

28 November 2024
EMA/CHMP/330692/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 24-27 June 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

Health and safety information

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

Disclaimers

Some of the information contained in 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 in-person.

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

Participants were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. 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 24-27 June 2024.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 27-30 May 2024.

The CHMP adopted the minutes for the 27-30 May 2024 plenary.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Lecanemab - EMEA/H/C/005966

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: Oral explanation

Action: Oral explanation to be held on 25 June 2024 at 14:00

Participation of patient representatives.

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

An oral explanation was held on 25 June 2024. The presentation by the applicant focused on the clinical data in support of the application.

See 3.2

2.1.2. Pegcetacoplan - EMEA/H/C/005954

Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Scope: Oral explanation

Action: Oral explanation to be held on 25 June 2024 at 16:00

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

An oral explanation was held on 25 June 2024. The presentation by the applicant focused on the clinical data in support of the application.

See 3.1

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

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

PTC Therapeutics International Limited

Rapporteur: Peter Mol, Co-Rapporteur: Antonio Gomez-Outes

Scope: Oral explanation

Action: Oral explanation to be held on 25 June 2024 at 11:00

Participation of patient representatives.

Request for Supplementary Information adopted on 25.05.2023.

An oral explanation was held on 25 June 2024. The presentation by the applicant focused on the clinical data in support of the application.

See 9.1

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

Novo Nordisk A/S

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

Scope: "Extension of indication to include risk reduction of major adverse cardiovascular

events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and BMI ≥ 27 kg/m² for WEGOVY, 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. As a consequence, section 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. 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)

Scope: Oral explanation

Action: Oral explanation to be held on 26 June 2024 at 09:00

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

An oral explanation was held on 26 June 2024. The presentation by the applicant focused on the clinical data in support of the application.

See 5.1

2.4. Referral procedure oral explanations

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

Advanz Pharma Limited

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

Scope: Oral explanation

Action: Oral explanation to be held on 25 June 2024 at 09:00

Participation of patient representatives.

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.

List of outstanding issues adopted on 25.04.2024 and 25.01.2024. List of Questions adopted on 12.10.2023.

An oral explanation was held on 25 June 2024. The presentation by the applicant focused on the clinical data in support of the application.

See 10.1

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Balversa - Erdafitinib - EMEA/H/C/006050

Janssen-Cilag International N.V.; treatment of adult patients with locally advanced unresectable or metastatic urothelial carcinoma (UC)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024. 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.

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

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

The summary of opinion was circulated for information.

3.1.2. Enzalutamide Viatris - Enzalutamide - EMEA/H/C/006299

Viatris Limited; treatment of prostate cancer

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024. 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 medical prescription.

The summary of opinion was circulated for information.

3.1.3. EURneffy - Epinephrine - EMEA/H/C/006139

Ars Pharmaceuticals Irl Limited; Treatment of allergic reactions (anaphylaxis) and idiopathic or exercise induced anaphylaxis

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, 12.10.2023. List of Questions adopted on 23.02.2023.

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 medical prescription.

The summary of opinion was circulated for information.

The EMA public health communication was circulated for information.

3.1.4. 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: 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, 25.01.2024, 25.05.2023. List of Questions adopted on 15.12.2022.

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

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

3.1.5. mRESVIA - Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation - EMEA/H/C/006278

Moderna Biotech Spain S.L.; Prevention of lower respiratory tract disease (LRTD) and acute respiratory disease (ARD) caused by respiratory syncytial virus (RSV)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024. 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.

Furthermore, the CHMP considered that Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation is a new active substance, as claimed by the applicant.

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

The summary of opinion was circulated for information.

3.1.6. Nilotinib Accord - Nilotinib - EMEA/H/C/006315

Accord Healthcare S.L.U.; treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (CML)

Scope: Opinion

Action: For adoption

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

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

3.1.7. Ordspono - Odronextamab - Orphan - EMEA/H/C/006215

Regeneron Ireland Designated Activity Company; treatment of blood cancers (follicular lymphoma (FL) or diffuse large B cell lymphoma (DLBCL) and large B cell lymphoma)

Scope: Opinion

Action: For adoption

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

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

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

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

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

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

The summary of opinion was circulated for information.

3.1.8. [Piasky - Crovalimab - EMEA/H/C/006061](#)

Roche Registration GmbH; treatment of paroxysmal nocturnal haemoglobinuria

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024. 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.

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

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

The CHMP noted the letter of recommendations dated 17 June 2024.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

3.1.9. [Syfovre - Pegcetacoplan - EMEA/H/C/005954](#)

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

Scope: Opinion, third-party intervention

Action: For adoption

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

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

An oral explanation was held on 25 June 2024. The presentation by the applicant focused on the clinical data in support of the application.

The CHMP noted the report from the AHEG.

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

The divergent position was appended to the opinion.

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

The CHMP noted the third-party intervention.

See 2.1

3.1.10. STEQEYMA - Ustekinumab - EMEA/H/C/005918

Celltrion Healthcare Hungary Kft.; treatment of adult patients with moderately to severely active Crohn's disease, 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)

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 12.10.2023.

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.

3.1.11. Tauvid - Flortaucipir (18F) - EMEA/H/C/006064

Eli Lilly Nederland B.V.; indicated for Positron Emission Tomography (PET) imaging of the brain

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 22.02.2024, 14.12.2023. 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.

Furthermore, the CHMP considered that Flortaucipir (18F) is a new active substance, as

claimed by the applicant.

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

The summary of opinion was circulated for information.

3.1.12. [Winrevair Sotatercept - PRIME - Orphan - EMEA/H/C/005647](#)

Merck Sharp & Dohme B.V.; treatment of pulmonary arterial hypertension in adults

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 23.01.2024.

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.

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

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

The CHMP noted the letter of recommendations dated 20 June 2024.

The summary of opinion was circulated for information.

The EMA public health communication 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. [Ustekinumab - EMEA/H/C/006585](#)

treatment of active plaque psoriasis, paediatric plaque psoriasis, psoriatic arthritis (PsA) and Crohn's disease.

Scope: List of outstanding issues

Action: For adoption

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

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

3.2.2. Aflibercept - EMEA/H/C/006150

treatment of age-related macular degeneration (AMD), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO), due to diabetic macular oedema (DME) and due to myopic choroidal neovascularisation (myopic CNV) or central RVO).

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.

3.2.3. Axitinib - EMEA/H/C/006206

treatment of adult patients with advanced renal cell carcinoma (RCC)

Scope: Opinion

Action: For adoption

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

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

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

3.2.4. 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: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.10.2023.

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

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

3.2.5. 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: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.07.2023.

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

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

3.2.6. [Mirvetuximab soravtansine - Orphan - EMEA/H/C/005036](#)

Immunogen Biopharma (Ireland) Limited; treatment of ovarian, fallopian tube, or primary peritoneal cancer

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.

3.2.7. [Vilobelimab - EMEA/H/C/006123](#)

treatment of adult patients with SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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

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

3.2.8. [Ustekinumab - EMEA/H/C/006221](#)

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

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.

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

Orphelia Pharma; treatment of neuroblastoma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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

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

3.2.10. Lecanemab - EMEA/H/C/005966

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: List of outstanding issues, third-party intervention.

Action: For adoption

Participation of patient representatives.

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

An oral explanation was held on 25 June 2024. The presentation by the applicant focused on the clinical data in support of the application.

The CHMP noted the report from the SAG-Neurology.

The CHMP noted the third-party intervention.

See 2.1

3.2.11. Meningococcal group A, B, C, W and Y vaccine - EMEA/H/C/006165

indicated for active immunisation to prevent invasive disease caused by *Neisseria meningitidis* groups A, B, C, W, and Y

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.10.2023.

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

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

3.2.12. Aflibercept - EMEA/H/C/006056

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.03.2024.

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

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

3.2.13. rdESAT-6 / rCFP-10 - EMEA/H/C/006177

Diagnosis of infection with *Mycobacterium tuberculosis*

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 22.06.2023.

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

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

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

3.3.1. Tocilizumab - EMEA/H/C/006196

treatment of rheumatoid arthritis (RA)

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.2. Datopotamab - EMEA/H/C/006547

Treatment of adult patients with inoperable or metastatic HR-positive / HER2-negative breast cancer with disease progression following chemotherapy in the metastatic setting

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. Datopotamab - EMEA/H/C/006081

treatment of adult patients with locally advanced or metastatic non squamous non-small cell lung cancer (NSCLC)

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. Pegfilgrastim - EMEA/H/C/006407

treatment of neutropenia

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

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

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. Seladelpar lysine dihydrate - PRIME - Orphan - EMEA/H/C/004692

CymaBay Ireland, Ltd; treatment of primary biliary cholangitis (PBC) including pruritus in adults without cirrhosis or with compensated cirrhosis (Child-Pugh A) in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

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

Springworks Therapeutics Ireland Limited; treatment of desmoid tumours

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.8. Aflibercept - EMEA/H/C/006339

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

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. Resmetirom - EMEA/H/C/006220

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

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. Aflibercept - EMEA/H/C/006551

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

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. Ustekinumab - EMEA/H/C/006444

for the treatment of Crohn's disease and ulcerative colitis

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

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

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

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

Action: For information

List of Questions adopted on 19.04.2024.

The CHMP noted the timetable adopted by the CAT.

The CHMP endorsed the request by the applicant for an extension to the clock stop to respond to the list of questions adopted in April 2024, as adopted by CAT.

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

No items

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Dabigatran etexilate - EMEA/H/C/006023

Prevention of venous thromboembolic events

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 30.03.2023. List of Questions adopted on 21.07.2022.

The CHMP noted the withdrawal of the marketing authorisation application.

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

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

4.1.1. Betmiga - Mirabegron - EMEA/H/C/002388/X/0039/G

Astellas Pharma Europe B.V.

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

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (8 mg/ml prolonged-release granules for oral suspension), grouped with a type II variation (C.I.6.a) to include treatment of neurogenic detrusor overactivity (NDO) in paediatric patients aged 3 to less than 18 years. The RMP (version 9.2) is updated in accordance.

Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

List of Outstanding Issues adopted on 22.02.2024, 15.09.2022. List of Questions adopted on 22.04.2022.

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

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

4.1.2. Cresemba - Isavuconazole - Orphan - EMEA/H/C/002734/X/0042/G

Basilea Pharmaceutica Deutschland GmbH

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to add a new strength of 40 mg hard capsule to be used in paediatric patients 6 years and older grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of paediatric patients aged 1 year and older for Cresemba 200 mg powder, based on final results from studies 9766-CL-0107 and 9766-CL-0046. Study 9766-CL-0046 is a Phase 1, open-label, multicentre study to evaluate the PK, safety and tolerability of intravenous and oral isavuconazonium sulfate in paediatric patients. This study was conducted in two sequential parts: Part 1 with three intravenous dosing cohorts, and Part 2 with two oral dosing cohorts. Study 9766-CL-0107 is a Phase 2, open-label, non-comparative, multicentre study to evaluate the safety and tolerability, efficacy, and PK of isavuconazole for the treatment of invasive aspergillosis or mucormycosis in paediatric patients aged 1 to < 18 years. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.1, 6.5 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. A revised RMP version 10 has been approved."

Action: For adoption

List of Outstanding Issues adopted on 25.04.2024. 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 by consensus together with the CHMP Assessment Report and translation timetable.

The CHMP noted the letter of recommendations.

4.1.3. **XALKORI - Crizotinib - EMEA/H/C/002489/X/0080/G**

Pfizer Europe MA EEIG

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Extension application to introduce a new pharmaceutical form (granules in capsules for opening) associated with new strengths (20, 50 and 150 mg), grouped with a type II variation (C.I.6.a) to include the treatment of paediatric patients with relapsed or refractory, systemic ALK-positive ALCL or unresectable, recurrent, or refractory ALK-positive IMT to change the lower end of the age range from ≥ 6 years to ≥ 1 year for Xalkori following the assessment of II/0072 based on final results from study ADVL0912. 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 9.1 of the RMP has also been submitted."

Action: For adoption

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 12.10.2023.

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.

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. **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 new strengths (1 and 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 1 month to less than 18 years of age of WHO Functional Class (FC) I to III for OPSUMIT, based on interim results from AC-055-312 study (TOMORROW). This 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 film-coated tablets are updated. The Package Leaflet and Labelling are updated in accordance. Version 14.1 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 relating to clinical aspects.

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

4.2.2. **PHEBURANE - Sodium phenylbutyrate - EMEA/H/C/002500/X/0037**

Eurocept International B.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu

Scope: “Extension application to introduce a new pharmaceutical form associated with new strength (500 mg film-coated tablets). The RMP (version 1.1) is updated in accordance.”

Action: For adoption

List of Questions adopted on 25.01.2024.

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 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. **Aqumeldi - Enalapril maleate - EMEA/H/C/005731/X/0001/G**

Proveca Pharma Limited

Rapporteur: John Joseph Borg, PRAC Rapporteur: Mari Thorn

Scope: “Extension application to add a new strength of 1 mg orodispersible tablet grouped with a type IB variation (C.I.z) to correct the SmPC to remove the recommended dose of pinephrine from Section 4.4.”

Action: For adoption

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

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

4.3.2. **BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/X/0014/G**

Hipra Human Health S.L.

Rapporteur: Beata Maria Jakline Ullrich, PRAC rapporteur: Zane Neikena

Scope: Extension application and Quality variation

Action: For adoption

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

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

4.3.3. Uzpruvo - Ustekinumab - EMEA/H/C/006101/X/0001

STADA Arzneimittel AG

Rapporteur: Christian Gartner, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (130 mg concentrate for solution for infusion) and a new route of administration (intravenous use). The RMP version 1.1 is updated in accordance."

Action: For adoption

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

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

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

No items

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

No items

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

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

5.1.1. Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0005

Sanofi Winthrop Industrie

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of children up to 24 months of age who remain vulnerable to severe Respiratory Syncytial Virus (RSV) disease through their second RSV season for BEYFORTUS, based on interim results from studies D5290C00005 and D5290C00008.

Study D5290C00005 (MEDLEY) is a Phase II/III, randomized, double-blind, placebo-controlled study to evaluate the safety of Beyfortus in high-risk children. Study D5290C00008 (MUSIC) is a Phase II, open-label, uncontrolled, single-dose study to evaluate the safety and tolerability, pharmacokinetics, and occurrence of antidrug antibody for Beyfortus in immunocompromised children \leq 24 Months of Age.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 2.1 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."

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024, 25.04.2024, 25.01.2024, 12.10.2023, 20.07.2023.

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.

5.1.2. Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0072

Janssen-Cilag International N.V.

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include, in combination with bortezomib, lenalidomide and dexamethasone, the treatment of adult patients with newly diagnosed multiple myeloma, who are eligible for autologous stem cell transplant for Darzalex, based on the primary analysis results from the pivotal study 54767414MMY3014 (PERSEUS) and the results from study 54767414MMY2004 (GRIFFIN) and the D-VRd cohort of study 54767414MMY2040 (PLEIADES).

MMY3014 (PERSEUS) is a randomised, open-label, active-controlled, multicentre phase 3 study in adult subjects with newly diagnosed multiple myeloma, who are eligible for high dose therapy (as required for autologous stem cell transplant). The primary objective is to compare the efficacy of (subcutaneous) daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) versus bortezomib, lenalidomide and dexamethasone (VRd) in terms of progression free survival (PFS).

MMY2004 (GRIFFIN) is a randomised, open-label, active controlled, multicentre phase 2 study in adult subjects with newly diagnosed multiple myeloma, who are eligible for high dose therapy and autologous stem cell transplant. The primary objective is to compare the efficacy of daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) versus bortezomib, lenalidomide and dexamethasone (VRd), in terms of stringent complete response (sCR) rate.

MMY2040 (PLEIADES) is a randomised, open-label, multicentre phase 2 study to evaluate subcutaneous daratumumab in combination with standard multiple myeloma treatment

regimens. The D-VRd cohort included adult subjects with newly diagnosed multiple myeloma, who were evaluated for clinical benefit in terms of very good partial response or better (VGPR) rate.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 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.”

Action: For adoption

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

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

5.1.3. [Esperoct - Turoctocog alfa pegol - EMEA/H/C/004883/II/0023](#)

Novo Nordisk A/S

Rapporteur: Daniela Philadelphia, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Gabriele Maurer

Scope: “Extension of indication to include children below 12 years of age for treatment and prophylaxis of bleeding with haemophilia A for Esperoct, including previously untreated patients (PUPs) based on the final results from studies 3776, 4410, 3908, 3859, 3885, 3860, 4033 and 4595. As a consequence, section 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4.”

Action: For adoption

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

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

5.1.4. [Fasenra - Benralizumab - EMEA/H/C/004433/II/0052](#)

AstraZeneca AB

Rapporteur: Fátima Ventura, PRAC Rapporteur: David Olsen

Scope: “Extension of indication to include treatment of eosinophilic granulomatosis with polyangiitis for Fasenra, based results from study D3253C00001 (Mandara); this was a randomised, double-blind, multicentre, parallel group, active-controlled, non-inferiority study that evaluated the efficacy and safety of benralizumab compared with mepolizumab in treatment of patients with EGPA on corticosteroid therapy with or without stable immunosuppressive therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.1 of the RMP has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes. 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.

5.1.5. [Hepcludex - Bulevirtide - Orphan - EMEA/H/C/004854/II/0031](#)

Gilead Sciences Ireland Unlimited Company

Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include treatment of chronic hepatitis delta virus (HDV) infection in paediatric patients 3 years of age and older weighing at least 10 kg with compensated liver disease for Hepcludex, based on a modelling and simulation study and an extrapolation study to evaluate the use of Bulevirtide for the treatment of chronic hepatitis D infection in children from 3 to less than 18 years of age. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet has been updated accordingly. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 22.02.2024.

