17 October 2024
EMA/CHMP/503277/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 14-17 October 2024

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

Health and safety information

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

Disclaimers

Some of the information contained in this set of minutes is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, these minutes are a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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

Table of contents

1. Introduction

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

The Chairperson opened the meeting by welcoming all participants. The meeting was held in-person.

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

Participants were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. 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 14-17 October 2024

The CHMP adopted the agenda.

1.3. Adoption of the minutes

No items

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

treatment of alopecia areata in children and adolescents

Scope: Oral explanation

Action: Oral explanation to be held on 15 October 2024 at 14:00

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

12.10.2023.

An oral explanation was held on 15 October 2024. The presentation by the applicant focused on the clinical, non-clinical and quality data in support of the application.

2.1.2. 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: Oral explanation

Action: Oral explanation to be held on 15 October 2024 at 11:00

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

An oral explanation was held on 15 October 2024. The presentation by the applicant focused on the clinical data in support of the application.

See 3.2

2.1.3. Avacincaptad pegol - EMEA/H/C/006153

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

Scope: Oral explanation

Action: Oral explanation to be held on 16 October 2024 at 14:00

Participation of patient representatives.

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

An oral explanation was held on 16 October 2024. The presentation by the applicant focused on the clinical data in support of the application.

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

Orphelia Pharma; treatment of neuroblastoma

Scope: Oral explanation

Action: Oral explanation to be held on 15 October 2024 at 16:00

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

An oral explanation was held on 15 October 2024. The presentation by the applicant focused on the clinical data in support of the application.

2.2. Re-examination procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 16 October 2024 at 11:00

Participation of patient representatives.

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

An oral explanation was held on 16 October 2024. The presentation by the applicant focused on the clinical data in support of the application.

See 3.5

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

PTC Therapeutics International Limited

Scope: Oral explanation

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

Participation of patient representatives.

Opinion adopted on 27.06.2024. Request for Supplementary Information adopted on 25.05.2023.

An oral explanation was held on 16 October 2024. The presentation by the applicant focused on the clinical data in support of the application.

See 9.1

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Absimky - Ustekinumab - EMEA/H/C/006585

Accord Healthcare S.L.U.; treatment of active plaque psoriasis, paediatric plaque psoriasis, psoriatic arthritis (PsA), Crohn's disease and ulcerative colitis.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 27.06.2024.

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

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

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

The summary of opinion was circulated for information.

3.1.2. Alhemo - Concizumab - EMEA/H/C/005938

Novo Nordisk A/S; routine prophylaxis of bleeding in patients with: haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors ≥ 12 years of age; haemophilia B (congenital factor IX deficiency) with FIX inhibitors ≥ 12 years of age

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, 12.10.2023. List of Questions adopted on 25.05.2023.

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 Concizumab 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 16 October 2024.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.3. Buprenorphine Neuraxpharm - Buprenorphine - EMEA/H/C/006188

Neuraxpharm Pharmaceuticals S.L.; treatment of opioid drug dependence

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 21.03.2024, 14.12.2023. List of Questions adopted on 22.06.2023.

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 special and restricted medical prescription.

The summary of opinion was circulated for information.

3.1.4. Eltrombopag Viatris - Eltrombopag - EMEA/H/C/006417

Viatris Limited; treatment of primary immune thrombocytopenia (ITP), thrombocytopenia in adult patients with chronic hepatitis C virus (HCV)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 19.09.2024. List of Questions adopted on 25.04.2024.

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

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

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

The summary of opinion was circulated for information.

3.1.5. Fluad - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/006538

Seqirus Netherlands B.V.; Prophylaxis of influenza in adults 50 years of age and older

Scope: Opinion

Action: For adoption

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

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

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

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

The CHMP noted the letter of recommendations dated 11 October 2024.

The summary of opinion was circulated for information.

3.1.6. Flucelvax - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - Article 28 - EMEA/H/C/006532

Seqirus Netherlands B.V.; Prophylaxis of influenza in adults and children from 2 years of age.

Scope: Opinion

Action: For adoption

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

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

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

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

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

The summary of opinion was circulated for information.

