAZYRE, based on final results from study INCB 54828-203 (FIGHT-203); this is a phase 2, open-label, monotherapy, multicentre study to evaluate the efficacy and safety of INCB054828 in subjects with myeloid/lymphoid neoplasms with FGFR1 rearrangement. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 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 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.", 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 25.04.2024.

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

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

5.1.15. Rybrevant - Amivantamab - EMEA/H/C/005454/II/0011

Janssen-Cilag International N.V.

Rapporteur: Filip Josephson, Co-Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Gabriele Maurer

Scope: " Extension of indication to include amivantamab in combination with carboplatin and pemetrexed for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI) for RYBREVANT, based on the final results from study 61186372NSC3002 (MARIPOSA 2); this is a randomized, open label, multicenter Phase 3 study that compares efficacy and safety of amivantamab in combination with carboplatin and pemetrexed (ACP) with carboplatin and pemetrexed (CP). The primary objective of the MARIPOSA 2 study is to compare efficacy, as demonstrated by PFS, in participants treated with ACP versus CP alone. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2 of the EU RMP has also been agreed."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

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

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

The summary of opinion was circulated for information.

5.1.16. SARCLISA - Isatuximab - EMEA/H/C/004977/II/0030

Sanofi Winthrop Industrie

Rapporteur: Peter Mol, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Extension of indication to include in combination with bortezomib, lenalidomide, and dexamethasone the treatment of adult patients with newly diagnosed active multiple myeloma who are not eligible for autologous stem cell transplant (ASCT) or with no intent for ASCT as initial therapy for Sarclisa, based on results from EFC12522 (IMROZ) pivotal phase III study and the supportive TCD13983 phase 1b/2 study. EFC12522 is an ongoing prospective, multicentre, international, randomized, open-label, 2-arm parallel group study to assess the clinical benefit of VRd (control group) versus IVRd (active group) for the treatment of participants with NDMM who are not eligible for ASCT. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.7, 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."

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. Slenyto - Melatonin - EMEA/H/C/004425/II/0025

RAD Neurim Pharmaceuticals EEC SARL

Rapporteur: Kristina Dunder, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication to include treatment of neurogenetic disorders (e.g., Angelman syndrome, Rett syndrome, Tuberous sclerosis complex and Williams syndrome) for SLENYTO, based on Phase III study NEU_CH_7911, post-marketing data and literature; As a consequence, sections 4.1 and 4.8 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.", 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 21.03.2024.

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

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

The summary of opinion was circulated for information.

5.1.18. TAGRISSO - Osimertinib - EMEA/H/C/004124/II/0056

AstraZeneca AB

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy for TAGRISSO as monotherapy, based on results from study D5160C00048 (LAURA); this is a Phase III, randomised, double-blind, placebo-controlled, multicentre international study of osimertinib as maintenance therapy in patients with locally advanced unresectable EGFR mutation-positive non-small cell lung cancer (stage III) whose disease has not progressed following definitive platinum-based chemoradiation therapy. 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 17.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

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. Tecentriq - Atezolizumab - EMEA/H/C/004143/II/0082

Roche Registration GmbH

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) who are ineligible for platinum-based therapy (see section 5.1 for selection criteria), for TECENTRIQ, based on final results from study MO29872 (IPSOS); this is a phase 3, open-label, multicenter, randomised study to investigate the efficacy and safety of atezolizumab compared with chemotherapy in patients with treatment naive advanced or recurrent (stage IIIB not amenable for multimodality treatment) or metastatic (stage IV) NSCLC who are deemed unsuitable for platinum-containing therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The new indication has been reflected in the SmPC for the IV and the SC formulations. Version 29.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024, 14.12.2023.

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

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

The summary of opinion was circulated for information.

5.1.20. Wegovy - Semaglutide - EMEA/H/C/005422/II/0017

Novo Nordisk A/S

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

Scope: "Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC based on results from study EX9536-4388 (SELECT); this is a randomised, double-blind, placebo-controlled, trial comparing semaglutide 2.4 mg with placebo both administered s.c. once weekly in subjects with established cardiovascular disease and overweight or obesity. The Package Leaflet is updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 27.06.2024, 25.04.2024, 25.01.2024.

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.

5.1.21. WS2538
Braftovi - Encorafenib - EMEA/H/C/004580/WS2538/0034
Mektovi - Binimetinib - EMEA/H/C/004579/WS2538/0030

Pierre Fabre Medicament

Lead Rapporteur: Janet Koenig, PRAC Rapporteur: Rugile Pilviniene

Scope: "Extension of indication to include binimetinib in combination with encorafenib for

the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with a BRAF V600E mutation for MEKTOVI and BRAFTOVI based on results from study PHAROS (Study ARRAY-818-202) at the primary completion date; this is a Phase II, open-label, multicentre, non-comparative study (interventional). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the Braftovi SmPC and sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the Mektovi SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of Braftovi and Mektovi RMPs have also been approved."