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. [IMCIVREE - Setmelanotide - Orphan - EMEA/H/C/005089/II/0018](#)

Rhythm Pharmaceuticals Netherlands B.V.

Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Anna Mareková

Scope: "Extension of indication to include the population of children aged 2 years and above for the treatment of pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin Type 1 (PCSK1) deficiency or biallelic leptin receptor (LEPR) deficiency and Bardet-Biedl Syndrome (BBS) for IMCIVREE, based on the final results from study RM-493-033 "A Phase 3 Multicentre, One-Year, Open-Label Study of Setmelanotide in Paediatric Patients Aged 2 To <6 Years of Age with Rare Genetic Causes of Obesity"; this is an open label study to evaluate the weight-related parameters along with the safety and tolerability of setmelanotide in patients aged 2 to <6 years. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

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.

5.1.7. [Infanrix hexa - Diphtheria, tetanus, pertussis \(acellular, component\), hepatitis B \(rDNA\), poliomyelitis \(inact.\) and haemophilus type B conjugate vaccine \(adsorbed\) - EMEA/H/C/000296/II/0340/G](#)

GlaxoSmithkline Biologicals SA

Rapporteur: Christophe Focke

Scope: "A grouped application consisting of two type II variations, as follows:

C.I.6.a: To modify the approved therapeutic indication to include treatment from the age of 6 weeks for the administration of the primary vaccination, section 4.1 of the SmPC is updated accordingly.

C.I.4: Update of section 4.2 of the SmPC for the use of mixed hexavalent/pentavalent primary vaccination schedule and vaccine interchangeability.

The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity implement editorial changes to the SmPC and the Package Leaflet."

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.

5.1.8. [Jaypirca - Pirtobrutinib - EMEA/H/C/005863/II/0002](#)

Eli Lilly Nederland B.V.

Rapporteur: Alexandre Moreau, Co-Rapporteur: Edward Laane, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of adult patients with chronic lymphocytic leukemia (CLL) who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor for JAYPIRCA, based on interim results from study LOXO-BTK-20020 (BRUIN CLL-321); this is a phase 3 open-label, randomized study of LOXO-305 versus investigator's choice of idelalisib plus rituximab or bendamustine plus rituximab in BTK inhibitor pretreated CLL/SLL.

As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.

As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of data exclusivity for a new indication (Article 10(5) of Directive 2001/83/EC).

Action: For adoption

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

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

5.1.9. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0145

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy) the treatment of high-risk locally advanced cervical cancer in adults who have not received prior definitive therapy [Stage IB2-IIB (with node-positive disease) or Stage III-IVA based on FIGO 2014] for Keytruda, based on KEYNOTE-A18: A Randomized, Phase 3, Double-Blind Study of Chemoradiotherapy With or Without Pembrolizumab for the Treatment of High-risk, Locally Advanced Cervical Cancer. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 44.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

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.

5.1.10. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0153

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication for KEYTRUDA in combination with carboplatin and paclitaxel to include first-line treatment of primary advanced or recurrent endometrial carcinoma in adults, based on final results from study KEYNOTE-868. This is a randomized Phase 3, placebo-controlled, double-blind study of pembrolizumab vs placebo in combination with chemotherapy (paclitaxel plus carboplatin) for newly diagnosed Stage III/Stage IVA, Stage IVB, or recurrent endometrial cancer.

As a consequence, sections 4.1 and 5.1 of the SmPC are updated. Version 46.1 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.

5.1.11. Pegasys - Peginterferon alfa-2a - EMEA/H/C/000395/II/0119/G

Pharmaand GmbH

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extensions of indication to include treatment of Polycythaemia Vera (PV) and Essential thrombocytopenia (ET) for PEGASYS for the pre-filled syringes, based on published data of clinical studies conducted in support of the efficacy and safety of Pegasys for the treatment of ET and PV. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.2 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024, 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 summary of opinion was circulated for information.

5.1.12. [Pravafenix - Fenofibrate / Pravastatin sodium - EMEA/H/C/001243/II/0037](#)

Laboratoires SMB s.a.

Rapporteur: Jean-Michel Race, PRAC Rapporteur: Nathalie Gault

Scope: "Extension of indication to include treatment of mixed hyperlipidaemia in adult patients while on a treatment with pravastatin 40 mg monotherapy or on another moderate-intensity statin regimen for PRAVAFENIX, based on final results from the non-interventional PASS: POSE (Pravafenix Observational Study in Europe); this is a European, observational, three-year cohort comparative study on the safety of the fixed dose combination pravastatin 40 mg/fenofibrate 160 mg (Pravafenix) versus statin alone in real clinical practice. As a consequence, sections 4.1 and 4.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

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

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

5.1.13. [Tepkinly - Epcoritamab - Orphan - EMEA/H/C/005985/II/0001](#)

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Peter Mol, Co-Rapporteur: Ingrid Wang, PRAC Rapporteur: Monica Martinez Redondo

Scope: " Extension of indication to include treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy for TEPKINLY, based on results from the indolent Non-Hodgkins Lymphoma (iNHL) expansion cohort of Study GCT3013-01, the First In Human (FIH) Phase 1/2 study in R/R B-NHL, with key supportive data from the Phase 1b/2 Study GCT3013-04 in Japanese subjects. Study

GCT3013-01 is an ongoing global, single-arm, Phase 1/2 study designed to evaluate epcoritamab as monotherapy in R/R B-NHL. As a consequence, sections 1, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3, 6.4, 6.5 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024, 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 summary of opinion was circulated for information.

5.1.14. Vabysmo - Faricimab - EMEA/H/C/005642/II/0005

Roche Registration GmbH

Rapporteur: Jayne Crowe, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) for Vabysmo, based on results from the two phase 3 studies: GR41984 (BALATON) in patients with branch retinal vein occlusion (BRVO) and GR41986 (COMINO) in patients with central retinal vein occlusion (CRVO) or hemiretinal vein occlusion (HRVO). These are global, multicentre, randomized, double-masked, active comparator-controlled, parallel-group, 2-part studies evaluating the efficacy, safety, and PK of faricimab. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been 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."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024, 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.

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

Novo Nordisk A/S

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

Scope: "Extension of indication to include risk reduction of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults

with established cardiovascular disease and BMI ≥ 27 kg/m² for WEGOVY, 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. As a consequence, section 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. 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, 25.01.2024.

An oral explanation was held on 26 June 2024. The presentation by the applicant focused on the clinical data in support of the application.

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

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

See 2.3

5.1.16. Zavicefta - Ceftazidime / Avibactam - EMEA/H/C/004027/II/0035

Pfizer Ireland Pharmaceuticals

Rapporteur: Ingrid Wang, Co-Rapporteur: Larisa Gorobets, PRAC Rapporteur: Rugile Pilviniene

Scope: “Extension of indication to include treatment of paediatric patients from birth to less than 3-months of age in the following infections: complicated intra-abdominal infection (cIAI), complicated urinary tract infection (cUTI), including pyelonephritis, hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) and in the treatment of infections due to aerobic Gram-negative organisms in patients with limited treatment options, for ZAVICEFTA, based on final results from study C3591024 and the population PK modelling/simulation analyses. Study C3591024 is a Phase 2a, 2-part, open-label, non-randomized, multicentre, single and multiple dose trial to evaluate pharmacokinetics, safety and tolerability of ceftazidime and avibactam in neonates and infants from birth to less than 3 months of age with suspected or confirmed infections due to gram-negative pathogens requiring intravenous antibiotic treatment. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.3 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

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.

5.1.17. **WS2463**
Imfinzi - Durvalumab - EMEA/H/C/004771/WS2463/0063
Lynparza - Olaparib - EMEA/H/C/003726/WS2463/0066

AstraZeneca AB

Lead Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include Imfinzi (durvalumab) in combination with carboplatin and paclitaxel for the first line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with durvalumab as monotherapy in endometrial cancer that is mismatch repair deficient (dMMR) or in combination with olaparib in endometrial cancer that is mismatch repair proficient (pMMR) and to include Lynparze (olaparib) in combination with durvalumab for the maintenance treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch proficient (pMMR) whose disease has not progressed on first-line treatment with durvalumab in combination with carboplatin and paclitaxel, based on the results from pivotal Phase III study, D9311C00001 (DUO-E). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 5.1 and 5.2 of the Imfinzi SmPC and sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the Lynparza SmPC are updated. The Annex II, the Package Leaflet and the Risk Management Plan (version 10.2 for Imfinzi and version 30.2 for Lynparza) are updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 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.

The summary of opinion was circulated for information.

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

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: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

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

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

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. mirdametinib - H0006460

Treatment of neurofibromatosis type 1-plexiform neurofibroma

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

Action: For adoption

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

8.2. Priority Medicines (PRIME)

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

The CHMP adopted the recommendations for PRIME eligibility.

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Erbitux - Cetuximab - EMEA/H/C/000558/II/0099

Merck Europe B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Update of sections 4.2, 4.4 and 4.9 of the SmPC in order to introduce every two-weeks (Q2W) dosing regimen as an alternative to the already approved every week (Q1W) dosing regimen for the indications of metastatic colorectal cancer (CRC) and the recurrent/metastatic squamous cell cancer of the head and neck (SCCHN) in combination with platinum-based chemotherapy, based on pharmacokinetic (PK)-TGI-OS modelling and simulations. The Package Leaflet is updated accordingly. The RMP version 19.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information."

Action: For adoption

The Committee discussed the issues identified in this application.

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

9.1.2. JCOVDEN – COVID-19 vaccine (Ad26.COV2-S [recombinant]) – EMEA/H/C/005737

Janssen-Cilag International N.V.; prevention of coronavirus disease-2019 (COVID-19)

Rapporteur: Christophe Focke, Co-Rapporteur: Sol Ruiz

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

9.1.3. Tremelimumab AstraZeneca (SRD) - tremelimumab – EMEA/H/C/004650

AstraZeneca; treatment of metastatic non-small cell lung cancer (NSCLC)

Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Carolina Prieto Fernandez

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

9.1.4. COMIRNATY - COVID-19 mRNA vaccine - EMEA/H/C/005735/II/0216

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson

Scope: Quality variation

Action: For adoption

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

9.1.5. Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0136

Moderna Biotech Spain S.L.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Quality variation

Action: For adoption

The Committee discussed the issues identified in this application.

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

9.1.6. Evicel - Human fibrinogen/Human thrombin – EMEA/H/C/000898

Omrix Biopharmaceuticals N. V.; supportive treatment in surgery, improvement of haemostasis and suture support for haemostasis in vascular surgery

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Ewa Balkowiec Iskra

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

9.1.7. [Translarna - ataluren - EMEA/H/C/002720/R/0071 - Orphan](#)

PTC Therapeutics International Limited

Rapporteur: Peter Mol, Co-Rapporteur: Antonio Gomez-Outes

Scope: Renewal of conditional marketing authorization

Action: For adoption

Participation of patient representatives.

Request for Supplementary Information adopted on 25.05.2023.

An oral explanation was held on 25 June 2024. The presentation by the applicant focused on the clinical data in support of the application.

The CHMP noted the third-party intervention.

The CHMP noted the report from the SAG-Neurology.

The CHMP adopted a negative opinion by consensus, recommending not to renew the conditional marketing authorisation in accordance with Article 6(3) of Regulation (EC) No 507/2006.

The CHMP adopted the assessment report.

The EMA public health communication was circulated for information.

See 2.3

10. Referral procedures

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

10.1.1. [Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/A20/0065](#)

Orexigen Therapeutics Ireland Limited

Referral Rapporteur: Kristina Dunder, Referral Co-Rapporteur: Daniela Philadelphia

Scope: Revised timetable

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 Mysimba (naltrexone/bupropion), taking into account any consequences from the failure to comply with the obligations laid down in the marketing authorisation.

This review of all available data on the potential long-term cardiovascular risk and its impact on the benefit-risk balance of Mysimba in its approved indication was considered needed in view of the remaining concern and lack of adequate study plan to address the uncertainty about this risk.

CHMP list of questions adopted on 30.05.2024, 25.04.2024 and 14.12.2023. List of Questions adopted on 14.09.2023.

The CHMP adopted a revised timetable.

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: Opinion

Action: For adoption

Participation of patient representatives.

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.

List of outstanding issues adopted on 25.04.2024 and 25.01.2024. List of Questions adopted on 12.10.2023.

An oral explanation was held on 25 June 2024. The presentation by the applicant focused on the clinical data in support of the application.

The CHMP noted the report from the AHEG.

The CHMP adopted an opinion by consensus, recommending to revoke the marketing authorisation for Ocaliva. The CHMP concluded that the benefits of the medicine did not outweigh its risks. The CHMP assessment report was adopted.

The CHMP endorsed the DHPC.

See 2.4

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

10.5.1. Havrix and associated names – Hepatitis A virus (inactivated, adsorbed) - EMEA/H/A-30/1527

GlaxoSmithKline Biologicals

Referral Rapporteur: Maria Grazia Evandri, Referral Co-Rapporteur: Lyubina Racheva

Scope: Opinion

Action: For adoption

Harmonisation exercise for Havrix and associated names. Product Information harmonisation was triggered by the MAH.

List of outstanding issues adopted on 21.03.2024. List of questions adopted on 09.11.2023.

The CHMP adopted an opinion by consensus, recommending the revision and harmonisation of the product information for Havrix and associated names.

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

10.11.1. Lorazepam Macure – lorazepam - EMEA/H/A-13/1536

Macure Pharma ApS

Referral Rapporteur: Peter Mol, Referral Co-Rapporteur: Kristina Dunder

Scope: Opinion

Action: For adoption

Variation number in decentralised procedure: NL/H/4353/001/II/004, notification sent by the Agency of The Netherlands dated 01 February 2024 notifying of the start of a referral under Article 13(1) of Regulation No 1234/2008.

List of questions adopted on 21.03.2024.

The CHMP adopted an opinion by consensus recommending that the marketing authorisations for the above- mentioned medicinal product(s) should be varied. The CHMP assessment report was adopted.

11. Pharmacovigilance issue

11.1. Early Notification System

June 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. Timetable for August 2024 Written Procedure

Action: For adoption

The CHMP adopted the timetable for the August 2024 Written Procedure.

14.1.2. Vote by proxy

Martine Trauffler gave a proxy to Daniela Philadelphia for votes from Wednesday 13h until the end of the meeting. Blanka Hirschlerova gave proxy to Tomas Radimersky for the whole meeting. Simona Badoi gave a proxy to Bruno Sepodes 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 June 2024

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

Agenda of the June 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. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 18-19 June 2024.

Action: For adoption

The CHMP adopted the Table of Decisions from the NRG meeting held on 18-19 June 2024.

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 10-13 June 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

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

Q2-2024 initial marketing authorisation application submissions with eligibility request to central procedure.

Action: For information

The CHMP noted the report.

14.9. Others

14.9.1. CHMP Learnings

CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

Action: For information

The CHMP noted the information.

15. Any other business

15.1. AOB topic

No items

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 24-27 June 2024 CHMP meeting, which was held in person.