3.1.7. Imuldosa - Ustekinumab - EMEA/H/C/006221

Accord Healthcare S.L.U.; treatment of plaque psoriasis, paediatric plaque psoriasis, psoriatic arthritis (PsA) and Crohn’s disease

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 27.06.2024. 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.

3.1.8. Korjuny - Catumaxomab - EMEA/H/C/005697

Lindis Biotech GmbH; indicated for the treatment of malignant ascites

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024, 09.11.2023. List of Questions adopted on 15.12.2022.

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

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by majority (27 out of 31) together with the CHMP assessment report and translation timetable.The divergent position (Antonio Gomez-Outes, Outi Mäki-Ikola, Peter Mol, Sol Ruiz) was appended to the opinion.

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

The CHMP noted the letter of recommendations dated 18 October 2024.

The summary of opinion was circulated for information.

3.1.9. SIILTIBCY - rdESAT-6 / rCFP-10 - EMEA/H/C/006177

Serum Life Science Europe GmbH; Diagnosis of infection with *Mycobacterium tuberculosis*

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 19.09.2024, 27.06.2024, 21.03.2024. List of Questions adopted on 22.06.2023.

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 rdESAT-6 / rCFP-10 is a new active substance, as claimed by the applicant.

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

The CHMP noted the letter of recommendations dated 11 October 2024.

The summary of opinion was circulated for information.

3.1.10. Wainzua - Eplontersen - Orphan - EMEA/H/C/006295

AstraZeneca AB; treatment of hereditary transthyretin-mediated amyloidosis (ATTRv) in adult patients with stage 1 or stage 2 polyneuropathy.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.07.2024. List of Questions adopted on 22.02.2024.

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

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

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

3.2.1. Acoramidis - Orphan - EMEA/H/C/006333

BridgeBio Europe B.V.; for the treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.05.2024.

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

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

3.2.2. Tiratricol - Orphan - EMEA/H/C/005220

Rare Thyroid Therapeutics International AB; treatment of monocarboxylate transporter 8 (MCT8) deficiency

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.

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

See 2.1

An oral explanation was held on 15 October 2024. The presentation by the applicant focused on the clinical data in support of the application.

The Committee was reminded of the status of this application and its remaining outstanding issuesThe Committee adopted a 2nd list of outstanding issues with a specific timetable.

3.2.4. Ivermectin / Albendazole - Article 58 - EMEA/H/W/005186

prevention and treatment of lymphatic filariasis, and soil-transmitted helminths infections.

Scope: List of outstanding issues; CHMP request for PRAC advice

Action: For adoption

List of Questions adopted on 30.05.2024.

The Committee was reminded of the status of this application and its remaining outstanding issuesThe Committee adopted a list of outstanding issues with a specific timetable.

The CHMP agreed to request advice from the PRAC.

3.2.5. 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 outstanding issues

Action: For adoption

List of Questions adopted on 27.06.2024.

The Committee was reminded of the status of this application and its remaining outstanding issuesThe Committee adopted a list of outstanding issues with a specific timetable.

3.2.6. Linvoseltamab - EMEA/H/C/006370

monotherapy for the treatment of adult patients with relapsed or refractory multiple myeloma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.05.2024.

The Committee was reminded of the status of this application and its remaining outstanding issuesThe CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in October 2024.The Committee adopted a list of outstanding issues with a specific timetable.

3.2.7. Nemolizumab - EMEA/H/C/006149

for the treatment of moderate-to-severe atopic dermatitis and for the treatment of prurigo nodularis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.05.2024.

The Committee was reminded of the status of this application and its remaining outstanding issuesThe Committee adopted a list of outstanding issues with a specific timetable.

3.2.8. Denosumab - EMEA/H/C/006424

treatment of osteoporosis and bone loss

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

The Committee was reminded of the status of this application and its remaining outstanding issuesThe Committee adopted a list of outstanding issues with a specific timetable.

3.2.9. Guanfacine - EMEA/H/C/006312

treatment of ADHD

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.

3.2.10. Pegfilgrastim - PUMA - EMEA/H/C/006348

treatment of neutropenia in paediatric patients

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.05.2024.

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

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

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

3.2.11. Imetelstat - Orphan - EMEA/H/C/006105

Geron Netherlands B.V.; for the treatment of transfusion-dependent anaemia in adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS), for the treatment of transfusion-dependent anaemia in adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS)

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

3.2.12. Tisotumab vedotin - EMEA/H/C/005363

treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.05.2024.