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024, 25.01.2024.

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

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

The summary of opinion was circulated for information.

5.1.22. WS2672
OPDIVO - Nivolumab - EMEA/H/C/003985/WS2672/0141
Yervoy - Ipilimumab - EMEA/H/C/002213/WS2672/0111

Bristol-Myers Squibb Pharma EEIG

Lead Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

Scope: "A Worksharing application for OPDIVO and YERVOY, as follows:
Extension of indication to include OPDIVO in combination with ipilimumab in the first-line treatment of adult patients with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) unresectable or metastatic colorectal cancer, based on interim results from study CA2098HW; this is a phase 3 randomised clinical trial of nivolumab alone, nivolumab in combination with ipilimumab, or investigator's choice chemotherapy in participants with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 37.0 of the RMP has also been submitted.
Extension of indication to include YERVOY in combination with nivolumab in the first-line treatment of adult patients with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) unresectable or metastatic colorectal cancer, based on interim results from study CA2098HW; this is a phase 3 randomised clinical trial of nivolumab alone, nivolumab in combination with ipilimumab, or investigator's choice chemotherapy in participants with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer. 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 41.0 of the RMP has also been submitted."

Action: For adoption

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

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

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

5.2.1. WS2551
Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/WS2551/0043
Kalydeco - Ivacaftor - EMEA/H/C/002494/WS2551/0121

Vertex Pharmaceuticals (Ireland) Limited

Lead Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

Scope: "Extension of the indication for Kaftrio (ivacaftor/tezacaftor/elexacaftor) and Kalydeco (ivacaftor) in a combination regimen to include the treatment of patients with cystic fibrosis (CF) aged 2 years and older who do not carry any F508del mutations and have at least one ivacaftor/tezacaftor/elexacaftor-responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene based on study VX21-445-124, study VX21-445-125 and study VX22-CFD-016. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the Kaftrio SmPC are updated; sections 4.1 and 5.1 of the Kalydeco SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

Scope: Third-party intervention

Action: For information

Request for Supplementary Information adopted on 30.05.2024, 22.02.2024.

The CHMP noted the third-party intervention.

5.2.2. Sialanar - Glycopyrronium - EMEA/H/C/003883/II/0029

Proveca Pharma Limited

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Zane Neikena

Scope: "Extension of indication to include treatment of children aged from 2 years and older for SIALANAR, based on the interim results from study PRO/GLY/005. This is a retrospective analysis of real-world data from children aged under 3 years treated with glycopyrronium for severe drooling. As a consequence, sections 4.1, 4.2, and 4.4 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 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.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Request for an extension to the clock stop to respond to the request for supplementary information adopted in May 2024.

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024.

The CHMP agreed to the request by the applicant via written procedure on 3 July 2024 for an extension to the clock stop to respond to the request for supplementary information

adopted in May 2024.

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006536

to detect ITD and TKD mutations in the FLT3 gene in patients with acute myelogenous leukaemia (AML).

Scope: Opinion

Action: For adoption

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

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

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006530

to detect somatic alterations in human DNA and RNA isolated from formalin-fixed, paraffin-embedded (FFPE) solid tumour samples.

Scope: Opinion

Action: For adoption

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

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

6.3.3. In vitro diagnostic medical device - EMEA/H/D/006543

Qualitative immunohistochemical assay using mouse monoclonal anti-claudin 18, clone 43 14A, intended for laboratory use in the assessment of claudin 18 (CLDN18) protein in formalin-fixed, paraffin-embedded (FFPE) gastric adenocarcinoma including gastroesophageal junction (GEJ) tissue specimens by light microscopy.

Scope: Opinion

Action: For adoption

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

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

6.3.4. In vitro diagnostic medical device - EMEA/H/D/006545

laboratory use in the assessment of folate receptor alpha (FOLR1) protein in formalin-fixed paraffin embedded (FFPE) epithelial ovarian, fallopian tube or primary peritoneal cancer tissue specimens by light microscopy

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

None

8.2. Priority Medicines (PRIME)

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

The CHMP adopted the recommendations for PRIME eligibility.