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 Philadelphia	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	
Emilia Mavrokordatou	Alternate	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No participation in discussion, final deliberations and voting on:	2.1.3. Wegovy - Semaglutide - EMEA/H/C/005422 /II/0017 5.1.3. Esperoct - Turoctocog alfa pegol - EMEA/H/C/004883 /II/0023
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	
Alexandre Moreau	Member	France	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	
Robert Porszasz	Member	Hungary	No restrictions applicable to this meeting	
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Hjalti Kristinsson	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Finbarr Leacy	Alternate	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Larisa Gorobets	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffer	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	5.1.1. Beyfortus - Nirsevimab - EMEA/H/C/005304 /II/0005
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	
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	
Panagiota Tsantili	Expert	Greece	No interests declared	
Lisa Nika	Expert	Austria	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
Florian Klinglmueller	Expert	Austria	No interests declared	
Bojana Divkovic	Expert	Austria	No interests declared	
Tobias Gluexam	Expert	Austria	No interests declared	
Larissa Higgins	Expert	Ireland	No interests declared	
Catherine Byrne	Expert	Ireland	No interests declared	
Ferran Torres	Expert	Spain	No restrictions applicable to this meeting	
Maria Concepcion Payares	Expert	Spain	No participation in discussion, final deliberations and voting on:	5.1.8. Jaypirca - Pirtobrutinib - EMEA/H/C/005863 /II/0002 3.1.11. Tauvid - Flortaucipir (18F) - EMEA/H/C/006064
Nikolina Torti	Expert	Croatia	No interests declared	
Marija Kristina Josipovic	Expert	Croatia	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Torsten Holm Nielsen	Expert	Denmark	No interests declared	
Mogens Westergaard	Expert	Denmark	No interests declared	
Anne-Mette Hoberg	Expert	Denmark	No interests declared	
Veronica Krogstad	Expert	Norway	No interests declared	
Gro Dahlseng Hakonsen	Expert	Norway	No interests declared	
Lars Krueger	Expert	Germany	No restrictions applicable to this meeting	
Niklas Walther	Expert	Germany	No restrictions applicable to this meeting	
Irene Nowotny	Expert	Germany	No interests declared	
Samira Alina Marx	Expert	Germany	No interests declared	
Jörg Engelbergs	Expert	Germany	No interests declared	
Maija Tarkkanen	Expert	Finland	No interests declared	
Elina Asikanius	Expert	Finland	No restrictions applicable to this meeting	
Franziska Wolter	Expert	Germany	No interests declared	
George Aislaitner	Expert	Germany	No interests declared	
Marion Haberkamp	Expert	Germany	No interests declared	
Gabriele Schlosser-Weber	Expert	Germany	No interests declared	
Elmer Schabel	Expert	Germany	No interests declared	
Martin Mengel	Expert	Germany	No interests declared	
Bruna Dekic	Expert	Germany	No interests declared	
Rou-Afza Gunput	Expert	Netherlands	No interests declared	
Illiana Meurs	Expert	Netherlands	No interests declared	
Richard IJzerman	Expert	Netherlands	No restrictions applicable to this meeting	
Andre Elferink	Expert	Netherlands	No interests declared	
Luca Fancsalszky	Expert	Hungary	No interests declared	
Yseult Brun	Expert	France	No interests declared	
Céline Jumeau	Expert	France	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Anissa Benlazar	Expert	France	No interests declared	
Umberto CASALEGNO	Expert	France	No interests declared	
Cristina Migali	Expert	Italy	No interests declared	
Sara Galluzzo	Expert	Italy	No interests declared	
Maja Sommerfelt Grønvold	Expert	Norway	No interests declared	
Anna Mari Lone	Expert	Norway	No restrictions applicable to this meeting	
Aina Jannicke Øvrebust	Expert	Norway	No interests declared	
Peter Mayer	Expert	Germany	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Mario Miguel Coelho da Silva Rosa	Expert	Portugal	No interests declared	
Lukas Malte Aguirre Davila	Expert	Germany	No interests declared	
Kristian Wennmalm	Expert	Sweden	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
João Manuel Lopes de Oliveira	Expert	Portugal	No interests declared	
Joerg Zinserling	Expert	Germany	No interests declared	
Taco Monster	Expert	Netherlands	No interests declared	
Angelo Molinaro	Expert	Italy	No interests declared	
Liam Childs	Expert	Germany	No interests declared	
Sif Ormarsdóttir	Expert	Iceland	No participation in discussion, final deliberations and voting on:	5.1.16. Zavicefta - Ceftazidime / Avibactam - EMEA/H/C/004027 /II/0035
Rene Anour	Expert	Austria	No interests declared	
Anna Kubandová	Expert	Slovakia	No interests declared	
Jana Schweigertova	Expert	Slovakia	No interests declared	
María Jesús Lamas Díaz	Expert	Spain	No interests declared	
Redmer Van Leeuwen	Expert	Netherlands	No restriction against giving the AHEG report on Syfovre	
Serge Bakchine	Expert	France	No interests declared	
Luis Lopes	Expert	Spain	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Charlotte Hejl	Expert	Denmark	No restrictions applicable to this meeting	
Paula Contreras Alarcón	Expert	Spain	No restrictions applicable to this meeting	
Christoph Furtmann	Expert	Germany	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Elly Vereyken	Expert	Netherlands	No interests declared	
Robine Donken	Expert	Netherlands	No interests declared	
Regula Johner	Expert	Swissmedic	No interests declared	
Thomas Schochat	Expert	Swissmedic	No interests declared	
Kira Blankenbach	Expert	Swissmedic	No interests declared	
A representative from the European Commission attended the meeting				

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 *(section 5.3)*

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 Pharmacovigilance Risk Assessment Committee (PRAC).

Invented name issues (section 14.3)

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

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 November 2024
EMA/CHMP/302381/2024

Annex to 24-27 June 2024 CHMP Minutes

Pre-submission and post-authorisations issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for June 2024: For adoption	Adopted
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A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications

Final Outcome of Rapporteurship allocation for June 2024: For adoption	Adopted
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A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

Information related to pre-submission of initial applications cannot be released at the present time as these contain commercially confidential information.

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

Evoltra - Clofarabine - EMA/H/C/000613/S/0081 Sanofi B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.
Lamzede - Velmanase alfa - EMA/H/C/003922/S/0035, Orphan Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jan Neuhauser	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal

B.2.2. Renewals of Marketing Authorisations for unlimited validity

BAQSIMI - Glucagon - EMA/H/C/003848/R/0015 Amphastar France Pharmaceuticals, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Eamon O Murchu	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
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Cegfila - Pegfilgrastim - EMA/H/C/005312/R/0020 Mundipharma Corporation (Ireland) Limited, Duplicate of Pelmeg, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Christian Gartner, PRAC Rapporteur: Bianca Mulder	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
Clopidogrel/Acetylsalicylic acid Viatris - Clopidogrel / Acetylsalicylic acid - EMA/H/C/004996/R/0012 Viatris Limited, Generic of DuoPlavin, Rapporteur: Kristina Nadrah, PRAC Rapporteur: Carla Torre	Positive Opinion adopted by consensus together with the CHMP assessment report. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
Evenity - Romosozumab - EMA/H/C/004465/R/0025 UCB Pharma S.A., Rapporteur: Kristina Dunder, Co-Rapporteur: Christian Gartner, PRAC Rapporteur: Tiphaine Vaillant	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
Quofenix - Delafloxacin - EMA/H/C/004860/R/0026 A. Menarini Industrie Farmaceutiche Riunite s.r.l., Rapporteur: Janet Koenig, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Petar Mas	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
Rhokiinsa - Netarsudil - EMA/H/C/004583/R/0022 Santen Oy, Rapporteur: Jayne Crowe, Co- Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Maria del Pilar Rayon	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.
Spravato - Esketamine - EMA/H/C/004535/R/0023 Janssen-Cilag International N.V., Rapporteur: Martina Weise, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Kirsti Villikka	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity.

B.2.3. Renewals of Conditional Marketing Authorisations

Jaypirca - Pirtobrutinib -	Positive Opinion adopted by consensus together
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EMA/H/C/005863/R/0004 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Edward Laane, PRAC Rapporteur: Bianca Mulder	with the CHMP assessment report and translation timetable. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
ROCTAVIAN - Valoctocogene roxaparvovec - EMA/H/C/005830/R/0011, Orphan, ATMP BioMarin International Limited, Rapporteur: Violaine Closson Carella, Co-Rapporteur: Silke Dorner, CHMP Coordinator: Jean-Michel Race, PRAC Rapporteur: Bianca Mulder Request for Supplementary Information adopted on 24.05.2024.	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
Translarna - Ataluren - EMA/H/C/002720/R/0071, Orphan PTC Therapeutics International Limited, Rapporteur: Peter Mol, Co-Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Liana Martirosyan Request for Supplementary Information adopted on 25.05.2023.	The CHMP adopted a negative opinion by consensus, recommending not to renew the conditional marketing authorisation in accordance with Article 6(3) of Regulation (EC) No 507/2006. The CHMP adopted the assessment report. See 9.1

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 10-13 June 2024
PRAC:

Signal of secondary malignancy of T-cell origin

Adopted

Axicabtagene ciloleucel; idcabtagene vicleucel; lisocabtagene maraleucel; ciltabtagene autoleucel; tisagenlecleucel; brexucabtagene autoleucel - YESCARTA, ABECMA, BREYANZI, CARVYKTI, KYMRIAH, TECARTUS (CAP)

CAT Rapporteur: multiple, CHMP Coordinator: multiple, PRAC Rapporteur: multiple

PRAC recommendation on a variation; DHPC and communication plan

Action: For adoption

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its June 2024 meeting:

EMA/H/C/PSUSA/0000102/202311

(respiratory syncytial virus vaccine (bivalent, recombinant))

CAPS:

Abrysvo (EMA/H/C/006027) (Respiratory syncytial virus vaccine (bivalent, recombinant)), Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe, PRAC Rapporteur: Liana Martirosyan, "30/05/2023 To: 30/11/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):
Update of section(s) 4.8 of the SmPC to remove the footnote a under the Table 1 regarding adverse reaction GBS. The proposed amendment is not relevant for the Package Leaflet [which does not include the footnote].

EMA/H/C/PSUSA/00002014/202310

(methotrexate)

CAPS:

Jylamvo (EMA/H/C/003756) (Methotrexate), Therakind (Europe) Limited, Rapporteur: Bruno Sepodes

Nordimet (EMA/H/C/003983) (Methotrexate), Nordic Group B.V., Rapporteur: Bruno Sepodes

NAPS:

NAPs - EU

PRAC Rapporteur: Martin Huber, "01/11/2021 To: 31/10/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance, concerning the following change(s):
Update of section 4.8 of the SmPC to add or revise photosensitivity reactions and section 4.4 of the SmPC to add wording on photosensitivity and update of section 4.5 of the SmPC to amend the interaction regarding methotrexate and metamizole. The Package leaflet is updated accordingly.

EMA/H/C/PSUSA/00009253/202310

(pasireotide)

CAPS:

Signifor (EMA/H/C/002052) (Pasireotide), Recordati Rare Diseases, Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, "24/10/2020 To: 24/10/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):
Update of section 4.8 of the SmPC to add the adverse reactions steatorrhea and faeces discoloured with a frequency "Not known". The Package leaflet is updated accordingly.

EMA/H/C/PSUSA/00010279/202310

(obinutuzumab)

CAPS:

Gazyvaro (EMA/H/C/002799)

(Obinutuzumab), Roche Registration GmbH,

Rapporteur: Aaron Sosa Mejia, PRAC

Rapporteur: Ulla Wändel Liminga,

"31/10/2020 To: 31/10/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):

Update of section 4.8 of the SmPC to add hypogammaglobulinemia with a frequency of uncommon. The Package leaflet is updated accordingly.

EMA/H/C/PSUSA/00010301/202311

(ibrutinib)

CAPS:

Imbruvica (EMA/H/C/003791) (Ibrutinib),

Janssen-Cilag International N.V., Rapporteur:

Filip Josephson, PRAC Rapporteur: Barbara

Kovacic Bytyqi, "13/11/2022 To: 12/11/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):

Update of section 4.8 of the SmPC to add the adverse reaction Cutaneous vasculitis with a frequency uncommon. The Package leaflet is updated accordingly.

EMA/H/C/PSUSA/00010535/202311

(ixazomib)

CAPS:

NINLARO (EMA/H/C/003844) (Ixazomib),

Takeda Pharma A/S, Rapporteur: Paolo

Gasparini, PRAC Rapporteur: Ulla Wändel

Liminga, "19/05/2023 To: 19/11/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):

- Update of section 4.8 of the SmPC, SOC Musculoskeletal and connective tissue disorders conditions to add the adverse reaction arthralgia, frequency very common.
- Update of section 4.8 of the SmPC, SOC General disorders and administrative site to add the adverse reaction pyrexia, frequency very common.

The Package leaflet is updated accordingly.

EMA/H/C/PSUSA/00010577/202311

(insulin glargine / lixisenatide)

CAPS:

Suliqua (EMA/H/C/004243) (Insulin glargine / Lixisenatide), Sanofi Winthrop Industrie,

Rapporteur: Kristina Dunder, PRAC

Rapporteur: Bianca Mulder, "21/11/2022 To: 21/11/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended together with the detailed explanation of the scientific grounds for the differences with the PRAC recommendation, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):
Update of section 4.8 of the SmPC to add the adverse drug reaction dysgeusia with frequency uncommon. The Package leaflet is updated accordingly.

EMA/H/C/PSUSA/00010974/202311

(pegcetacoplan)

CAPS:

ASPAVELI (EMA/H/C/005553)

(Pegcetacoplan), Swedish Orphan Biovitrum

AB (publ), Rapporteur: Alexandre Moreau,

PRAC Rapporteur: Kimmo Jaakkola,

"14/05/2023 To: 13/11/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):
Update of section 4.8 of the SmPC to add the adverse reaction urticaria with a frequency uncommon. The Package leaflet is updated accordingly.

EMA/H/C/PSUSA/00011019/202311

(tirzepatide)

CAPS:

Mounjaro (EMA/H/C/005620) (Tirzepatide),

Eli Lilly Nederland B.V., Rapporteur: Martina

Weise, PRAC Rapporteur: Bianca Mulder,

"14/05/2023 To: 13/11/2023"

The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s):
Update of section 4.8 of the SmPC to add the adverse reaction dysgeusia with a frequency uncommon. The package leaflet is updated accordingly.

B.4. EPARs / WPARs

ADZYNMA - rADAMTS13 -**EMA/H/C/006198, Orphan**

Takeda Manufacturing Austria AG, treatment of congenital thrombotic thrombocytopenic purpura (cTTP) due to ADAMTS13 deficiency,

For information only. Comments can be sent to the PL in case necessary.

New active substance (Article 8(3) of Directive No 2001/83/EC)	
AKANTIOR - Polihexanide - EMEA/H/C/005858, Orphan SIFI SPA, treatment of acanthamoeba keratitis, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Apexelsin - Paclitaxel - EMEA/H/C/005997 Whiteoak Pharmaceutical B.V., treatment of metastatic breast cancer, Generic, Generic of Abraxane, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Avzivi - Bevacizumab - EMEA/H/C/005574 FGK Representative Service GmbH, treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer; first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer. first line treatment of patients with advanced and/or metastatic renal cell cancer., Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Cejemly - Sugemalimab - EMEA/H/C/006088 SFL Pharmaceuticals Deutschland GmbH, treatment of adults with metastatic non-small-cell lung cancer (NSCLC), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Dasatinib Accord Healthcare - Dasatinib - EMEA/H/C/006251 Accord Healthcare S.L.U., indicated for the treatment of chronic myelogenous leukaemia (CML), indicated for the treatment of chronic myelogenous leukaemia (CML), Generic of Sprycel, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
DURVEQTIX - Fidanacogene elaparvovec - EMEA/H/C/004774, ATMP Pfizer Europe MA EEIG, indicated for the treatment of severe and moderately severe haemophilia B, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Fluenz - Influenza vaccine (live attenuated, nasal) - EMEA/H/C/006514	For information only. Comments can be sent to

AstraZeneca AB, Prophylaxis of influenza, Known active substance (Article 8(3) of Directive No 2001/83/EC)	the PL in case necessary.
GalliaPharm - Germanium (68Ge) chloride / Gallium (68Ga) chloride - EMEA/H/C/006053 Eckert & Ziegler Radiopharma GmbH, indicated for in vitro radiolabelling of specific carrier molecules to be used for positron emission tomography (PET) imaging, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
IXCHIQ - Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated - EMEA/H/C/005797 Valneva Austria GmbH, prevention of disease caused by chikungunya (CHIKV) virus, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Nezglyal - Leriglitazone - EMEA/H/C/005757, Orphan Minoryx Therapeutics S.L., the treatment of cerebral progression and myelopathy in male patients with adrenoleukodystrophy (ALD)., New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Pomalidomide Accord - Pomalidomide - EMEA/H/C/006273 Accord Healthcare S.L.U., treatment of adult patients with multiple myeloma, Generic, Generic of Imnovid, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Pomalidomide Krka - Pomalidomide - EMEA/H/C/006314 KRKA, d.d., Novo mesto, treatment of multiple myeloma, Generic, Generic of Imnovid, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Pomalidomide Zentiva - Pomalidomide - EMEA/H/C/006294 Zentiva, k.s., treatment of adults with multiple myeloma, Generic, Generic of Imnovid, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Zegalogue - Dasiglucagon - EMEA/H/C/006214 Zealand Pharma A/S, treatment of severe	For information only. Comments can be sent to the PL in case necessary.

hypoglycemia in patients with diabetes, New active substance (Article 8(3) of Directive No 2001/83/EC)

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

Scopes related to Chemistry, Manufacturing, and Controls cannot be released at the present time as these contain commercially confidential information.

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

AQUIPTA - Atogepant - EMA/H/C/005871/II/0001/G	Positive Opinion adopted by consensus on 06.06.2024.
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AbbVie Deutschland GmbH & Co. KG,

Rapporteur: Janet Koenig

Opinion adopted on 06.06.2024.

Request for Supplementary Information adopted on 04.04.2024.

BEKEMV - Eculizumab - EMA/H/C/005652/II/0005	Positive Opinion adopted by consensus on 27.06.2024.
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Amgen Technology (Ireland) Unlimited

Company, Rapporteur: Outi Mäki-Ikola

Opinion adopted on 27.06.2024.

Besremi - Ropeginterferon alfa-2b - EMA/H/C/004128/II/0033/G	Positive Opinion adopted by consensus on 27.06.2024.
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AOP Orphan Pharmaceuticals GmbH,

Rapporteur: Janet Koenig

Opinion adopted on 27.06.2024.

Request for Supplementary Information adopted on 30.05.2024.

Braftovi - Encorafenib - EMA/H/C/004580/II/0035/G	Positive Opinion adopted by consensus on 20.06.2024.
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Pierre Fabre Medicament, Rapporteur: Janet

Koenig

Opinion adopted on 20.06.2024.

Request for Supplementary Information adopted on 14.03.2024.

Buvidal - Buprenorphine - EMA/H/C/004651/II/0025	Positive Opinion adopted by consensus on 20.06.2024.
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Camurus AB, Rapporteur: Finbarr Leacy

Opinion adopted on 20.06.2024.

Request for Supplementary Information adopted on 25.04.2024.

Circadin - Melatonin - EMA/H/C/000695/II/0071/G	Positive Opinion adopted by consensus on 06.06.2024.
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RAD Neurim Pharmaceuticals EEC SARL,

Rapporteur: Bruno Sepodes

Opinion adopted on 06.06.2024.
Request for Supplementary Information adopted
on 08.02.2024.

**COMIRNATY - COVID-19 mRNA vaccine -
EMA/H/C/005735/II/0216**

BioNTech Manufacturing GmbH, Rapporteur:
Filip Josephson
Opinion adopted on 27.06.2024.

Positive Opinion adopted by consensus on
27.06.2024.