The Committee was reminded of the status of this application and its remaining outstanding issuesThe CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues adopted in October 2024.The Committee adopted a list of outstanding issues with a specific timetable.

3.2.13. Methylphenidate hydrochloride - PUMA - EMEA/H/C/005975

treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years of age

and over

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 08.06.2023.

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.

3.2.14. Beremagene geperpavec - PRIME - Orphan - ATMP - EMEA/H/C/006330

Krystal Biotech Netherlands B.V.; treatment of patients from birth with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 15.03.2024.

The CHMP was updated on discussions at the CAT. The CHMP 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 as adopted by CAT.

3.2.15. Clascoterone - EMEA/H/C/006138

indicated for the topical treatment of acne vulgaris in adults and adolescents

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.

3.2.16. Denosumab - EMEA/H/C/006468

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

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

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

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

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

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

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. Denosumab - EMEA/H/C/006269

prevention of skeletal related events with advanced malignancies

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.3. Denosumab - EMEA/H/C/006268

treatment of osteoporosis and bone loss

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

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

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

Scope: List of questions

Action: For information

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

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

3.3.5. Emtricitabine / Tenofovir alafenamide - EMEA/H/C/006469

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

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

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

neoadjuvant treatment of adult patients with locally advanced fully resectable melanoma

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application

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

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

3.3.7. Chikungunya virus virus-like particle - PRIME - Article 28 - EMEA/H/C/005470

Accelerated assessment

prevention of disease caused by chikungunya (CHIKV) virus

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

Accelerated assessment

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

Scope: List of questions

Action: For information

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

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

3.3.9. Zanidatamab - Orphan - EMEA/H/C/006380

Jazz Pharmaceuticals Ireland Limited; Treatment of biliary tract cancer

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

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

3.4.1. Aflibercept - EMEA/H/C/005899

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

Scope: Letter by the applicant dated 02.10.2024 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in September 2024.

Action: For adoption

List of Outstanding Issues adopted on 19.09.2024. List of Questions adopted on 25.04.2024.

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

3.4.2. 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 dated 27.09.2024 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 to 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.

3.4.3. Aflibercept - EMEA/H/C/006192

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

Scope: Letter by the applicant dated 27.09.2024 requesting an extension to the clock stop to respond to the list of questions adopted in July 2024.

Action: For adoption

List of Questions adopted on 25.07.2024.

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

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

treatment of multiple sclerosis

Scope: Letter by the applicant dated 11.10.2024 requesting an extension to the clock stop to respond to the list of questions adopted in July 2024.

Action: For adoption

List of Questions adopted on 25.07.2024.

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

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

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

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

Scope: Opinion, third-party intervention

Action: For adoption

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

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

An oral explanation was held on 16 October 2024. The presentation by the applicant focused on the clinical data in support of the application.

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.

The CHMP noted the third-party intervention.

See 2.2

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Apremilast Viatris - Apremilast - EMEA/H/C/006193

Viatris Limited; treatment of psoriatic arthritis, psoriasis, Behçet's disease

Scope: Withdrawal of marketing authorisation application

Action: For information

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

List of Outstanding Issues adopted on 25.07.2024. List of Questions adopted on 22.02.2024.

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

3.7.2. Epixram - Levetiracetam - EMEA/H/C/006186

Neuraxpharm Pharmaceuticals S.L.; treatment of partial onset seizures

Scope: Withdrawal of marketing authorisation application

Action: For information

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

List of Outstanding Issues adopted on 25.07.2024. List of Questions adopted on 09.11.2023.

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

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

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

Scope: Withdrawal of marketing authorisation application

Action: For information

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

Re-examination opinion adopted on 19.09.2024. Opinion adopted on 27.06.2024. List of Outstanding Issues adopted on 25.04.2024, 12.10.2023. List of Questions adopted on 25.05.2023.

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

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

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

4.1.1. 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

Scope: Line extension grouped with a strain update and other quality variations.

Action: For adoption

List of Outstanding Issues adopted on 19.09.2024. List of Questions adopted on 27.06.2024.

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

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

The CHMP noted the letter of recommendation dated 18.10.2024.