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0013

Gilead Sciences Ireland Unlimited Company

Rapporteur: Filip Josephson

Scope: "Update of section 5.3 of the SmPC in order to include non-clinical information based on final results from study TX-200-2046 entitled, "104 Week Subcutaneous Injection Carcinogenicity and Toxicokinetic Study of GS-6207 Administered Every 13 Weeks in Wistar-Han Rats". In addition, the MAH took the opportunity introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 13.06.2024, 11.04.2024, 18.01.2024.

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

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

9.1.2. Wegovy - Semaglutide - EMEA/H/C/005422/II/0019

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: "Update of sections 4.1, 4.4, 4.8 and 5.1 in order to include information in patients with obesity-related HFpEF, with and without type 2 diabetes based on the final reports from studies EX9536-4665 STEP-HFpEF, EX9536-4773 STEP HFpEF-DM and EX9536-4388 SELECT. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 11.04.2024.

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

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

timetable.

9.1.3. Mysimba - Naltrexone hydrochloride / Bupropion hydrochloride - EMEA/H/C/003687/II/0063

Orexigen Therapeutics Ireland Limited

Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig

Scope: "To update sections 4.3, 4.4 and 4.5 of the SmPC to update and streamline the relevant wording on opioids following the assessment of PSUSA/00010366/202209 procedure. The Package Leaflet is updated accordingly. The RMP version 12.9 has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 16.05.2024, 09.02.2024, 31.08.2023.

The Committee adopted a negative opinion by consensus recommending the refusal of the variation to the terms of the marketing authorisation.

The CHMP adopted the assessment report.

9.1.4. Alofisel - Darvadstrocel - EMEA/H/C/004258/II/0051/G - Orphan -ATMP

Takeda Pharma A/S

Rapporteur: Maria Luttgen, CHMP Coordinator: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer

Scope: "A grouped application comprised of 4 Type II Variations, as follows:
(C.I.4): Update of sections 4.8 and 5.1 of the SmPC in order to update the safety information, based on pooled safety data from the two phase 3 controlled studies (ADMIRE-CD & ADMIRE-CD II) and to update efficacy information based on final results from study ADMIRE-CD II, listed as an obligation in the Annex II. ADMIRE-CD II (Cx601-0303) is a Phase III randomised double blind, placebo-controlled study to assess efficacy and safety of Cx601, adult allogeneic expanded adipose-derived stem cells (eASC) for the treatment of complex perianal fistula(s) in patients with Crohn's disease. The Annex II is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI, including to section 4.2 of the SmPC and to the Package Leaflet.
3 x (C.I.13): Submission of interim results from studies Darvadstrocel-3003 and Alofisel-5003 (INSPIRE) and final results from study Darvadstrocel-3002 to support the benefit-risk assessment of darvadstrocel based on all new available clinical data.
The RMP version 8.0 has also been submitted."

Action: For adoption

The CHMP was updated on discussions at the CAT.

The Committee discussed the issues identified in this application.

The Committee endorsed the request for supplementary information with a specific timetable as adopted by the CAT.

9.1.5. Translarna - ataluren - EMEA/H/C/002720/R/0071 - Orphan

PTC Therapeutics International Limited

Scope: Re-examination request, appointment of re-examination rapporteurs

Action: For adoption

The CHMP noted the re-examination request.

9.1.6. Privigen– Human normal immunoglobulin – EMEA/H/C/000831

CSL Behring GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Paolo Gasparini

Scope: DHPC and communication plan

Action: For adoption

The CHMP adopted the DHPC and communication plan.

9.1.7. NovoSeven – Eptacog alfa (activated) – EMEA/H/C/000074

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alexandre Moreau

Scope: DHPC and communication plan

Action: For adoption

The CHMP adopted the DHPC and communication plan.

10. Referral procedures

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

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

Pfizer Europe MA EEIG

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

Scope: appointment of rapporteurs, list of questions, timetable

Action: For adoption

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

the benefit-risk balance of Oxbryta in its authorised indication.
In addition, the EC requests the Agency to give its opinion, as soon as possible, as to whether temporary measures are necessary to ensure the safe and effective use of this medicinal product.

At an extraordinary CHMP meeting on 29 July 2024, the CHMP discussed this referral.

On 29 July 2024, the CHMP appointed Patrick Vrijlandt as Referral Rapporteur and Alexandre Moreau as Referral Co-Rapporteur.

The CHMP agreed that no temporary measures were necessary at this stage. The CHMP considered at this point that a detailed assessment of all available data from the two trials in which a potential safety concern was observed in the context of all available data on Oxbryta was necessary, before making recommendations on its authorised use.