See 9.1

**Cosentyx - Secukinumab -
EMA/H/C/003729/II/0116**

Novartis Europharm Limited, Rapporteur: Outi
Mäki-Ikola
Opinion adopted on 20.06.2024.

Positive Opinion adopted by consensus on
20.06.2024.

**Darzalex - Daratumumab -
EMA/H/C/004077/II/0073/G, Orphan**

Janssen-Cilag International N.V., Rapporteur:
Aaron Sosa Mejia
Request for Supplementary Information adopted
on 06.06.2024.

Request for supplementary information adopted
with a specific timetable.

**Ebixa - Memantine / Memantine
hydrochloride -
EMA/H/C/000463/II/0101**

H. Lundbeck A/S, Duplicate of Axura,
Rapporteur: Antonio Gomez-Outes

Opinion adopted on 20.06.2024.
Request for Supplementary Information adopted
on 25.04.2024, 11.01.2024.

Positive Opinion adopted by consensus on
20.06.2024.

**Eylea - Aflibercept -
EMA/H/C/002392/II/0088**

Bayer AG, Rapporteur: Jean-Michel Race

Opinion adopted on 20.06.2024.
Request for Supplementary Information adopted
on 04.04.2024.

Positive Opinion adopted by consensus on
20.06.2024.

**Fluad Tetra - Influenza vaccine (surface
antigen, inactivated, adjuvanted) -
EMA/H/C/004993/II/0053**

Seqirus Netherlands B.V., Rapporteur: Sol Ruiz
Request for Supplementary Information adopted
on 27.06.2024.

Request for supplementary information adopted
with a specific timetable.

**Flucelvax Tetra - Influenza vaccine
(surface antigen, inactivated, prepared in
cell cultures) -
EMA/H/C/004814/II/0045**

Seqirus Netherlands B.V., Rapporteur: Sol Ruiz
Request for Supplementary Information adopted
on 27.06.2024.

Request for supplementary information adopted
with a specific timetable.

Fluenz - Influenza vaccine (live attenuated, nasal) - EMEA/H/C/006514/II/0001 AstraZeneca AB, Rapporteur: Christophe Focke Request for Supplementary Information adopted on 27.06.2024.	Request for supplementary information adopted with a specific timetable.
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0151/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 27.06.2024. Request for Supplementary Information adopted on 18.04.2024.	Positive Opinion adopted by consensus on 27.06.2024.
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0155 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 20.06.2024.	Positive Opinion adopted by consensus on 20.06.2024.
Ibandronic Acid Teva - Ibandronic acid - EMEA/H/C/001195/II/0021 Teva B.V., Generic of Bondronat, Bonviva, Rapporteur: Hrefna Gudmundsdottir Opinion adopted on 06.06.2024. Request for Supplementary Information adopted on 11.04.2024, 29.02.2024, 16.11.2023.	Positive Opinion adopted by consensus on 06.06.2024.
Inhixa - Enoxaparin sodium - EMEA/H/C/004264/II/0109 Techdow Pharma Netherlands B.V., Duplicate of Thorinane (EXP), Rapporteur: Christian Gartner Request for Supplementary Information adopted on 20.06.2024.	Request for supplementary information adopted with a specific timetable.
Inhixa - Enoxaparin sodium - EMEA/H/C/004264/II/0109 Techdow Pharma Netherlands B.V., Duplicate of Thorinane (EXP), Rapporteur: Christian Gartner Request for Supplementary Information adopted on 20.06.2024.	Request for supplementary information adopted with a specific timetable.
Kovaltry - Octocog alfa - EMEA/H/C/003825/II/0044/G Bayer AG, Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 27.06.2024, 21.03.2024.	Request for supplementary information adopted with a specific timetable.
Mounjaro - Tirzepatide - EMEA/H/C/005620/II/0022 Eli Lilly Nederland B.V., Rapporteur: Martina Weise Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 20.06.2024.

NexoBrid - Concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0068

MediWound Germany GmbH, Rapporteur: Janet Koenig

Positive Opinion adopted by consensus on 20.06.2024.

Opinion adopted on 20.06.2024.

Nucala - Mepolizumab - EMEA/H/C/003860/II/0066/G

GlaxoSmithKline Trading Services Limited, Rapporteur: Finbarr Leacy

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 02.05.2024.

Positive Opinion adopted by consensus on 13.06.2024.

Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0070/G

Novavax CZ a.s., Rapporteur: Patrick Vrijlandt

Request for Supplementary Information adopted on 20.06.2024.

Request for supplementary information adopted with a specific timetable.

Ovaleap - Follitropin alfa - EMEA/H/C/002608/II/0039

Theramex Ireland Limited, Rapporteur: Patrick Vrijlandt

Opinion adopted on 27.06.2024.

Request for Supplementary Information adopted on 11.04.2024, 07.12.2023.

Positive Opinion adopted by consensus on 27.06.2024.

OXERVATE - Cenegermin - EMEA/H/C/004209/II/0059, Orphan

Dompe farmaceutici S.p.A., Rapporteur: Antonio Gomez-Outes

Opinion adopted on 06.06.2024.

Request for Supplementary Information adopted on 02.05.2024.

Positive Opinion adopted by consensus on 06.06.2024.

Pelgraz - Pegfilgrastim - EMEA/H/C/003961/II/0052/G

Accord Healthcare S.L.U., Rapporteur: Sol Ruiz

Opinion adopted on 06.06.2024.

Positive Opinion adopted by consensus on 06.06.2024.

Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0202/G

CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Opinion adopted on 27.06.2024.

Request for Supplementary Information adopted on 18.04.2024.

Positive Opinion adopted by consensus on 27.06.2024.

Skyclarys - Omaveloxolone -

Positive Opinion adopted by consensus on

EMEA/H/C/006084/II/0003/G, Orphan Reata Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 13.06.2024.	13.06.2024.
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0123/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 27.06.2024, 25.04.2024.	Request for supplementary information adopted with a specific timetable.
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0132/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 20.06.2024.	Request for supplementary information adopted with a specific timetable.
Steen Solution - Human albumin solution - EMEA/H/D/000002/II/0005 XVIVO Perfusion AB, Rapporteur: Filip Josephson "To reconfirm the Scientific opinion granted under MDD (93/42/EEC) for the purpose of certification under MDR (MDR/2017/745)." Request for Supplementary Information adopted on 20.06.2024.	Request for supplementary information adopted with a specific timetable.
Stimufend - Pegfilgrastim - EMEA/H/C/004780/II/0007 Fresenius Kabi Deutschland GmbH, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 20.06.2024, 16.05.2024.	Request for supplementary information adopted with a specific timetable.
Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0015/G Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 06.06.2024, 08.02.2024.	Request for supplementary information adopted with a specific timetable.
TEPADINA - Thiotepa - EMEA/H/C/001046/II/0050/G ADIENNE S.r.l. S.U., Rapporteur: Alexandre Moreau Opinion adopted on 13.06.2024. Request for Supplementary Information adopted on 04.04.2024.	Positive Opinion adopted by consensus on 13.06.2024.
TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0030/G	Positive Opinion adopted by consensus on 20.06.2024.

Gilead Sciences Ireland UC, Rapporteur: Jan
Mueller-Berghaus
Opinion adopted on 20.06.2024.
Request for Supplementary Information adopted
on 21.03.2024.

Tyenne - Tocilizumab - EMA/H/C/005781/II/0003 Fresenius Kabi Deutschland GmbH, Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 27.06.2024.	Request for supplementary information adopted with a specific timetable.
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Vabysmo - Faricimab - EMA/H/C/005642/II/0011/G Roche Registration GmbH, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 27.06.2024.	Request for supplementary information adopted with a specific timetable.
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Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMA/H/C/003982/II/0141 MCM Vaccine B.V., Rapporteur: Christophe Focke Opinion adopted on 06.06.2024.	Positive Opinion adopted by consensus on 06.06.2024.
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Vaxneuvance - Pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) - EMA/H/C/005477/II/0020 Merck Sharp & Dohme B.V., Rapporteur: Patrick Vrijlandt Opinion adopted on 06.06.2024.	Positive Opinion adopted by consensus on 06.06.2024.
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Vyvgart - Efgartigimod alfa - EMA/H/C/005849/II/0017, Orphan Argenx, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 27.06.2024. Request for Supplementary Information adopted on 02.05.2024.	Positive Opinion adopted by consensus on 27.06.2024.
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Ximluci - Ranibizumab - EMA/H/C/005617/II/0010 STADA Arzneimittel AG, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 20.06.2024.	Request for supplementary information adopted with a specific timetable.
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Zilbrysq - Zilucoplan - EMA/H/C/005450/II/0002	Positive Opinion adopted by consensus on 13.06.2024.
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UCB Pharma S.A., Rapporteur: Kristina Dunder
Opinion adopted on 13.06.2024.

**Zometa - Zoledronic acid -
EMA/H/C/000336/II/0103/G**

Phoenix Labs Unlimited Company, Rapporteur:
Thalia Marie Estrup Blicher
Request for Supplementary Information adopted
on 06.06.2024, 21.03.2024.

Request for supplementary information adopted
with a specific timetable.

**WS2652/G
Edistride- EMA/H/C/004161/WS2652/G
Forxiga- EMA/H/C/002322/WS2652/G**

AstraZeneca AB, Lead Rapporteur: Kristina
Dunder
Opinion adopted on 27.06.2024.

Positive Opinion adopted by consensus on
27.06.2024.

**WS2663/G
Infanrix hexa-
EMA/H/C/000296/WS2663/0344/G**

GlaxoSmithkline Biologicals SA, Lead
Rapporteur: Christophe Focke
Opinion adopted on 13.06.2024.

Positive Opinion adopted by consensus on
13.06.2024.

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

**AREXVY - Respiratory syncytial virus,
glycoprotein F, recombinant, stabilised in
the pre-fusion conformation, adjuvanted
with AS01E - EMA/H/C/006054/II/0004**

GlaxoSmithkline Biologicals S.A., Rapporteur:
Patrick Vrijlandt, "Update of sections 4.8 and
5.1 of the SmPC in order to include data on
persistence of protection over at least 2 RSV
seasons following administration of a single
dose of Arexvy based on final results from study
RSV OA=ADJ-006 (A Phase 3, randomized,
placebo-controlled, observer-blind, multi-
country study to demonstrate the efficacy of a
single dose and annual revaccination doses of
GSK's RSVPreF3 OA investigational vaccine in
adults aged 60 years and above) and RSV
OA=ADJ-004 (A phase 3, randomized, open-
label, multi-country study to evaluate the
immunogenicity, safety, reactogenicity and
persistence of a single dose of the RSVPreF3 OA
investigational vaccine and different
revaccination schedules in adults aged 60 years
and above)."

Opinion adopted on 27.06.2024.

Request for Supplementary Information adopted

Positive Opinion adopted by consensus on
27.06.2024.

on 25.04.2024, 25.01.2024.

**Arixtra - Fondaparinux sodium -
EMA/H/C/000403/II/0092**

Viartis Healthcare Limited, Rapporteur: Kristina Dunder, "Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic information based on final results from study FDPX-IJS-7001; this is a retrospective cohort study to evaluate long-term dosing, efficacy, and safety of fondaparinux for treatment of venous thromboembolism in paediatric patients. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI, to bring it in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet."

Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

**Biktarvy - Bictegravir / Emtricitabine /
Tenofovir alafenamide -
EMA/H/C/004449/II/0059**

Gilead Sciences Ireland UC, Rapporteur: Jean-Michel Race, "Update of sections 4.4, 4.5, 4.6, 4.8, 5.1 and 5.2 of the SmPC in order to update information on pregnancy and dosing recommendations with polyvalent cation-containing products for pregnant individuals based on final results from study GS-US-380-5310; A Phase 1b, Open-label study to Evaluate the Pharmacokinetics (PK), Safety and Efficacy of B/F/TAF in HIV-1 infected, Virologically Suppressed, Pregnant Women in their Second and Third Trimesters; study GS-US-380-3909 and the Antiretroviral Pregnancy Registry. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes throughout the product information."

Opinion adopted on 27.06.2024.

Request for Supplementary Information adopted on 25.04.2024.

Positive Opinion adopted by consensus on 27.06.2024.

**BIMERVAX - SARS-CoV-2, variant XBB.1.16,
spike protein, receptor binding domain
fusion homodimer / Selvacovatein -
EMA/H/C/006058/II/0013**

Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to change

Request for supplementary information adopted with a specific timetable.

posology recommendations in individuals 16 years of age and older, amend an existing warning on hypersensitivity and anaphylaxis, delete insomnia and back pain from the list of adverse drug reactions (ADRs), change frequency of odynophagia, abdominal pain and injection site hypersensitivity from Uncommon to Rare and update immunogenicity information based on final results from study HIPRA-HH-2 (PART A and PART B) listed as a category 3 study in the RMP; HIPRA-HH-2 was a Phase IIb, double-blind, randomised, active-controlled, multi-centre, non-inferiority trial in adults fully vaccinated against COVID-19. The objective was to assess immunogenicity and safety of a booster vaccination with a recombinant protein RBD fusion heterodimer vaccine candidate (PHH-1V) against SARS-CoV-2 (Part A). An extension to the study was introduced to add a fourth dose as described below (Part B)."

Request for Supplementary Information adopted on 06.06.2024, 21.03.2024.

Bylvay - Odevixibat -

EMA/H/C/004691/II/0018, Orphan

Ipsen Pharma, Rapporteur: Patrick Vrijlandt, "Update of section 4.2 of the SmPC in order to add instructions for odevixibat administration in liquids. The Package Leaflet is updated accordingly."

Opinion adopted on 27.06.2024.

Positive Opinion adopted by consensus on 27.06.2024.

CAMZYOS - Mavacamten -

EMA/H/C/005457/II/0009

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Patrick Vrijlandt, "Update of section 4.2 of the SmPC in order to remove the sentence restricting the use of lower strength capsules to achieve higher prescribed dose, based on results from the bioequivalence study CV0271090; this is an open-label, randomized, single-dose, 2-way crossover study to establish bioequivalence of 1 × 15-mg mavacamten capsule to 3 × 5-mg mavacamten capsules in healthy participants. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the Product Information."

Opinion adopted on 27.06.2024.

Positive Opinion adopted by consensus on 27.06.2024.

Cimzia - Certolizumab pegol -

Request for supplementary information adopted

EMA/H/C/001037/II/0110

UCB Pharma S.A., Rapporteur: Kristina Dunder, "Update of sections 4.2 and 4.6 of the SmPC in order to update information on pregnancy based on final results from study UP0085, OTIS Phase I report and post marketing data. UP0085 is a Phase 1b, prospective, longitudinal, interventional, open-label study evaluating the impact of pregnancy on the PK of CZP. OTIS Phase I report presents the formal analysis of pregnancy outcome and infant and child follow-up data from the OTIS CZP Pregnancy Registry (RA0023). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4." Request for Supplementary Information adopted on 13.06.2024.

with a specific timetable.

Clopidogrel Zentiva - Clopidogrel - EMA/H/C/000975/II/0091

Zentiva k.s., Duplicate of Clopidogrel BMS (SRD), Informed Consent of Iscover, Rapporteur: Bruno Sepodes, "Update of section 4.4 and 4.8 of the SmPC in order to update an existing warning on 'Bleeding and haematological disorders' by adding a statement on triple antiplatelet therapy (clopidogrel + aspirin + dipyridamole) for stroke secondary prevention based on the cumulative review of the MAH global safety database and scientific literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes." Opinion adopted on 06.06.2024.

Positive Opinion adopted by consensus on 06.06.2024.

Constella - Linaclotide - EMA/H/C/002490/II/0063

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC in order to update the statement relating to guanylate cyclase-C (GCC) receptor expression in the paediatric population to reflect current clinical data, including final results from study MCP-103-311; this is a non-interventional clinical research study to characterize GCC mRNA expression in duodenal and colonic mucosal biopsies in children aged 0

Request for supplementary information adopted with a specific timetable.

to 17 years. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information and to bring it in line with the latest QRD template.”

Request for Supplementary Information adopted on 13.06.2024.

**Cuprior - Trientine -
EMA/H/C/004005/II/0028**

Positive Opinion adopted by consensus on 13.06.2024.

Orphalan, Rapporteur: Jayne Crowe,
“Submission of the final report from study TRIUMPH-2: Trientine dihydrochloride (Syprine capsules) vs. tetrahydrochloride (tablets): a Phase 1, single centre, randomised, interventional, open-label, 4-way crossover study in adult healthy male and female subjects to evaluate the pharmacokinetics and the safety and tolerability of 2 different oral formulations.”
Opinion adopted on 13.06.2024.
Request for Supplementary Information adopted on 11.04.2024.

**Dengvaxia - Dengue tetravalent vaccine (live, attenuated) -
EMA/H/C/004171/II/0029**

Positive Opinion adopted by consensus on 27.06.2024.

Sanofi Pasteur, Rapporteur: Christophe Focke,
“Submission of the final report from study CYD69 listed as a category 3 study in the RMP. This is an Observational study: Effectiveness of the tetravalent dengue vaccine, CYD-TDV (DENGIVAXIA) in the Philippines.
This procedure fulfils post-authorisation commitment MEA 005 for Dengvaxia.”
Opinion adopted on 27.06.2024.

**Erleada - Apalutamide -
EMA/H/C/004452/II/0037**

Request for supplementary information adopted with a specific timetable.

Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez, “Update of section 5.1 of the SmPC in order to include information on Prostate Specific Antigen (PSA) reduction to undetectable levels, based on results from the TITAN (56021927PCR3002) and SPARTAN (ARN-509-003) studies. TITAN is a Phase 3 randomized, placebo-controlled, double-blind study of Apalutamide Plus Androgen Deprivation Therapy (ADT) versus ADT in subjects with Metastatic Hormone-sensitive Prostate Cancer (mHSPC). SPARTAN is a Phase 3, randomized, double-blind, placebo-controlled study of ARN-509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer.”