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

Sanofi B.V.

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

Scope: "Extension application to introduce a new strength (21 mg capsule, hard) grouped with an extension of indication (C.I.6.a) to include treatment of paediatric patients with GD1 who are 6 years and older with a minimum body weight of 15 kg, who are stable on enzyme replacement therapy (ERT), and who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs) or extensive metabolisers (EMs), based on interim results from study EFC13738 (Open label, two cohort (with and without imiglucerase), multicentre study to evaluate pharmacokinetics, safety, and efficacy of eliglustat in paediatric patients with Gaucher disease type 1 and type 3). The above indication is approved for the new strength (21 mg) and the existing strength (84 mg) and 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. In addition, the MAH took this opportunity to introduce editorial changes and to align the product information with the latest version of the QRD guideline. The RMP version 8.3 was agreed during the procedure."

Action: For adoption

List of Outstanding Issues adopted on 25.07.2024. List of Questions adopted on 25.04.2024.

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

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

The summary of opinion was circulated for information.

4.1.3. Hukyndra - Adalimumab - EMEA/H/C/005548/X/0026

STADA Arzneimittel AG

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Mari Thorn

Scope: "Extension application to add a new strength of 20 mg for adalimumab solution for injection in the pre-filled syringe administered by subcutaneous use."

Action: For adoption

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

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

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. Jakavi - Ruxolitinib - EMEA/H/C/002464/X/0070/G

Novartis Europharm Limited

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (5 mg/ml oral solution) and a new route of administration (gastric use), indicated for the treatment of Graft versus host disease (GvHD) in patients aged 28 days or older.
The above line extension is grouped with a type II variation:
- C.I.6.a - To include treatment of paediatric patients aged 28 days to less than 18 years old in acute and chronic Graft versus Host Disease for JAKAVI, based on final results from studies REACH4 (CINC424F12201) and REACH5 (Study CINC424G12201). REACH4 is a Phase I/II open-label, single-arm, multi-centre study of ruxolitinib added to corticosteroids in paediatric patients with grade II-IV acute graft vs. host disease after allogeneic hematopoietic stem cell transplantation; while REACH5 is a Phase II open-label, single-arm, multi-centre study of ruxolitinib added to corticosteroids in paediatric subjects with moderate and severe chronic graft vs. host disease after allogeneic stem cell transplantation (both for oral solution and already approved tablets presentations). 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.
The RMP (version 16) is updated in accordance. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to implement editorial changes to Annex II."

Action: For adoption

List of Questions adopted on 25.04.2024.

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. 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

List of Questions adopted on 27.06.2024.

The Committee discussed the issues identified in this application, relating to quality, product information and RMP 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. Adempas - Riociguat - EMEA/H/C/002737/X/0041

Bayer AG

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Kimmo Jaakkola

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

Action: For adoption

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

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

4.3.2. OPDIVO - Nivolumab - EMEA/H/C/003985/X/0144

Bristol-Myers Squibb Pharma EEIG

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

Scope: "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."

Action: For adoption

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

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

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

Janssen-Cilag International N.V.

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension application to introduce a new strength (675 mg/150 mg film-coated tablets) grouped with an extension of indication (C.I.6.a) to include, treatment of HIV-1 infected paediatric patients (aged 6 years and older with body weight at least 25 kg) for REZOLSTA, based on the 48-week ad hoc interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicentre, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of cobicistat-boosted darunavir in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1,4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.3, 6.5 and 8 of the SmPC and Annex II are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

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.

4.3.4. Rybrevant - Amivantamab - EMEA/H/C/005454/X/0014

Janssen-Cilag International N.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

Scope: "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)."

Action: For adoption

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

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

4.3.5. Taltz - Ixekizumab - EMEA/H/C/003943/X/0051

Eli Lilly and Co (Ireland) Limited

Rapporteur: Kristina Dunder

Scope: "Extension application to add a new strength of 40 mg for Taltz, Solution for injection"

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.