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

Notification: 26.07.2024

Start of the procedure (CHMP): 29.07.2024

List of questions: 29.07.2024

Submission of responses: 29.08.2024

Re-start of the procedure: 19.09.2024

Rapporteur/co-rapporteur assessment report(s) circulated to CHMP: 26.09.2024

Comments: 03.10.2024

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 09.10.2024

CHMP list of outstanding issues or CHMP Opinion: October 2024 CHMP

10.1.2. Ocaliva - obeticholic acid - EMEA/H/A-20/1531

Advanz Pharma Limited

Referral Rapporteur: Carolina Prieto Fernandez, Referral Co-Rapporteur: Paolo Gasparini

Scope: Revised CHMP opinion, third-party intervention, letters from MAH

Action: For adoption

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Ocaliva (obeticholic acid). The review was prompted by final study results raising concerns of a potential lack of efficacy and worsened safety profile. These findings need to be reviewed in the context of all available data and their potential impact on the benefit-risk of Ocaliva assessed.
Negative opinion adopted on 27.06.2024. List of outstanding issues adopted on 25.04.2024 and 25.01.2024. List of Questions adopted on 12.10.2023.

At an extraordinary CHMP meeting on 29 July2024, the CHMP discussed this referral.

On 29 July 2024, the Committee adopted a revised Opinion in order to clarify the status of the regulatory procedure in the DHPC and the communication plan.

The CHMP noted the third-party intervention and the letters from the MAH.

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

July 2024 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

The CHMP noted the information.

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

No items

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

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

Hrefna Gudmundsdottir gave a proxy to Outi Mäki-Ikola for the whole meeting.

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for July 2024

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

Agenda of the July 2024 PDCO plenary meeting

Action: For information

The CHMP noted the agenda.

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

Reports from the BWP meeting for CHMP adoption

Action: For adoption

The CHMP adopted the BWP reports.

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 08-11 July 2024. 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 update.

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

No items

15. Any other business

15.1. AOB topic

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 July 2024 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
Harald Enzmann	Chair	Germany	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 interests declared	
Gergana Lazarova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Helena Panayiotopoulou	Member	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	
Aaron Sosa Mejia	Alternate	Denmark	No participation in discussion, final deliberations and voting on:	4.1.3. Rybelsus - Semaglutide - EMEA/H/C/004953/X/0039 5.1.20. Wegovy - Semaglutide - EMEA/H/C/005422/II/0017 9.1.2. Wegovy - Semaglutide - EMEA/H/C/005422/II/0019
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Finbarr Leacy	Alternate	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	4.2.1. Cerdelga - Eliglustat - Orphan - EMEA/H/C/003724/X/0036/G 5.1.5. Dupixent - Dupilumab - EMEA/H/C/004390/II/0081 5.1.7. Kevzara - Sarilumab - EMEA/H/C/004254/II/0044 5.1.16. SARCLISA - Isatuximab - EMEA/H/C/004977/II/0030
John Joseph Borg	Member	Malta	No interests declared	
Peter Mol	Member	Netherlands	No interests declared	
Patrick Vrijlandt	Alternate	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Kristina Nadrah	Member	Slovenia	No restrictions applicable to this meeting	
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Mario Miguel Coelho da Silva Rosa	Expert	Portugal	No interests declared	
Ailise Carleton	Expert	Ireland	No interests declared	
Catherine Byrne	Expert	Ireland	No interests declared	
Emma Fagan	Expert	Ireland	No interests declared	
Liam McDonough	Expert	Ireland	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Beatriz Gutiérrez Eugenio	Expert	Spain	No interests declared	
Cristina Migali	Expert	Italy	No interests declared	
Christoph Furtmann	Expert	Germany	No interests declared	
George Aislaitner	Expert	Germany	No interests declared	
Marion Haberkamp	Expert	Germany	No interests declared	
Christine Greiner	Expert	Germany	No interests declared	
Claire Beuneu	Expert	Belgium	No interests declared	
Alexandru Mihail Simion	Expert	Belgium	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Lies (Elizabeth) Van Vlijmen	Expert	Netherlands	No interests declared	
Viktoriia Starokozhko	Expert	Netherlands	No restrictions applicable to this meeting	
Nicole Jaspers	Expert	Netherlands	No interests declared	
Elly Vereyken	Expert	Netherlands	No interests declared	
Ilse Boekhoud	Expert	Netherlands	No interests declared	
Johannes Petrus Theodorus Span	Expert	Netherlands	No interests declared	
Jacoba (Jacqueline) van Kuijk	Expert	Netherlands	No interests declared	
Illiana Meurs	Expert	Netherlands	No interests declared	
Loes Maton	Expert	Netherlands	No interests declared	
Eline Kuipers	Expert	Netherlands	No restrictions applicable to this meeting	
Steffen Gross	Expert	Germany	No interests declared	
Kendra Schafti	Expert	Germany	No interests declared	
Benjamin Hofner	Expert	Germany	No restrictions applicable to this meeting	
Katja Findeisen	Expert	Germany	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Susanne Mueller-Egert	Expert	Germany	No interests declared	
Samira Alina Marx	Expert	Germany	No interests declared	
Robert Pollmann	Expert	Germany	No interests declared	
Jörg Engelbergs	Expert	Germany	No interests declared	
Hilke Zander	Expert	Germany	No interests declared	
Sara Tognarelli	Expert	Germany	No restrictions applicable to this meeting	
Umberto CASALEGNO	Expert	France	No interests declared	
Anissa Benlazar	Expert	France	No interests declared	
Laura Andreoli	Expert	France	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Armin Koch	Expert	Germany	no part in discussions, final deliberations and voting as appropriate as regards the medicinal product or a rival product:	3.1.11. Vevizye - Ciclosporin - EMEA/H/C/006250
Carin Bergquist	Expert	Sweden	No interests declared	
Michaela Dlouhá	Expert	Czechia	No interests declared	
Jana Kopecká	Expert	Czechia	No interests declared	
Jutta Dedorath	Expert	Germany	No interests declared	
Susanna Hausmann	Expert	Germany	No interests declared	
Federico De Angelis	Expert	Italy	No interests declared	
Gaby Wangorsch	Expert	Germany	No interests declared	
Meeting run with the help of EMA staff.				