Request for Supplementary Information adopted on 20.06.2024.

**Evrysdi - Risdiplam -
EMA/H/C/005145/II/0022**

Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Submission of the final report from study 'BP39055 (SUNFISH)' listed as a category 3 study in the RMP; this is a Two-Part Seamless, Multi-Centre Randomized, Placebo-Controlled, Double-blind Study to Investigate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Efficacy of RO7034067 in Type 2 and 3 Spinal Muscular Atrophy Patients."

Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

**KIMMTRAK - Tebentafusp -
EMA/H/C/004929/II/0005, Orphan**

Immunocore Ireland Limited, Rapporteur: Aaron Sosa Mejia, "Update of section 5.1 of the SmPC in order to include the updated Overall Survival (OS) data based on results from study IMCgp100-202; this is a phase III randomized, open-label, multi-centre study of the safety and efficacy of IMCgp100 compared with investigator's choice in HLA-A*0201 positive patients with previously untreated advanced uveal melanoma."

Opinion adopted on 20.06.2024.

Positive Opinion adopted by consensus on 20.06.2024.

**LIBTAYO - Cemiplimab -
EMA/H/C/004844/II/0043**

Regeneron Ireland Designated Activity Company, Rapporteur: Aaron Sosa Mejia, "Update of section 4.8 of the SmPC in order to add 'uveitis' to the list of adverse drug reactions (ADRs) with frequency rare, based on a safety evaluation report. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor corrections to the efficacy data in section 5.1 of the SmPC based on an erratum for the interim report for study R2810-ONC-1620, as well as to introduce minor editorial and formatting changes to the PI and to update the list of local representatives in the Package Leaflet."

Opinion adopted on 20.06.2024.

Positive Opinion adopted by consensus on 20.06.2024.

**Mounjaro - Tirzepatide -
EMA/H/C/005620/II/0021/G**

Request for supplementary information adopted with a specific timetable.

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, "A grouped application consisting of two Type II variations, as follows:

C.I.4: Update of sections 4.6, 4.8 and 5.1 of the SmPC in order to include information on weight management (WM) based on final results from Phase 3 interventional WM studies (SURMOUNT-2, -3, and -4) and Phase 1 mechanism of action studies (GPGU and GPHH studies). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity implement editorial changes to the SmPC.

C.I.4: Update of section 5.1 of the SmPC in order to update the mechanism of action based on final results from in vitro studies ENDO123, QSB24, ENDO187, ENDO188 and ENDO190. The Package Leaflet is updated accordingly."

Request for Supplementary Information adopted on 13.06.2024.

**Nuvaxovid - Covid-19 Vaccine
(recombinant, adjuvanted) -
EMA/H/C/005808/II/0069**

Positive Opinion adopted by consensus on 20.06.2024.

Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from study 2019nCoV-311 Part 1 listed as a category 3 study in the RMP. This is a 2-part, phase 3, randomized, observer blinded study to evaluate the safety and immunogenicity of Omicron subvariant and bivalent SARS-CoV-2 rS vaccines in adults previously vaccinated with other COVID-19 vaccines."

Opinion adopted on 20.06.2024.

**Ocrevus - Ocrelizumab -
EMA/H/C/004043/II/0040/G**

Request for supplementary information adopted with a specific timetable.

Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, "A grouped application comprised of three Type II Variations and one Type IA Variation, as follows:

3 Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to update clinical safety information based on final results from the three studies: study WA21092 (OPERA I), study WA21093 (OPERA II) and study WA25046 (ORATORIO). Study WA21092 (OPERA I) and study WA21093 (OPERA II) are randomized, double-blind, double-dummy, parallel-group studies to evaluate the efficacy and safety of ocrelizumab in comparison to interferon beta-1a (Rebif) in patients with relapsing multiple

sclerosis (RMS), while study WA25046 (ORATORIO) is a phase 3, multicentre, randomized, parallel-group, double blinded, placebo controlled study to evaluate the efficacy and safety of ocrelizumab in adults with primary progressive multiple sclerosis (PPMS). In addition, the MAH took the opportunity to introduce minor editorial change to the Product Information.

Type IA (A.6): Change the ATC Code of ocrelizumab from L04AA36 to L04AG08.”
Request for Supplementary Information adopted on 06.06.2024.

**Orgovyx - Relugolix -
EMA/H/C/005353/II/0020**

Positive Opinion adopted by consensus on 27.06.2024.

Accord Healthcare S.L.U., Rapporteur: Patrick Vrijlandt, “Update of sections 4.2 and 4.5 of the SmPC to add information on “Combination with other medicines for advanced hormone-sensitive prostate cancer” based on clinical studies and literature. In addition, the MAH took the opportunity to update section 5.1 of the SmPC with 2 minor corrections.”
Opinion adopted on 27.06.2024.
Request for Supplementary Information adopted on 23.05.2024.

**Orladeyo - Berotralstat -
EMA/H/C/005138/II/0017/G**

Positive Opinion adopted by consensus on 27.06.2024.

BioCryst Ireland Limited, Rapporteur: Finbarr Leacy, “A grouped application comprised of two type II variations, as follows:

C.I.4: Update of section 4.5 of the SmPC in order to remove the recommendation for close monitoring for adverse events with concomitant use of P-gp and BCRP inhibitors based on final safety results from the drug-drug interaction study BCX7353-119, as well as to update the effects of cyclosporine on berotralstat. Study BCX7353-119 is a phase 1 drug-drug interaction study to evaluate the effect of cyclosporine on the pharmacokinetics of berotralstat in healthy subjects.

C.I.13: Submission of the final reports from parts 2 and 3 of study BCX7353-301; this is a phase 3, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of two dose levels of

BCX7353 as an oral treatment for the suppression of events in subjects with hereditary angioedema.

In addition, the MAH took the opportunity to add additional wording for patients with severely reduced kidney function in the Package Leaflet and to introduce minor editorial changes to the PI, as per previous guidance.”

Opinion adopted on 27.06.2024.

Request for Supplementary Information adopted on 30.05.2024, 21.03.2024.

**Pombiliti - Cipaglucosidase alfa -
EMA/H/C/005703/II/0010**

Positive Opinion adopted by consensus on 27.06.2024.

Amicus Therapeutics Europe Limited,
Rapporteur: Patrick Vrijlandt, “Update of sections 4.6 and 5.3 of the SmPC in order to provide information regarding pre-implantation loss based on the reassessment of non-clinical data. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3 and to introduce editorial changes.”

Opinion adopted on 27.06.2024.

Request for Supplementary Information adopted on 18.04.2024.

**RINVOQ - Upadacitinib -
EMA/H/C/004760/II/0049**

Positive Opinion adopted by consensus on 13.06.2024.

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Kristina Dunder, “Update of section 5.1 of the SmPC in order to include long term efficacy and safety information (up to week 104 data) from study SELECT-AXIS 2 (M19-944 (Study 2)); this is a phase 3, randomized, double-blind study evaluating the long-term safety, tolerability, and efficacy of upadacitinib 15 mg QD in subjects with nr-axSpA who completed the double-blind period on study drug. The MAH took also the opportunity to update the ATC code from L04AA44 into L04AF03.”

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 14.03.2024.

**RINVOQ - Upadacitinib -
EMA/H/C/004760/II/0050**

Positive Opinion adopted by consensus on 13.06.2024.

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Kristina Dunder, “Update of section 5.1 of the SmPC in order to include long term

efficacy and safety information (up to week 104 data) from study M19-944 (Study 1); this is a phase 3 randomized, placebo-controlled, double-blind program to evaluate efficacy and safety of upadacitinib in adult subjects with axial spondyloarthritis followed by a remission-withdrawal period.”

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 04.04.2024.

Rystiggo - Rozanolixizumab -

EMA/H/C/005824/II/0002, Orphan

UCB Pharma, Rapporteur: Thalia Marie Estrup Blicher, “Update of sections 4.4 and 4.8 of the SmPC in order to amend a prior warning on aseptic meningitis to reflect the post-marketing cases and to add ‘aseptic meningitis’ to the list of adverse drug reactions (ADRs) with frequency ‘not known’ based on post-marketing data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.”

Opinion adopted on 20.06.2024.

Positive Opinion adopted by consensus on 20.06.2024.

Scemblix - Asciminib -

EMA/H/C/005605/II/0013/G, Orphan

Novartis Europharm Limited, Rapporteur: Janet Koenig, “Grouped application comprising three type II variations as follows:

C.I.4 - Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with P-gp Substrates based on the final results from studies 2301078, CABL001A2301 and CABL001X2101, listed as a category 3 study in the RMP.

C.I.4 - Update of section 4.8 of the SmPC in order to update the Summary of the safety profile and safety information based on final results from study CABL001A2301 and CABL001X2101, listed as a category 3 study in the RMP.

C.I.4 - Update of section 5.1 of the SmPC in order to update safety information based on final results from study CABL001A2301.

The Package Leaflet is updated accordingly.”

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 02.05.2024.

Positive Opinion adopted by consensus on 13.06.2024.

Siklos - Hydroxycarbamide -

Positive Opinion adopted by consensus on

<p>EMEA/H/C/000689/II/0061</p> <p>Theravia, Rapporteur: Karin Janssen van Doorn, "Update of section 4.5 of the SmPC in order to update information regarding the interference with certain Continuous Glucose Monitoring (CGM) sensors, based on a literature review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."</p> <p>Opinion adopted on 27.06.2024.</p>	27.06.2024.
<p>Sivextro - Tedizolid phosphate - EMEA/H/C/002846/II/0053</p> <p>Merck Sharp & Dohme B.V., Rapporteur: Bruno Sepodes, "Update of section 5.1 of the SmPC in order to implement the revised EUCAST MIC breakpoints of tedizolid. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."</p> <p>Opinion adopted on 06.06.2024.</p>	Positive Opinion adopted by consensus on 06.06.2024.
<p>Spravato - Esketamine - EMEA/H/C/004535/II/0024</p> <p>Janssen-Cilag International N.V., Rapporteur: Martina Weise, "Update of section 4.8 of the SmPC in order to add 'hypotension' to the list of adverse drug reactions (ADRs) with frequency uncommon, based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI."</p> <p>Opinion adopted on 20.06.2024.</p>	Positive Opinion adopted by consensus on 20.06.2024.
<p>Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0013</p> <p>Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, "Update of section 5.3 of the SmPC in order to update 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."</p> <p>Request for Supplementary Information adopted on 13.06.2024, 11.04.2024, 18.01.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p>Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0009</p>	Positive Opinion adopted by consensus on 20.06.2024.

Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, "Update of section 5.1 of the SmPC in order to update efficacy information based on the overall survival (OS) final analyses for study BGB-A317-302; this is a randomized, controlled, open-label, global phase 3 study comparing the efficacy of the anti-PD-1 antibody tislelizumab (BGB-A317) versus chemotherapy as second line treatment in patients with advanced unresectable/metastatic oesophageal squamous cell carcinoma."

Opinion adopted on 20.06.2024.

**Trulicity - Dulaglutide -
EMA/H/C/002825/II/0070**

Positive Opinion adopted by consensus on 27.06.2024.

Eli Lilly Nederland B.V., Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC in order to add a new warning on gastroparesis based on clinical data, post marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."

Opinion adopted on 27.06.2024.

**Ultomiris - Ravulizumab -
EMA/H/C/004954/II/0043/G**

Request for supplementary information adopted with a specific timetable.

Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, "A grouped application comprised of a Type II Variation and a Type IA Variation, as follows:

Type II (C.I.4): Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update clinical information regarding the atypical haemolytic uremic syndrome (aHUS) indication, based on final results from studies ALXN1210-aHUS-311 and ALXN1210-aHUS-312. ALXN1210-aHUS-311 is a phase 3, open-label, uncontrolled, multicentre, single treatment arm study in adolescent and adult patients with evidence of TMA who are naïve to complement inhibitor treatment, while ALXN1210-aHUS-312 is a phase 3, open-label, uncontrolled, multicentre, single treatment arm study in paediatric patients with evidence of TMA who are naïve to complement inhibitor treatment (Cohort 1) or are clinically stable after having been treated with eculizumab (Cohort 2). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

Type IA (A.6): To change the ATC Code for ravulizumab from L04AA43 to L04AJ02.”
Request for Supplementary Information adopted on 20.06.2024, 14.03.2024.

**Ultomiris - Ravulizumab -
EMA/H/C/004954/II/0045**

Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, “Update of sections 4.8 and 5.1 of the SmPC in order to update the summary of safety profile and information in adult patients with Generalised Myasthenia Gravis based on final results from study ALXN1210-MG-306; this is a Phase 3, randomized, double-blind, parallel-group, placebo-controlled, multi-centre study with an ongoing Open-Label Extension Period of up to 2 years in adult patients with gMG who were naïve to complement inhibitor treatment. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”
Request for Supplementary Information adopted on 20.06.2024.

Request for supplementary information adopted with a specific timetable.

**Xarelto - Rivaroxaban -
EMA/H/C/000944/II/0110/G**

Bayer AG, Rapporteur: Kristina Dunder, “A grouped application consisting of:
Type II (C.I.4): Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on in vitro study report PH-41585. In addition, the MAH took the opportunity to implement editorial changes in the SmPC.
Type IB unforeseen (C.I.z): Update of sections 6.5 and 6.6 of the SmPC to mitigate the risk of misinterpretation regarding the volume of the suspension to be prepared. The Labelling and Package Leaflet are updated accordingly.”
Opinion adopted on 27.06.2024.

Positive Opinion adopted by consensus on 27.06.2024.

**Xeljanz - Tofacitinib -
EMA/H/C/004214/II/0059**

Pfizer Europe MA EEIG, Rapporteur: Paolo Gasparini, “Update of section 4.4 of the SmPC in order to update serious infections section based on post marketing data and literature. In addition, the MAH has taken the opportunity to implement changes to improve readability and to update the list of local representatives in the Package Leaflet.”
Request for Supplementary Information adopted on 13.06.2024, 14.03.2024.

Request for supplementary information adopted with a specific timetable.

**Xevudy - Sotrovimab -
EMA/H/C/005676/II/0028**

Glaxosmithkline Trading Services Limited,
Rapporteur: Thalia Marie Estrup Blicher,
"Update of section 5.1 of the SmPC with new
data on the in antiviral activity of sotrovimab
against the Omicron variants named:
XBB.1.16.6, FL.1.5.1, JN.1, BA.2.86 variants
and XBB.2.3."

Opinion adopted on 13.06.2024.

Positive Opinion adopted by consensus on
13.06.2024.

**WS2647
Mekinist-
EMA/H/C/002643/WS2647/0066
Tafinlar-
EMA/H/C/002604/WS2647/0071**

Novartis Europharm Limited, Lead Rapporteur:
Peter Mol, "Update of section 5.1 of the SmPC
for Tafinlar and Mekinist in order to update
efficacy information based on final results from
study CDRB436F2301 (COMBI-AD); this is a
phase 3 randomized double blind study of
dabrafenib in combination with trametinib
versus two placebos in the adjuvant treatment
of high-risk BRAF V600 mutation-positive
melanoma after surgical resection. The RMP
version 11.1 for Tafinlar and version 19.2 for
Mekinist have also been submitted. In addition,
MAH took the opportunity to introduce minor
editorial changes to the Product Information."
Request for Supplementary Information adopted
on 27.06.2024.

Request for supplementary information adopted
with a specific timetable.

**WS2658
Braftovi-
EMA/H/C/004580/WS2658/0039
Mektovi-
EMA/H/C/004579/WS2658/0031**

Pierre Fabre Medicament, Lead Rapporteur:
Janet Koenig, "Update of sections 5.1 of the
SmPC in order to update efficacy and safety
information following the outcome of procedures
004579/0000 and R/0024 based on final results
from study C4221004 (CMEK162B2301). This
was a 2-part, multi-centre, randomized, open
label, Phase III study comparing the efficacy
and safety of encorafenib plus binimetinib to
vemurafenib and encorafenib monotherapy in
participants with locally advanced unresectable
or metastatic melanoma with BRAF V600
mutation. In addition, the MAH took the
opportunity to introduce editorial changes to the

Request for supplementary information adopted
with a specific timetable.

PI.”

Request for Supplementary Information adopted
on 20.06.2024

WS2700
M-M-RvaxPro-
EMA/H/C/000604/WS2700/0123
ProQuad-
EMA/H/C/000622/WS2700/0166

Positive Opinion adopted by consensus on
27.06.2024.

Merck Sharp & Dohme B.V., Lead Rapporteur:
Jan Mueller-Berghaus, “Update of section 4.6 of
the SmPC in order to update information on
pregnancy based on literature search. In
addition, the MAH took the opportunity to
update the list of local representatives in the
Package Leaflet and to introduce minor editorial
changes to the PI.”
Opinion adopted on 27.06.2024.

B.5.3. CHMP-PRAC assessed procedures

Byooviz - Ranibizumab -
EMA/H/C/005545/II/0016/G

Request for supplementary information adopted
with a specific timetable.

Samsung Bioepis NL B.V., Rapporteur: Christian
Gartner, PRAC Rapporteur: Ulla Wändel Liminga
Request for Supplementary Information adopted
on 13.06.2024.

Dapivirine Vaginal Ring 25 mg - Dapivirine
- EMA/H/W/002168/II/0025/G

Request for supplementary information adopted
with a specific timetable.