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

GlaxoSmithKline (Ireland) Limited

Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn

Scope: "Extension of indication to include treatment of paediatric patients from 5 years of age with active, autoantibody-positive systemic lupus erythematosus (SLE) for BENLYSTA, based on final results from study 200908; this is a worldwide population pharmacokinetic analysis of subcutaneous administered belimumab plus standard therapy to pediatric patients aged 5-17 years with systematic lupus erythematous (SLE), which was aimed to describe the pharmacokinetic (PK) analysis of belimumab to support an appropriate weight-based dosing regimen for subcutaneous administration in paediatric patients aged 5-17 years with SLE. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 46.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is

brought in line with the latest QRD template version 10.4."

Action: For adoption

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

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

5.1.2. BLINCYTO - Blinatumomab - Orphan - EMEA/H/C/003731/II/0056

Amgen Europe B.V.

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jana Lukacisinova

Scope: "Extension of indication to include treatment as part of consolidation therapy for the treatment of patients with Philadelphia chromosome negative CD19 positive B-cell precursor ALL for BLINCYTO. The proposed indication is supported by efficacy data from Studies E1910, 20120215, and AALL1331, safety data for Studies E1910, 20120215, AALL1331, MT103-202, and MT103-203, and Pharmacokinetic data for Studies 20120215, AALL1331, MT103-202, MT103-203, and 20190360. 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 18.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024.

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.

5.1.3. Bridion - Sugammadex - EMEA/H/C/000885/II/0047

Merck Sharp & Dohme B.V.

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Terhi Lehtinen

Scope: "Extension of indication to include treatment of paediatric patients from birth to less than 2 years of age for Bridion based on final results from paediatric study PN169 (MK-8616-P169); this is a Phase 4 double-blinded, randomized, active comparator-controlled clinical trial to study the efficacy, safety, and pharmacokinetics of sugammadex (MK-8616) for reversal of neuromuscular blockade in paediatric participants aged birth to <2 years. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, to implement minor editorial corrections and to update the information intended for healthcare professionals (HCPs) at the end of the Package Leaflet."

Action: For adoption

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

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

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

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher

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

Type IB (C.I.z): To update section 4.2 of the SmPC for the CellCept 500 mg tablets formulation in order to be in line with the other three CellCept formulations. And for alignment with the current QRD guidance, the Package Leaflet was updated to cross reference section 2 in section 6 for sodium content.

In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and bring the PI in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024, 21.03.2024, 14.09.2023.

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

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

5.1.5. FABHALTA - Iptacopan - Orphan - EMEA/H/C/005764/II/0001

Novartis Europharm Limited

Rapporteur: Janet Koenig, PRAC Rapporteur: Lina Seibokiene

Scope: "Extension of indication to include, in combination with a renin-angiotensin system (RAS) inhibitor, the treatment of adult patients with complement 3 glomerulopathy (C3G) for FABHALTA, based on interim analysis results from study CLNP023B12301 (APPEAR-C3G) and supported by additional evidence of efficacy and safety data from Phase II study CLNP023X2202 (X2202) and Phase IIIb study CLNP023B12001B (C3G-REP). APPEAR-C3G is a Phase 3, multicentre, randomized, double-blind, parallel arm, placebo-controlled study to evaluate the efficacy and safety of iptacopan in patients with C3G. The study included a 6-month blinded, placebo-controlled period, followed by a 6-month period in which all patients receive open-label iptacopan (total study duration of 12 months). As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8 and 5.1 of the SmPC are being updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

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

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

5.1.6. 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, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet has been updated accordingly. Version 4.1 of the RMP has also been adopted. 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 27.06.2024, 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.

5.1.7. Imfinzi - Durvalumab - EMEA/H/C/004771/II/0069

AstraZeneca AB

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy for IMFINZI, based on final results from study D933QC00001 (ADRIATIC); this is a phase III, randomized, double-blind, placebo-controlled, multi-centre, global study to assess the efficacy and safety of durvalumab monotherapy and durvalumab in combination with tremelimumab compared to placebo as consolidation treatment in patients with LS-SCLC whose disease had not progressed following definitive platinum-based chemoradiation therapy (ADRIATIC). 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 12,1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to Annex II. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

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

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

5.1.8. Inaqovi - Decitabine / Cedazuridine - EMEA/H/C/005823/II/0002

Otsuka Pharmaceutical Netherlands B.V.