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

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

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the extraordinary CHMP meeting held on 29 July 2024 which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Daniela Philadelphy	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No interests declared	
Gergana Lazarova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Alexandre Moreau	Member	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Larisa Gorobets	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No restrictions applicable to this meeting	
Patrick Vrijlandt	Alternate	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Kristina Nadrah	Member	Slovenia	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Carolina Prieto Fernandez	Member	Spain	No interests declared	
Antonio Gomez-Outes	Alternate	Spain	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Ulla Wändel Liminga	Expert	Sweden	No interests declared	
Sabine Straus	Expert	Netherlands	No interests declared	
Jo Robays	Expert	Belgium	No interests declared	
Anissa Benlazar	Expert	France	No interests declared	
Valerie Lescrainier	Expert	Belgium	No interests declared	
Kristina Bech Jensen	Expert	Denmark	No interests declared	
Antonella Isgrò	Expert	Italy	No interests declared	
Adrianus Van Gompel	Expert	Netherlands	No interests declared	
Lies (Elizabeth) Van Vlijmen	Expert	Netherlands	No interests declared	
Paula Contreras Alarcón	Expert	Spain	No restrictions applicable to this meeting	
Ana Maria IMEDIO	Expert	Spain	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Angelo Molinaro	Expert	Italy	No interests declared	
Sara Galluzzo	Expert	Italy	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with the help of EMA staff				

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

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

Explanatory notes

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

Oral explanations *(section 2)*

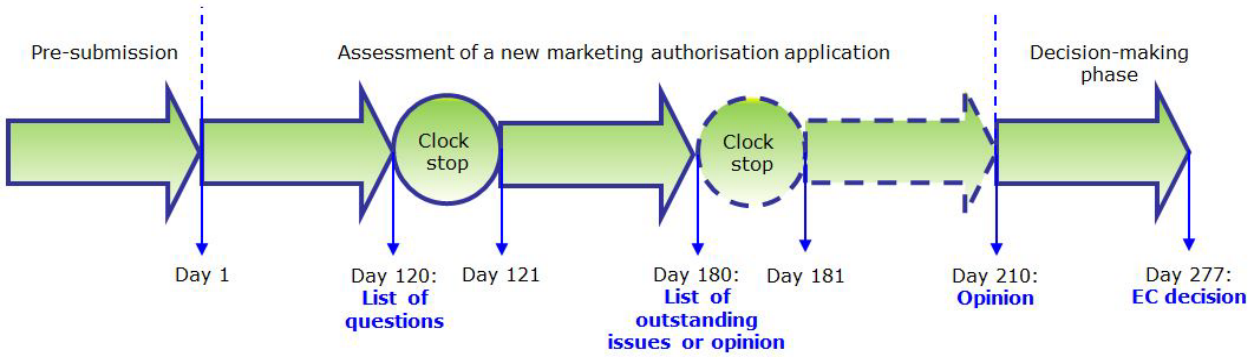
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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