International Partnership for Microbicides
Belgium AISBL, Rapporteur: Patrick Vrijlandt,
PRAC Rapporteur: Jan Neuhauser, “A grouped
application consisting of:
Type II (C.I.4): Update of section 4.6 of the
SmPC in order to update information on
breastfeeding based on final results from study
MTN-043 (B-PROTECTED) listed as a category 3
study in the RMP (MEA/009). MTN-043 is a
Phase 3b, randomized, open-label, safety, and
drug detection study of dapivirine vaginal ring
and oral truvada in breastfeeding mother-infant
pairs. The Package Leaflet is updated
accordingly. The RMP version 1.4 has also been
submitted. In addition, the MAH took the
opportunity to update Annex II of the PI.

Type IB (C.I.11.z): Submission of an updated
RMP version 1.4 in order to request a change on
the due date for the MTN-034 (REACH) study.”
Request for Supplementary Information adopted

on 13.06.2024.

**Erbix - Cetuximab -
EMA/H/C/000558/II/0099**

Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2, 4.4 and 4.9 of the SmPC in order to introduce every two-weeks (Q2W) dosing regimen as an alternative to the already approved every week (Q1W) dosing regimen for the indications of metastatic colorectal cancer (CRC) and the recurrent/metastatic squamous cell cancer of the head and neck (SCCHN) in combination with platinum-based chemotherapy, based on pharmacokinetic (PK)-TGI-OS modelling and simulations. The Package Leaflet is updated accordingly. The RMP version 19.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information."

Request for Supplementary Information adopted on 27.06.2024.

Request for supplementary information adopted with a specific timetable.

See 9.1

**Fintepla - Fenfluramine -
EMA/H/C/003933/II/0022/G, Orphan**

UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, "A grouped application comprised of three Type II variations, as follows:

C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to modify the list of adverse drug reactions based on a revised safety ADR methodology for Dravet and Lennox-Gastaut syndromes, which includes pooled analyses encompassing studies ZX008-1503 and ZX008-1601 cohort B. The Package Leaflet is updated accordingly.

C.I.4: Update of section 5.1 of the SmPC in order to update clinical efficacy information for Dravet syndrome based on final results from study ZX008-1503 listed as a category 3 study in the RMP. This is an open-label extension trial to assess the long-term safety of ZX008 (fenfluramine hydrochloride) oral solution as an adjunctive therapy in children and young adults with Dravet syndrome.

C.I.4: Update of section 5.1 of the SmPC in order to update clinical efficacy information for Lennox-Gastaut syndrome based on final results

Request for supplementary information adopted with a specific timetable.

from study ZX008-1601 Part 1 cohort B and interim results for study ZX008-1601 Part 2 cohort B. Study 1601 Part 1 was an international, randomized, double-blind, parallel-group, placebo-controlled study in subjects with LGS 2 to 35 years of age, while study 1601 Part 2 is a long-term, open-label, flexible-dose extension for subjects who completed study 1601 Part 1.

The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information, including to section 4.2 of the SmPC"

Request for Supplementary Information adopted on 27.06.2024, 21.03.2024.

**Ilumetri - Tildrakizumab -
EMA/H/C/004514/II/0055**

Positive Opinion adopted by consensus on 13.06.2024.

Almirall S.A, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski
Opinion adopted on 13.06.2024.
Request for Supplementary Information adopted on 11.04.2024.

**Kalydeco - Ivacaftor -
EMA/H/C/002494/II/0126**

Request for supplementary information adopted with a specific timetable.

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Monica Martinez Redondo, "Submission of the final report from study VX15-770-126 (study 126) listed as a category 3 study in the RMP; this is a phase 3, 2-arm, multicentre open-label study to evaluate the safety and pharmacodynamics of long-term ivacaftor treatment in subjects with cystic fibrosis who are less than 24 months of age at treatment initiation and have an approved ivacaftor-responsive mutation. The RMP version 16.0 has also been submitted."
Request for Supplementary Information adopted on 13.06.2024.

**Kuvan - Sapropterin -
EMA/H/C/000943/II/0078**

Positive Opinion adopted by consensus on 13.06.2024.

BioMarin International Limited, Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu, "Submission of the final report from study KOGNITO, listed as a category 3 study in the RMP. This is a Phase IV Open-Label, Single-Cohort Study of the Long-Term Neurocognitive

Outcomes in 4-to 5-Year-Old Children with Phenylketonuria Treated with Sapropterin Dihydrochloride (Kuvan) for 7 Years. The RMP version 16.1 has also been submitted.”
Opinion adopted on 13.06.2024.
Request for Supplementary Information adopted on 07.03.2024, 11.01.2024, 28.09.2023.

**Leqvio - Inclisiran -
EMA/H/C/005333/II/0021**

Positive Opinion adopted by consensus on 13.06.2024.

Novartis Europharm Limited, Rapporteur:
Martina Weise, PRAC Rapporteur: Kimmo Jaakkola, “Submission of the final report from study ORION-8 - A long-term extension trial of the Phase III lipid-lowering trials to assess the effect of long-term dosing of inclisiran given as subcutaneous injections in subjects with high cardiovascular risk and elevated LDL-C, listed as a category 3 study in the RMP. The RMP version 3.0 has also been submitted.”
Opinion adopted on 13.06.2024.
Request for Supplementary Information adopted on 11.04.2024.

**Loargys - Pegzilarginase -
EMA/H/C/005484/II/0002/G, Orphan**

Request for supplementary information adopted with a specific timetable.

Immedica Pharma AB, Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, “Grouped application comprising two type II variations as follows:

C.I.4 – Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study CAEB1102-300A (SOB 003), listed as a specific obligation in Annex II. Study 300A was a Phase 3, randomized, double blind, placebo-controlled study of the efficacy and safety of pegzilarginase in adults, adolescents and children with arginase 1 deficiency (ARG1 D).

C.I.4 – Update of section 4.8 of the SmPC in order to update efficacy and safety information based on final results from study CAEB1102-102A (SOB 004), listed as a specific obligation in Annex II.

Study 102A was an open label extension study to evaluate the long-term safety, tolerability, and efficacy of pegzilarginase in adults, adolescents and children with arginase 1 deficiency (ARG1 D).

The Package Leaflet and Annex II are updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the

opportunity to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes.”
Request for Supplementary Information adopted on 13.06.2024.

**Lupkynis - Voclosporin -
EMA/H/C/005256/II/0013**

Positive Opinion adopted by consensus on 13.06.2024.

Otsuka Pharmaceutical Netherlands B.V.,
Rapporteur: Kristina Dunder, PRAC Rapporteur: Adam Przybylkowski, “Update of sections 4.6 and 5.2 of the SmPC in order to update breast-feeding information based on final results from study AUR-VCS-2021-04. This study is a single-centre, open-label, Phase 1, lactation study to investigate the amount of voclosporin excreted in breast milk following a single oral dose of 23.7 mg voclosporin in healthy, lactating, female volunteers. The Package Leaflet is updated accordingly. The updated RMP version 5.0 is agreed.”
Opinion adopted on 13.06.2024.
Request for Supplementary Information adopted on 11.04.2024.

**MVABEA - Ebola vaccine (rDNA, replication-incompetent) -
EMA/H/C/005343/II/0021**

Request for supplementary information adopted with a specific timetable.

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné, “Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy based on final results from study VAC52150EBL3010 listed as a category 3 study in the RMP as well as study VAC52150EBL3008 and two post-authorization vaccination campaigns. Study VAC52150EBL3010 is a phase 3 open-label randomized clinical trial to evaluate the safety, reactogenicity and immunogenicity of a 2-dose Ebola vaccine regimen of Ad26.ZEBOV followed by MVA-BN-Filo in healthy pregnant women. The Package Leaflet is updated accordingly. The RMP version 3.3 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”
Request for Supplementary Information adopted on 27.06.2024.

**Retsevmo - Selpercatinib -
EMA/H/C/005375/II/0028**

Positive Opinion adopted by consensus on 27.06.2024.

Eli Lilly Nederland B.V., Rapporteur: Alexandre

Moreau, PRAC Rapporteur: Bianca Mulder, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on interim results from study LIBRETTO-431 (JZJC) listed as a specific obligation in the Annex II (SOB/002); this is a randomized Phase 3 study comparing selpercatinib to platinum-based and pemetrexed therapy with or without pembrolizumab in patients with locally advanced or metastatic, RET-fusion-positive NSCLC. The Package Leaflet is updated accordingly. The variation leads to amendments to the Annex II. The RMP version 10.1 has also been agreed."

Opinion adopted on 27.06.2024.

Request for Supplementary Information adopted on 07.03.2024.

**RoActemra - Tocilizumab -
EMA/H/C/000955/II/0121**

Positive Opinion adopted by consensus on 13.06.2024.

Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Submission of the final report from study ZUMA-8 (PAM). This is a phase 1 multicentre study evaluating the safety and tolerability of KTE-X19 in adult subjects with Relapsed/Refractory Chronic Lymphocytic Leukaemia and Small Lymphocytic Lymphoma. The RMP version 29.0 has also been submitted."

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 07.03.2024.

**Spikevax - COVID-19 mRNA vaccine -
EMA/H/C/005791/II/0136**

Request for supplementary information adopted with a specific timetable.

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Request for Supplementary Information adopted on 27.06.2024.

See 9.1

**VELSIPITY - Etrasimod -
EMA/H/C/006007/II/0001**

Positive Opinion adopted by consensus on 13.06.2024.

Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Mari Thorn, "Update of section 4.4 to modify the macular oedema warning based on the evaluation of the cases of MO/cystoid MO reported in the etrasimod clinical studies and other S1P labels in the EU. The Package Leaflet and Annex II are updated in accordance. RMP version 1.5 has also been submitted. In addition, the MAH took this

opportunity to introduce editorial changes to the PI.”

Opinion adopted on 13.06.2024.

ZABDENO - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337/II/0019

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné, “Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy based on final results from study VAC52150EBL3010 listed as a category 3 study in the RMP as well as study VAC52150EBL3008 and two post-authorisation vaccination campaigns. Study VAC52150EBL3010 is a phase 3 open-label randomized clinical trial to evaluate the safety, reactogenicity and immunogenicity of a 2-dose Ebola vaccine regimen of Ad26.ZEBOV followed by MVA-BN-Filo in healthy pregnant women. The Package Leaflet is updated accordingly. The RMP version 3.3 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information.”

Request for Supplementary Information adopted on 27.06.2024.

Request for supplementary information adopted with a specific timetable.

Zeposia - Ozanimod - EMEA/H/C/004835/II/0024/G

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, “Grouped application comprising two variations as follows:

Type II (C.I.4) – Update of sections 4.4 and 4.8 the SmPC in order to add a new warning on liver injury, to add Liver injury to the list of adverse drug reactions (ADRs) with frequency rare based on the cumulative review of the MAH safety database, clinical trials and literature search. The RMP version 8.0 also been submitted.

Type IA (A.6) – To change the ATC code from L04AA38 to L04AE02.”

Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0006, Orphan

Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, “Update of section 5.1 of the

Positive Opinion adopted by consensus on 27.06.2024.

SmPC in order to update open-label data based on the final report from study 1042-CDD-3001 OLE listed as a category 3 study in the RMP. This was the open-label portion of the pivotal study 1042-CDD-3001; a double-blind, randomized, placebo-controlled trial of adjunctive ganaxolone treatment in children and young adults with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) followed by long-term open-label treatment. The RMP version 1.4 has also been submitted."

Opinion adopted on 27.06.2024.

Request for Supplementary Information adopted on 11.04.2024.

WS2619/G

Invokana-

EMA/H/C/002649/WS2619/0066/G

Vokanamet-

EMA/H/C/002656/WS2619/0073/G

Janssen-Cilag International N.V., Lead Rapporteur: Martina Weise, Lead PRAC Rapporteur: Martin Huber, "A grouped application consisting of two Type II variations, as follows:

C.I.4: Update of section 4.4 of the SmPC in order to amend an existing warning on Diabetic Ketoacidosis based on literature. The Package Leaflet is updated accordingly.

C.I.4: Update of sections 4.6 and 5.3 of the SmPC in order to update information on pregnancy based on literature.

The RMP version 11.1 has also been submitted."

Request for Supplementary Information adopted on 13.06.2024, 11.04.2024.

Request for supplementary information adopted with a specific timetable.

WS2664

Ebymect-

EMA/H/C/004162/WS2664/0066

Qtern-EMA/H/C/004057/WS2664/0043

Xigduo-EMA/H/C/002672/WS2664/0076

AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Bianca Mulder, "Update of sections 4.2, 4.4, 4.5, 4.8, 5.1 and 6.1 of the SmPC in order to align dapagliflozin related information in Fixed Dose Combination with Forxiga. The Package Leaflet is updated accordingly. The RMPs version 15.1 (Xigduo and Wbymect) and 9.1 (Qtern) has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI."

Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted
on 13.06.2024.

B.5.4. PRAC assessed procedures

PRAC Led

**BESPONSA - Inotuzumab ozogamicin -
EMA/H/C/004119/II/0028, Orphan**

Pfizer Europe MA EEIG, PRAC Rapporteur:
Gabriele Maurer, PRAC-CHMP liaison: Jan
Mueller-Berghaus, "Submission of the final
report from study B1931028; this is a non-
interventional post-authorization safety study
(PASS) of inotuzumab ozogamicin to
characterize complications post-hematopoietic
stem cell transplantation (HSCT) following
inotuzumab ozogamicin treatment in adult and
paediatric patients with B-cell precursor acute
lymphoblastic leukaemia (ALL). The RMP version
3.0 has also been submitted."

Request for Supplementary Information adopted
on 13.06.2024.

Request for supplementary information adopted
with a specific timetable.

PRAC Led

**CAMZYOS - Mavacamten -
EMA/H/C/005457/II/0008**

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Patrick Vrijlandt, PRAC Rapporteur: Kimmo
Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola,
"Submission of an updated RMP version 3.0 in
order to revise the number of patients planned
to be enrolled in DISCOVER-HCM US-registry
study CV027012 (MEA 005). In addition, the
MAH took this opportunity to update protocol
title for MAVEL-HCM study (CV027013) and
include reference to study protocol in Annex 3 of
the RMP, following the assessment of PAM
procedure MEA 001."

Opinion adopted on 13.06.2024.

Positive Opinion adopted by consensus on
13.06.2024.

PRAC Led

**COMIRNATY - COVID-19 mRNA vaccine -
EMA/H/C/005735/II/0206/G**

BioNTech Manufacturing GmbH, PRAC
Rapporteur: Liana Martirosyan, PRAC-CHMP
liaison: Patrick Vrijlandt, "A grouped application
comprised of 3 Type II variations as follows:
C.I.13: Submission of the final report from
study C4591012 listed as a category 3 study in
the RMP. This is a non-interventional Post-
Emergency Use Authorisation active safety

Positive Opinion adopted by consensus on
13.06.2024.

surveillance study among individuals in the Veteran's Affairs health system receiving Comirnaty. The RMP version 13.0 is approved.
C.I.11.b: Update of RMP to version 13.0 in order to implement changes to an agreed post-authorisation study (C4591052 protocol amendments 1 & 2) in the RMP, where there is an impact on the description of the study.
C.I.11.b: Update of RMP to version 13.0 in order to implement changes to an agreed post-authorisation study (C4591021 protocol amendment 4) in the RMP, where there is an impact on the description of the study.
In addition, the MAH took the opportunity to update the milestones for the two studies C4591022 and C4591051 in the RMP."
Opinion adopted on 13.06.2024.
Request for Supplementary Information adopted on 11.04.2024.

PRAC Led
Gilenya - Fingolimod -
EMA/H/C/002202/II/0090/G
Novartis Europharm Limited, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Grouped application comprising two variations as follows:
Type II (C.I.3.b) - Update of sections 4.3 and 4.4 of the SmPC in order to add history of progressive multifocal leukoencephalopathy (PML) as a new contraindication and to amend an existing warning on PML and to update the educational material to improve the general readability of these documents and better address key messages and recommendations for healthcare professionals following the assessment of procedure PSUSA/00001393/202302. The Package Leaflet and Annex II are updated accordingly. The RMP version 20.0 has also been submitted.
Type IA (A.6) - To change the ATC Code of Fingolimod from L04AA27 to L04AE01."
Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led
MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine -
EMA/H/C/005084/II/0031
Sanofi Pasteur, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "Update of section 4.8 of the SmPC in

Positive Opinion adopted by consensus on 13.06.2024.

order to add 'Hypersensitivity' and 'Anaphylaxis' to the list of adverse drug reactions (ADRs) with frequency 'not known' and 'very rare' respectively, based on a cumulative review of cases of hypersensitivity/allergic reaction (including anaphylaxis) following the request by PRAC in the Assessment Report for PSUSA/00010044/202304. The Package Leaflet is updated accordingly."

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 11.04.2024.

PRAC Led	Request for supplementary information adopted with a specific timetable.
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Olumiant - Baricitinib -

EMA/H/C/004085/II/0047

Eli Lilly Nederland B.V., PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Submission of the final report from non-interventional Study I4V-MC-B012 listed as a category 3 study in the RMP. This is a post-marketing safety surveillance of baricitinib in three European registries. The RMP version 23.1 has also been submitted."

Request for Supplementary Information adopted on 13.06.2024.

PRAC Led	Request for supplementary information adopted with a specific timetable.
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Prolia - Denosumab -

EMA/H/C/001120/II/0100

Amgen Europe B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from the post marketing observational study 20090522, listed as a category 3 study in the RMP. This is a denosumab global safety assessment among women with postmenopausal osteoporosis (PMO), men with osteoporosis, and men and women who receive Prolia with glucocorticoid exposure in multiple observational databases."