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

Scope: "Grouped application consisting of:
C.I.6: Extension of indication to include treatment of adult patients with myelodysplastic syndromes (MDS) for INAQOVI.
C.I.6: Extension of indication to include treatment of adult patients with chronic myelomonocytic leukaemia (CMML) for INAQOVI.
Based on final results from studies ASTX727-01, ASTX727-02, ASTX727-04, E7727-01, and E7727-02. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3. As part of the application the MAH is requesting a 1-year extension of the market protection.
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024.

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

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

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

Sanofi Winthrop Industrie

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

Scope: "Extension of indication to include treatment of Polymyalgia Rheumatica (PMR) in adult patients who have had an inadequate response to corticosteroids or who experience a relapse during corticosteroid taper, based on results from study EFC15160; this is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of sarilumab in patients with polymyalgia rheumatica. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.1 of the SmPC are updated. The Package Leaflet and the labelling are updated in accordance. Furthermore, the PI is brought in line with the latest excipients guideline. Version 4.1 of the RMP is also approved. 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 25.07.2024, 21.03.2024.

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

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

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendation dated 09.10.2024.

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

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024.

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.

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

Novartis Europharm Limited

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

Scope: "Extension of indication to include Kisqali in combination with an aromatase inhibitor for the adjuvant treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative early breast cancer at high risk of recurrence. In pre- or perimenopausal women, or in men, the aromatase inhibitor should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. The indication is based on study CLEE011O12301C (NATALEE); This is a global, Phase III, multicentre, randomized, open-label trial to evaluate efficacy and safety of ribociclib with ET versus ET alone as adjuvant treatment in patients with HR-positive, HER2-negative, early breast cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated as well as Annex IID. The Package Leaflet is updated in accordance. Version 8.2 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 25.07.2024, 21.03.2024, 14.12.2023.

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

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

The summary of opinion was circulated for information.

5.1.12. Mounjaro - Tirzepatide - EMEA/H/C/005620/II/0027

Eli Lilly Nederland B.V.

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include, as an adjunct to diet and exercise, the treatment of moderate to severe obstructive sleep apnoea (OSA) in adults with obesity for MOUNJARO based on final results from studies I8F-MC-GPI1 and I8F-MC-GPI2; these are multicentre, randomized, parallel-arm, double-blind, placebo-controlled studies investigating the effects of tirzepatide compared with placebo in adult participants with moderate-to-severe OSA and obesity. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 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.

5.1.13. RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0056

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: "Extension of indication to include treatment of giant cell arteritis (GCA) in adult patients for RINVOQ based on final results from study M16-852. This is a phase 3, global, multicentre, randomized, double-blind, PBO-controlled study evaluating the efficacy and safety of upadacitinib in subjects with GCA. 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 15.0 of the RMP has also been submitted."

Action: For adoption

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

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

5.1.14. RXULTI - Brexpiprazole - EMEA/H/C/003841/II/0015

Otsuka Pharmaceutical Netherlands B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Miroslava Gocova

Scope: "Extension of indication to include treatment of schizophrenia in adolescent patients aged from 13 years to 17 years for RXULTI, based on results from the following clinical studies: one phase 1 dose-escalation trial (Trial 331-10-233) and two phase 3 clinical trials (Trial 331-10-234 and Trial 331-10-236). In addition, a paediatric extrapolation study was completed (Study 331-201-00185). These studies investigated the efficacy and safety of

brexpiprazole in paediatric patients (13-17 years old) with schizophrenia. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, and to bring the PI in line with the latest QRD template version 10.4."

Action: For adoption

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

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

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

Sanofi Winthrop Industrie

Rapporteur: Peter Mol, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Extension of indication to include in combination with bortezomib, lenalidomide, and dexamethasone the treatment of adult patients with newly diagnosed active multiple myeloma who are not eligible for autologous stem cell transplant (ASCT) or with no intent for ASCT as initial therapy for Sarclisa, based on results from EFC12522 (IMROZ) pivotal phase III study and the supportive TCD13983 phase 1b/2 study. EFC12522 is an ongoing prospective, multicentre, international, randomized, open-label, 2-arm parallel group study to assess the clinical benefit of VRd (control group) versus IVRd (active group) for the treatment of participants with NDMM who are not eligible for ASCT. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.7, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024.

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.

5.1.16. Sivextro - Tedizolid phosphate - EMEA/H/C/002846/II/0054

Merck Sharp & Dohme B.V.