Request for Supplementary Information adopted on 13.06.2024, 11.04.2024, 11.01.2024.

PRAC Led	Positive Opinion adopted by consensus on 13.06.2024.
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Reyataz - Atazanavir -

EMA/H/C/000494/II/0140

Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Jean-Michel Race, "Update of section 4.4 of the SmPC in order to clarify and update the warning regarding dyslipidaemia in relation to other comparators, following the PRAC's

recommendation in the outcome of the PSUSA/00000258/202106 procedure.
In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information.”
Opinion adopted on 13.06.2024.

PRAC Led
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0131
Moderna Biotech Spain S.L., PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, “Submission of the final report from study mRNA-1273-919 - An Observational Study to Assess Maternal and Infant Outcomes Following Exposure to Spikevax During Pregnancy, listed as a category 3 study in the RMP.”
Request for Supplementary Information adopted on 13.06.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led
Sprycel - Dasatinib - EMEA/H/C/000709/II/0090
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Aaron Sosa Mejia, “Update of the RMP (version 18.2) in order to reflect the proposed revised commitments to assess the growth and development disorders and bone mineral metabolism disorders in paediatric subjects.”
Opinion adopted on 13.06.2024.
Request for Supplementary Information adopted on 11.04.2024, 30.11.2023.

Positive Opinion adopted by consensus on 13.06.2024.

PRAC Led
Stelara - Ustekinumab - EMEA/H/C/000958/II/0100
Janssen-Cilag International N.V., PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, “Update of section 4.6 of the SmPC in order to update information on pregnancy based on the final synoptic report from study CNTO1275PSO4037 (OTIS); this is a pregnancy exposure registry for Stelara. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to correct 3 editorial discrepancies in the SmPC sections 4.8 and 6.6 and package leaflet section 5. The consolidated RMP version 28.1 has also been agreed.”

Positive Opinion adopted by consensus on 13.06.2024.

Opinion adopted on 13.06.2024.
Request for Supplementary Information adopted
on 11.01.2024, 31.08.2023.

PRAC Led
**Stelara - Ustekinumab -
EMA/H/C/000958/II/0104**
Janssen-Cilag International N.V., PRAC
Rapporteur: Rhea Fitzgerald, PRAC-CHMP
liaison: Jayne Crowe, "Submission of the final
report from study RRA-20745 listed as a
category 3 study in the RMP. This is an
observational post-authorization safety study
(PASS) to describe the safety of ustekinumab
and other Crohn's disease treatments in a
cohort of patients with Crohn's disease. The
RMP version 27.2 has also been submitted."
Request for Supplementary Information adopted
on 13.06.2024, 11.01.2024.

Request for supplementary information adopted
with a specific timetable.

PRAC Led
**TachoSil - Human thrombin / Human
fibrinogen - EMA/H/C/000505/II/0124**
Corza Medical GmbH, PRAC Rapporteur:
Gabriele Maurer, PRAC-CHMP liaison: Jan
Mueller-Berghaus, "Submission of an updated
RMP version 9.1 in order to reflect the extension
of indication to include the paediatric population
and to update the details of the planned non-
interventional post-authorisation safety study:
PASS-TachoSil Evaluation (PasTel)."
Request for Supplementary Information adopted
on 13.06.2024, 08.02.2024.

Request for supplementary information adopted
with a specific timetable.

PRAC Led
**Uptravi - Selexipag -
EMA/H/C/003774/II/0045**
Janssen-Cilag International N.V., PRAC
Rapporteur: Nathalie Gault, PRAC-CHMP liaison:
Alexandre Moreau, "Submission of the final
report from study 67896049PAH0002
(EXTRACT) and interim report for study AC-
065A401 (EXPOSURE), listed as a category 3
study in the RMP. EXTRACT is a Retrospective
Medical Chart Review of Patients with PAH newly
treated with either Uptravi (selexipag) or any
other PAH-specific therapy. EXPOSURE is an
observational cohort study of PAH patients
newly treated with either Uptravi (selexipag) or
any other PAH-specific therapy, in clinical
practice."
Request for Supplementary Information adopted

Request for supplementary information adopted
with a specific timetable.

on 13.06.2024.

PRAC Led

Vyndaqel - Tafamidis -

EMA/H/C/002294/II/0091/G, Orphan

Pfizer Europe MA EEIG, PRAC Rapporteur:

Tiphaine Vaillant, PRAC-CHMP liaison: Jean-Michel Race, "A grouped application comprised of two Type II Variations, as follows:

C.I.4: Update of the Annex II based on final results from study B3461001 (THAOS) listed as a category 3 study in the RMP. This is a global, multi-centre, longitudinal, observational survey of patients with documented transthyretin gene mutations or wild-type transthyretin amyloidosis.

C.I.13: Submission of the final report from study B3461042 listed as a category 3 study in the RMP. This is a post-marketing safety surveillance study in Japanese patients with ATTR-PN.

The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to provide B3461028 Clinical Study Report (CSR) Errata."

Request for Supplementary Information adopted on 13.06.2024, 11.04.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led

Xeljanz - Tofacitinib -

EMA/H/C/004214/II/0062

Pfizer Europe MA EEIG, PRAC Rapporteur: Liana Martirosyan, PRAC-CHMP liaison: Peter Mol,

"Submission of the final report from study A3921203 (Tofacitinib Pregnancy Exposure Registry OTIS Autoimmune Diseases in Pregnancy Project) listed as a category 3 study in the RMP; this is a prospective, observational cohort study of pregnancy outcomes in women with a disease for which tofacitinib had an approved indication."

Opinion adopted on 13.06.2024.

Positive Opinion adopted by consensus on 13.06.2024.

PRAC Led

Xeljanz - Tofacitinib -

EMA/H/C/004214/II/0063

Pfizer Europe MA EEIG, PRAC Rapporteur: Liana Martirosyan, PRAC-CHMP liaison: Peter Mol,

"Submission of an updated RMP version 32.0 in

Positive Opinion adopted by consensus on 13.06.2024.

order to propose the removal of category 3 study A3921329 (A Long-Term, Observational Study within the CorEvitas [formerly Corrona] Inflammatory Bowel Disease (IBD) Registry to Characterize the Safety of Tofacitinib in Patients with Ulcerative Colitis in the Post-Approval Setting). In addition, the MAH took the opportunity to update the RMP with some other minor updates.”

Opinion adopted on 13.06.2024.

PRAC Led

WS2571

Glyxambi-

EMA/H/C/003833/WS2571/0055

Jardiance-

EMA/H/C/002677/WS2571/0082

Synjardy-

EMA/H/C/003770/WS2571/0076

Boehringer Ingelheim International GmbH, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Carolina Prieto Fernandez, “Submission of the final report from study 1245-0201. This is an observational post-authorization safety study (PASS) to assess the risk of acute pancreatitis in type 2 diabetes mellitus (T2DM) patients newly initiating empagliflozin compared to other oral non-incretin/non-sodium glucose co-transporter-2 inhibitors (SGLT2i)-containing glucose lowering drugs. The RMP versions 22.0, 15.0 and 10.0 have also been submitted for Jardiance, Synjardy and Glyxambi, respectively.”

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted on 30.11.2023.

Positive Opinion adopted by consensus on 13.06.2024.

PRAC Led

WS2587

TECFIDERA-

EMA/H/C/002601/WS2587/0085

Vumerity-

EMA/H/C/005437/WS2587/0015

Biogen Netherlands B.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, “Submission of the final report from study 109MS401, a multicentre, global, observational study to collect information on safety and to document the drug utilization of Tecfidera (Dimethyl Fumarate) when used in routine medical practice in the treatment of Multiple Sclerosis (ESTEEM), listed as a category

Request for supplementary information adopted with a specific timetable.

3 study in the RMP (MEA007.6). The RMPs version 16.1 for Tecfidera and version 2.1 for Vumerity, have also been submitted.”
Request for Supplementary Information adopted on 13.06.2024, 08.02.2024.

PRAC Led

WS2686

Cinacalcet Accordpharma-

EMA/H/C/005236/WS2686/0011

Accord Healthcare S.L.U., Generic of Mimpara,
Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP
liaison: Kristina Dunder, “To update the RMP to
make updated in following safety concerns
(important identified risks) after approval of the
same changes in the reference product,
Mimpara (in procedure
EMA/H/C/000570/IB/0069):

-Update of "Hypocalcaemia" to "Hypocalcaemia
in the paediatric population"

-Removal of "QT prolongation and ventricular
arrhythmias secondary to hypocalcaemia"

-Removal of "Convulsions/seizures"

Furthermore, the Marketing Authorisation
Holder is taking the opportunity to consolidate
into a single RMP the RMPs approved for
Cinacalcet 30mg/60mg/90mg Film-coated
tablets through CP (EMA/H/C/005236) and
DCP (FI/H/869/01-03/DC) procedures.”
Opinion adopted on 27.06.2024.

Positive Opinion adopted by consensus on
27.06.2024.

B.5.5. CHMP-CAT assessed procedures

Abecma - Idecabtagene vicleucel -
EMA/H/C/004662/II/0048, Orphan,
ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Rune Kjekken, CHMP Coordinator: Ingrid Wang
Request for Supplementary Information adopted
on 21.06.2024.

Request for supplementary information adopted
with a specific timetable.

Breyanzi - Lisocabtagene maraleucel /
Lisocabtagene maraleucel -
EMA/H/C/004731/II/0036/G, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Concetta Quintarelli, CHMP Coordinator: Paolo
Gasparini, “Grouped application comprising two
variations as follows:

C.I.4 – Update of sections 4.4 of the SmPC in
order to add immune effector cell-associated
neurotoxicity syndrome (ICANS) and ICE

Positive Opinion adopted by consensus on
27.06.2024.

scoring in the table for neurologic adverse reaction and update of section 4.8 of the SmPC to add immune effector cell-associated neurotoxicity syndrome (ICANS) as an adverse drug reaction (ADR) with a "not known" frequency based on the cumulative review of MAH safety database and literature. The Package Leaflet is updated accordingly. An updated RMP version 4.1 has been provided including the relevant changes in accordance with the scope of this procedure. In addition, the MAH took this opportunity to introduce editorial changes and administrative updates concerning the PIP product status in section 4.2 and 5.1 of the SmPC.

A.6 – To include the ATC Code L01XL08 in section 5.1 of the SmPC."

Opinion adopted on 27.06.2024, 21.06.2024.

Request for Supplementary Information adopted on 24.05.2024, 16.02.2024.

Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0037/G, ATMP

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini

Request for Supplementary Information adopted on 21.06.2024, 15.03.2024.

Request for supplementary information adopted with a specific timetable.

Casgevvy - Exagamglogene autotemcel - EMEA/H/C/005763/II/0003/G, Orphan, ATMP

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus

Request for Supplementary Information adopted on 21.06.2024.

Request for supplementary information adopted with a specific timetable.

Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/II/0066/G, ATMP

Amgen Europe B.V., Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lähteenvuo, "A grouped application consisting of two Type II variations, as follows:

Positive Opinion adopted by consensus on 27.06.2024.

C.I.13: Submission of the final report from Study 5 (added in EMEA-001251-PIP01-11-M04) titled "Exposure-Response analysis of Talimogene Laherparepvec for adult subjects with melanoma from Study 20120324 and comparison to paediatric subjects' data from Study 20110261 in support of a paediatric

investigational plan".

C.I.13: Submission of the final report from Study 6 (added in EMEA-001251-PIP01-11-M04) titled "Efficacy Analysis of the Young Adult Melanoma Subgroup (from 18 to less than 36 years of age) From 4 Talimogene Laherparepvec Monotherapy Studies Using Bayesian Extrapolation With Data Collected From the Older Adult Melanoma Subgroup (from 36 years of age and older) to Support Extrapolation of Efficacy From Adult Patient With Advanced Melanoma to Adolescent Patients With Advanced Melanoma".

Opinion adopted on 27.06.2024, 21.06.2024.

WS2689
Tecartus-
EMA/H/C/005102/WS2689/0045

Request for supplementary information adopted with a specific timetable.

Yescarta-
EMA/H/C/004480/WS2689/0076

Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus

Request for Supplementary Information adopted on 21.06.2024.

B.5.6. CHMP-PRAC-CAT assessed procedures

Yescarta - Axicabtagene ciloleucel -
EMA/H/C/004480/II/0075/G, Orphan,
ATMP

Request for supplementary information adopted with a specific timetable.

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Erneholm, "Grouped application comprising two type II variations as follows:

C.I.13 - Submission of the final report from study KTE-C19-101 (ZUMA-1) listed as a category 3 study in the RMP. This is a Phase 1/2 Multicentre Study Evaluating The Safety And Efficacy Of Kte-C19 In Subjects With Refractory Aggressive Non-Hodgkin Lymphoma.

C.I.13 - Submission of the final report from study KTE-C19-106 (ZUMA-6) listed as a category 3 study in the RMP. This is a Phase 1-2 Multi-Centre Study Evaluating The Safety And Efficacy Of Kte-C19 In Combination With Atezolizumab In Subjects With Refractory Diffuse Large B-Cell Lymphoma (DLBCL). The RMP version 9.2 has also been submitted."

Request for Supplementary Information adopted

on 21.06.2024.

B.5.7. PRAC assessed ATMP procedures

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

WS2645/G Avamys- EMA/H/C/000770/WS2645/0052/G Elebrato Ellipta- EMA/H/C/004781/WS2645/0039/G Relvar Ellipta- EMA/H/C/002673/WS2645/0066/G Revinty Ellipta- EMA/H/C/002745/WS2645/0063/G Trelegy Ellipta- EMA/H/C/004363/WS2645/0036/G	Positive Opinion adopted by consensus on 06.06.2024.
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GlaxoSmithKline Trading Services Limited, Lead

Rapporteur: Finbarr Leacy, Quality variation

Opinion adopted on 06.06.2024.

Request for Supplementary Information adopted

on 11.04.2024.

WS2654 Aerius-EMA/H/C/000313/WS2654/0106 Azomyr- EMA/H/C/000310/WS2654/0110 Neoclarityn- EMA/H/C/000314/WS2654/0104	Positive Opinion adopted by consensus on 20.06.2024.
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Organon N.V., Duplicate of Allex (SRD),

Azomyr, Opulis (SRD), Lead Rapporteur:

Christophe Focke "To update section 4.4 of the

SmPC and section 2 of the package leaflet to

correct the content of benzyl alcohol from 0.75

mg to 0.375 mg and the content of propylene

glycol from 100.75 mg to 100.19 mg to comply

with the Annex to the European Commission

guideline on "Excipients in the labelling and

package leaflet of medicinal products for human

use".

Additionally, the MAH has taken the opportunity

to update section 2 of the SmPC to state the

excipient with known effect lactose

quantitatively. In addition, the MAH has taken

the opportunity to update section 4.8 of the

SmPC and section 4 of the package leaflet to

correct the link to QRD Appendix V for the

national reporting system.

Furthermore, the MAH has taken the

opportunity to update the package leaflet with

details of the local representative for Austria.
Lastly, the MAH has taken the opportunity to
introduce minor editorial corrections to the PI in
the following language: CS.”

Opinion adopted on 20.06.2024.

Request for Supplementary Information adopted
on 04.04.2024.

WS2656/G

Copalia HCT-

EMA/H/C/001159/WS2656/0112/G

Dafiro HCT-

EMA/H/C/001160/WS2656/0114/G

Exforge HCT-

EMA/H/C/001068/WS2656/0111/G

Novartis Europharm Limited, Lead Rapporteur:

Thalia Marie Estrup Blicher

Request for Supplementary Information adopted
on 27.06.2024, 02.05.2024.

Request for supplementary information adopted
with a specific timetable.

WS2665

Mircera-EMA/H/C/000739/WS2665/0101

NeoRecormon-

EMA/H/C/000116/WS2665/0125

Roche Registration GmbH, Lead Rapporteur:

Martina Weise

Opinion adopted on 20.06.2024.

Positive Opinion adopted by consensus on
20.06.2024.

WS2669

HyQvia-EMA/H/C/002491/WS2669/0098

Kiovig-EMA/H/C/000628/WS2669/0128

Baxalta Innovations GmbH, Lead Rapporteur:

Jan Mueller-Berghaus, Quality variation

Opinion adopted on 13.06.2024.

Request for Supplementary Information adopted
on 02.05.2024.

Positive Opinion adopted by consensus on
13.06.2024.

WS2681

Ambirix-

EMA/H/C/000426/WS2681/0133

Fendrix-

EMA/H/C/000550/WS2681/0086

Infanrix hexa-

EMA/H/C/000296/WS2681/0345

Twinrix Adult-

EMA/H/C/000112/WS2681/0168

Twinrix Paediatric-

EMA/H/C/000129/WS2681/0169

GlaxoSmithkline Biologicals SA, Lead

Rapporteur: Christophe Focke

Opinion adopted on 27.06.2024.

Positive Opinion adopted by consensus on
27.06.2024.

WS2694/G

Request for supplementary information adopted

GONAL-f- EMA/H/C/000071/WS2694/0170/G Pergoveris- EMA/H/C/000714/WS2694/0092/G Merck Europe B.V., Lead Rapporteur: Thalia Marie Estrup Blicher, Quality Variation Request for Supplementary Information adopted on 06.06.2024.	with a specific timetable.
WS2699 Adrovan- EMA/H/C/000759/WS2699/0054 FOSAVANCE- EMA/H/C/000619/WS2699/0057 VANTAVO- EMA/H/C/001180/WS2699/0044 Organon N.V., Lead Rapporteur: Christian Gartner, Quality variation Opinion adopted on 06.06.2024.	Positive Opinion adopted by consensus on 06.06.2024.

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

Spikevax - COVID-19 mRNA vaccine - EMA/H/C/005791/II/0130 Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, "To delete the following presentations (EU/1/20/1507/001; EU/1/20/1507/002; EU/1/20/1507/003; EU/1/20/1507/004; EU/1/20/1507/005; EU/1/20/1507/006; EU/1/20/1507/007; EU/1/20/1507/008; EU/1/20/1507/009; EU/1/20/1507/010) from the Spikevax marketing authorization. The SmPC, Package Leaflet and Labelling section of the Product Information are updated accordingly." Request for Supplementary Information adopted on 13.06.2024. Withdrawal request submitted on 18.06.2024.	The MAH withdrew the procedure on 18.06.2024.
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B.5.10. Information on type II variation / WS procedure with revised timetable

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

B.6.1. Start of procedure for New Applications: timetables for information

L-Acetyllecine - EMA/H/C/006327 is indicated in adults and children from birth for chronic treatment of Niemann-Pick Type C (NPC).

Denosumab - EMEA/H/C/006269,
prevention of skeletal related events with
advanced malignancies

Denosumab - EMEA/H/C/006268
treatment of osteoporosis and bone loss

**Delandistrogene moxeparvovec -
EMEA/H/C/005293, Orphan, ATMP**
Roche Registration GmbH, treatment of
ambulatory patients aged 3 to 7 years old with
Duchenne muscular dystrophy

**Emtricitabine / Tenofovir alafenamide -
EMEA/H/C/006469**
for the treatment of human immunodeficiency
virus type 1 (HIV-1)

**Influenza vaccine (surface antigen,
inactivated, adjuvanted) -
EMEA/H/C/006538**
Prophylaxis of influenza in adults 50 years of
age and older

**Influenza vaccine (surface antigen,
inactivated, prepared in cell cultures) -
EMEA/H/C/006532, Article 28**
Prophylaxis of influenza in adults and children
from 2 years of age.

Sipavibart - EMEA/H/C/006291 **Accelerated review**
indicated for the pre-exposure prophylaxis of
COVID-19 in adults and adolescents 12 years of
age and older

**Bifikafusp alfa / Onfekafusp alfa -
EMEA/H/C/005651**
neoadjuvant treatment of adult patients with
locally advanced fully resectable melanoma.

**Dorocubicel / Allogeneic umbilical cord-
derived CD34- cells, non-expanded -
EMEA/H/C/005772, Orphan, ATMP** **Accelerated review**
Cordex Biologics International Limited,
treatment of adult patients with haematological
malignancies

Zanidatamab - EMEA/H/C/006380, Orphan
Jazz Pharmaceuticals Ireland Limited, Treatment
of biliary tract cancer

B.6.2. Start of procedure for Extension application according to Annex I of Reg. 1234/2008): timetables for information

Adempas - Riociguat -

EMA/H/C/002737/X/0041

Bayer AG, Rapporteur: Patrick Vrijlandt, PRAC
Rapporteur: Kimmo Jaakkola, "Extension application to introduce a new pharmaceutical form associated with a new strength (0.15 mg/ml granules for oral suspension) for the Pulmonary arterial hypertension (PAH) paediatric indication. As a consequence, the film coated tablets presentations are updated to accommodate the new pharmaceutical form. In addition, contact details for local representatives of Belgium, Luxembourg, Greece and Ireland, have also been updated."

Hukyndra - Adalimumab -**EMA/H/C/005548/X/0026**

STADA Arzneimittel AG, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Mari Thorn, "Extension application to add a new strength of 20 mg for adalimumab solution for injection in the pre-filled syringe administered by subcutaneous use."

OPDIVO - Nivolumab -**EMA/H/C/003985/X/0144**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Martin Huber, "Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (600 mg) and a new route of administration (subcutaneous use).
Version 40.0 of the RMP has also been submitted."

REZOLSTA - Darunavir / Cobicistat -**EMA/H/C/002819/X/0054/G**

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli, "Extension application to introduce a new strength (675 mg/150 mg film-coated tablets) grouped with an extension of indication (C.I.6.a) to include, treatment of HIV-1 infected paediatric patients (aged 6 years and older with body weight at least 25 kg) for REZOLSTA, based on the 48-week ad hoc interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicentre, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of cobicistat-boosted darunavir in HIV-1 infected children. As a consequence, sections 1, 2, 3,

4.1,4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.3, 6.5 and 8 of the SmPC and Annex II are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4.”

**Rybrevant - Amivantamab -
EMA/H/C/005454/X/0014**

Janssen-Cilag International N.V., Rapporteur:
Filip Josephson, PRAC Rapporteur: Gabriele Maurer, “Extension application to introduce a new pharmaceutical form (solution for injection), two new strengths of 1600 mg and 2240 mg (160 mg/ml concentration) and a new route of administration (subcutaneous use).”

**Taltz - Ixekizumab -
EMA/H/C/003943/X/0051**

Eli Lilly and Co (Ireland) Limited, Rapporteur:
Kristina Dunder, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Gabriele Maurer, “Extension application to add a new strength of 40 mg for Taltz, Solution for injection”

B.6.3. Restart of procedure - responses received to Day 120 List of Questions timetables: for information

**In vitro diagnostic medical device -
EMA/H/D/006530**

to detect somatic alterations in human DNA and RNA isolated from formalin-fixed, paraffin-embedded (FFPE) solid tumour samples.
Request for Supplementary Information adopted on 30.05.2024.

B.6.4. Annual Re-assessments: timetables for adoption

**EVKEEZA - Evinacumab -
EMA/H/C/005449/S/0018**

Ultragenyx Germany GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Mari Thorn,

B.6.5. Renewals of Marketing Authorisations: timetables for adoption provided only if the validation has been completed

**Azacitidine Accord - Azacitidine -
EMA/H/C/005147/R/0019**

Accord Healthcare S.L.U., Generic of Vidaza, Rapporteur: Hrefna Gudmundsdottir, PRAC

Rapporteur: Bianca Mulder

**Azacitidine Mylan - Azacitidine -
EMA/H/C/004984/R/0019**

Mylan Ireland Limited, Generic of Vidaza,
Rapporteur: Hrefna Gudmundsdottir, PRAC
Rapporteur: Bianca Mulder

**Dexmedetomidine Accord -
Dexmedetomidine -
EMA/H/C/005152/R/0013**

Accord Healthcare S.L.U., Generic of Dexdor,
Rapporteur: John Joseph Borg, PRAC
Rapporteur: Ulla Wändel Liminga

**GIVLAARI - Givosiran -
EMA/H/C/004775/R/0020, Orphan**

Anylam Netherlands B.V., Rapporteur: Patrick
Vrijlandt, Co-Rapporteur: Fátima Ventura, PRAC
Rapporteur: Martin Huber

**Lyumjev - Insulin lispro -
EMA/H/C/005037/R/0019**

Eli Lilly Nederland B.V., Rapporteur: Outi Mäki-
Ikola, Co-Rapporteur: Karin Janssen van Doorn,
PRAC Rapporteur: Mari Thorn

**Nilemdo - Bempedoic acid -
EMA/H/C/004958/R/0042**

Daiichi Sankyo Europe GmbH, Rapporteur:
Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC
Rapporteur: Kimmo Jaakkola

**NUBEQA - Darolutamide -
EMA/H/C/004790/R/0021**

Bayer AG, Rapporteur: Alexandre Moreau, Co-
Rapporteur: Carolina Prieto Fernandez, PRAC
Rapporteur: Jan Neuhauser

**Nustendi - Bempedoic acid / Ezetimibe -
EMA/H/C/004959/R/0047**

Daiichi Sankyo Europe GmbH, Rapporteur:
Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC
Rapporteur: Kimmo Jaakkola

**Ruxience - Rituximab -
EMA/H/C/004696/R/0017**

Pfizer Europe MA EEIG, Rapporteur: Peter Mol,
PRAC Rapporteur: Karin Erneholm

**Rybelsus - Semaglutide -
EMA/H/C/004953/R/0042**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt,
Co-Rapporteur: Thalia Marie Estrup Blicher,

PRAC Rapporteur: Mari Thorn

**Trepulmix - Treprostinil sodium -
EMA/H/C/005207/R/0020, Orphan**

SciPharm Sarl, Rapporteur: Patrick Vrijlandt,
PRAC Rapporteur: Zane Neikena

B.6.6. VARIATIONS – START OF THE PROCEDURE

Timetables for adoption provided that the validation has been completed.

B.6.7. Type II Variations scope of the Variations: Extension of indication

**Abrysvo - Respiratory syncytial virus
vaccine (bivalent, recombinant) -
EMA/H/C/006027/II/0007**

Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Liana Martirosyan, "Extension of indication to include active immunization of individuals 18 through 59 years of age for ABRYSVO, based on final results from C3671023 Substudy A; this is a Phase 3 double-blinded, randomised, placebo-controlled study of safety, tolerability and immunogenicity of Abrysvo in participants ≥ 18 to < 60 years of age at high risk of severe RSV disease due to certain chronic medical conditions. 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 1.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, 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)

**JEMPERLI - Dostarlimab -
EMA/H/C/005204/II/0032**

GlaxoSmithKline (Ireland) Limited, Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre, "Extension of indication for JEMPERLI to include, in combination with carboplatin and paclitaxel, the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy based on Interim Analysis 1 and 2 from study RUBY Part 1 (213361). This is

a phase 3, randomized, double-blind, controlled study evaluating the efficacy and safety of dostarlimab plus carboplatin and paclitaxel in primary advanced or recurrent EC versus placebo plus carboplatin and paclitaxel.

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 4.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC and to align the PI with the latest QRD template version 10.4.”

LUTATHERA - Lutetium (177Lu)

oxodotreotide -

EMA/H/C/004123/II/0052, Orphan

Advanced Accelerator Applications, Rapporteur:

Janet Koenig, PRAC Rapporteur: Adam

Przybylkowski, “Extension of indication to

include the treatment of newly diagnosed, unresectable or metastatic, well-differentiated (G2 and G3), somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) adult patients for LUTATHERA, based on primary analysis results from study CAAA601A22301 (NETTER-2); NETTER-2 study is a Phase III, multicentre, stratified, open-label, randomized, comparator-controlled study comparing treatment with Lutathera plus octreotide LAR 30 mg (Lutathera arm) to treatment with high-dose octreotide LAR 60 mg (control arm). The main purpose of the NETTER-2 study was to determine if treatment in the Lutathera arm prolongs PFS in subjects with newly diagnosed SSTR-positive, G2 and G3 advanced GEP-NET when compared with treatment in the control arm.

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. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes in the SmPC. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.”

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

Ngenla - Somatrogen -

EMA/H/C/005633/II/0016, Orphan

Pfizer Europe MA EEIG, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan, "Extension of indication to include the long-term replacement of endogenous growth hormone of adults with growth hormone deficiency for Ngenla, based on supplemental results from study CP-4-005 and the Phase 2 supportive study CP-4-003. CP-4-005 is a Phase 3, multicentre study designed to evaluate the efficacy and safety of a Long Acting hGH Product (MOD-4023) in adult subjects with Growth Hormone Deficiency. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes."

**REKAMBYs - Rilpivirine -
EMA/H/C/005060/II/0022**

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Liana Martirosyan, "Extension of indication to include in combination with cabotegravir injection, the treatment of adolescents (at least 12 years of age and weighing at least 35 kg) for Rekambys, based on interim results from study 208580 (Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents). This is an ongoing Phase 1/Phase 2 multicentre, open-label, non-comparative study evaluating the safety, acceptability, tolerability, and PK of oral and LA injectable CAB and LA injectable RPV in virologically suppressed HIV-infected adolescents 12 to <18 years of age and weighing at least 35 kg who are receiving stable cART consisting of 2 or more drugs from 2 or more classes of ARV drugs. Consequently, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update a local representative in the Package

Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4"

**Slenyto - Melatonin -
EMA/H/C/004425/II/0028**

RAD Neurim Pharmaceuticals EEC SARL,
Rapporteur: Kristina Dunder, Co-Rapporteur:
Tomas Radimersky, PRAC Rapporteur: Ana Sofia
Diniz Martins, "Extension of indication to include
treatment of insomnia in children and
adolescents aged 2-18 with Attention-Deficit
Hyperactivity Disorder (ADHD), where sleep
hygiene measures have been insufficient, based
on results from phase III study NEU_CH_7911
and literature. As a consequence, sections 4.1
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. "

**Tremfya - Guselkumab -
EMA/H/C/004271/II/0044**

Janssen-Cilag International N.V., Rapporteur:
Beata Maria Jakline Ullrich, PRAC Rapporteur:
Gabriele Maurer, "Extension of indication for
TREMIFYA to include treatment of adult patients
with moderately to severely active Crohn's
disease (CD) who have had an inadequate
response, lost response, or were intolerant to
either conventional therapy or a biologic
treatment, based on results from GALAXI Phase
2/3 program and the GRAVITI Phase 3 study.
GALAXI is a Phase 2/3, randomized, double-
blind, placebo- and active-controlled, parallel-
group, multicentre protocol to evaluate the
efficacy and safety of guselkumab in
participants with moderately to severely active
CD who have demonstrated an inadequate
response or failure to tolerate previous
conventional or biologic therapy. GRAVITI is a
Phase 3, randomized, double-blind, placebo-
controlled, parallel-group, multicentre study to
evaluate the efficacy and safety of guselkumab
SC induction therapy in participants with
moderately to severely active CD.
As a consequence, sections 4.1, 4.2, 4.5, 4.8,
5.1, 5.2, and 5.3 of the SmPC are updated. The
Package Leaflet is updated in accordance.
Version 10.1 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)

Vocabria - Cabotegravir -

EMA/H/C/004976/II/0022

ViiV Healthcare B.V., Rapporteur: Jean-Michel Race, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "Extension of indication to include in combination with rilpivirine injection, the treatment of adolescents (at least 12 years of age and weighing at least 35 kg) for Vocabria, based on interim results from study 208580 (Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents). This is an ongoing Phase 1/Phase 2 multicentre, open-label, non-comparative study evaluating the safety, acceptability, tolerability, and PK of oral and LA injectable CAB and LA injectable RPV in virologically suppressed HIV-infected adolescents 12 to <18 years of age and weighing at least 35 kg who are receiving stable cART consisting of 2 or more drugs from 2 or more classes of ARV drugs. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Vyvgart - Efgartigimod alfa -

EMA/H/C/005849/II/0020, Orphan

Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald, "Extension of indication to include the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) with active disease despite treatment with corticosteroids or immunoglobulins for VYVGART, based on final results from study ARGX-113-1802; this is a pivotal study to investigate the efficacy, safety and tolerability of efgartigimod PH20 SC in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP); and based on interim results from study ARGX-113-1902; this is an

open-label extension study of the ARGX-113-1802 trial to investigate the long-term safety, tolerability and efficacy of efgartigimod PH20 SC in patients with (CIDP).

As a consequence, sections 4.1, 4.2. 4.4, 4.8, 5.1 and 5.2 of the SmPC has been updated. The Package Leaflet has been updated in accordance with the SmPC. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.”

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/II/0016

Hipra Human Health S.L., Co-Rapporteur:
Daniela Philadelphia

IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0104/G

Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus

B.6.9. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

B.6.10. CHMP-PRAC assessed procedures

B.6.11. PRAC assessed procedures

B.6.12. CHMP-CAT assessed procedures

WS2613

Tecartus-

EMEA/H/C/005102/WS2613/0046

Yescarta-

EMEA/H/C/004480/WS2613/0078

Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, Quality variation

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

B.6.15. Unclassified procedures and worksharing procedures of type I variations

WS2688

Corlantor-

EMA/H/C/000598/WS2688/0063

Ivabradine Anpharm-

EMA/H/C/004187/WS2688/0023

Procoralan-

EMA/H/C/000597/WS2688/0062

Les Laboratoires Servier, Lead Rapporteur:

Patrick Vrijlandt

WS2715

M-M-RvaxPro-

EMA/H/C/000604/WS2715/0125

ProQuad-

EMA/H/C/000622/WS2715/0167

Merck Sharp & Dohme B.V., Lead Rapporteur:

Jan Mueller-Berghaus,

WS2725/G

Efficib-

EMA/H/C/000896/WS2725/0115/G

Janumet-

EMA/H/C/000861/WS2725/0113/G

Ristfor-

EMA/H/C/001235/WS2725/0102/G

Velmetia-

EMA/H/C/000862/WS2725/0121/G

Merck Sharp & Dohme B.V., Lead Rapporteur:

Patrick Vrijlandt, Quality variation

WS2728

Blitzima-

EMA/H/C/004723/WS2728/0075

Truxima-

EMA/H/C/004112/WS2728/0078

Celltrion Healthcare Hungary Kft., Lead

Rapporteur: Sol Ruiz, Quality variation

B.7. DOCUMENTS TABLED IN MMD AFTER THE CHMP PLENARY

B.7.1. Yearly Line listing for Type I and II variations

B.7.2. Monthly Line listing for Type I variations

B.7.3. Opinion on Marketing Authorisation transfer (MMD only)

B.7.4. Notifications in accordance with Article 61(3) of Council Directive 2001/83/EC (MMD only)

B.7.5. Request for supplementary information relating to Notification of Type I variation (MMD only)

B.7.6. Notifications of Type I Variations (MMD only)

C. Annex C - Post-Authorisation Measures (PAMs), (Line listing of Post authorisation measures with a description of the PAM. Procedures starting in that given month with assessment timetabled)

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

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

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

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

G. ANNEX G

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

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

G.2. PRIME

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

H. ANNEX H - Product Shared Mailboxes – e-mail address