Rapporteur: Fatima Ventura, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension of indication to include treatment of paediatric patients aged from birth to less than 12 years for SIVEXTRO, based on final results from studies MK-1986-013, MK-1986-014 and MK-1986-018. MK-1986-013 is a single-dose trial to evaluate pharmacokinetics (PK) and safety of oral and intravenous (IV) administration of tedizolid phosphate in patients from 2 years to <12 years of age; MK-1986-014 is an open-label, multicentre, 2-part, single and multiple dose study to assess the PK of tedizolid phosphate and its active metabolite, tedizolid, and the safety of tedizolid phosphate following single and multiple dose IV and single oral dose. MK-1986-018 is a randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in patients from birth to less than 12 years of age; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.2 and 6.6 of the

SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement minor editorial corrections."

Action: For adoption

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

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

5.1.17. Stelara - Ustekinumab - EMEA/H/C/000958/II/0108

Janssen-Cilag International N.V.

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension of indication to include treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy or have medical contraindications to such therapies for STELARA, based on final results from study CNTO1275CRD3004. This is a Phase 3 Study of the Efficacy, Safety, and Pharmacokinetics of Ustekinumab as Open label Intravenous Induction Treatment Followed by Randomized Double blind Subcutaneous Ustekinumab Maintenance in Paediatric Participants with Moderately to Severely Active Crohn's Disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 29.1 of the RMP has also been submitted."

Action: For adoption

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

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

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

AstraZeneca AB

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy for TAGRISSO as monotherapy, based on results from study D5160C00048 (LAURA); this is a Phase III, randomised, double-blind, placebo-controlled, multicentre international study of osimertinib as maintenance therapy in patients with locally advanced unresectable EGFR mutation-positive non-small cell lung cancer (stage III) whose disease has not progressed following definitive platinum-based chemoradiation therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 17.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024.

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.

5.1.19. Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0003

Beigene Ireland Limited

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

Scope: "Extension of indication to include in combination with platinum-based chemotherapy the first-line treatment of adult patients with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma (OSCC) whose tumours express PD-L1 with a tumour area positivity (TAP) score ≥ 5% for TEVIMBRA, based on results from study BGB-A317-306; this is a multi-regional, randomized, placebo-controlled, double-blind phase 3 study evaluating the efficacy and safety of tislelizumab in combination with chemotherapy compared to placebo in combination with chemotherapy as first-line treatment in patients with unresectable or locally advanced recurrent or metastatic OSCC. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.5 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 19.09.2024, 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.

5.1.20. Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0006

Beigene Ireland Limited

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

Scope: "Extension of indication to include in combination with platinum and fluoropyrimidine-based chemotherapy the first-line treatment of adult patients with human epidermal growth factor receptor-2 (HER-2)-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma whose tumours express PD-L1 with a tumour area positivity (TAP) score ≥ 5% for TEVIMBRA, based on results from the phase 3 study BGB-A317-305 (study 305); this is a global, randomized, double-blind, placebo-controlled study at the approved registrational dosing regimen for Tevimbra (200 mg administered IV Q3W), in combination with platinum and fluoropyrimidine-based chemotherapy, in adult patients with HER-2 negative locally advanced unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are

updated. The Package Leaflet is updated in accordance. Version 2.5 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024.

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

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

The summary of opinion was circulated for information.

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

Roche Registration GmbH

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

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

Action: For adoption

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

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

5.1.22. Yselty - Linzagolix choline - EMEA/H/C/005442/II/0013

Theramex Ireland Limited

Rapporteur: Finbarr Leacy, Co-Rapporteur: Margareta Bego, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include treatment of endometriosis-associated pain in adult women of reproductive age for YSELTY, based on final results from studies Edelweiss 3 (18-OBE2109-003) and Edelweiss 6 (19-OBE2109-006) as well as additional supporting studies. Edelweiss 3 is a pivotal phase 3, randomised, double-blind, placebo-controlled, safety and efficacy study to evaluate linzagolix with add-back therapy as a therapy for pain associated with endometriosis, while Edelweiss 6 is an open-label extension study including patients who completed Edelweiss 3 pivotal study regardless of their previous treatment assignment and met the eligibility criteria. 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 1.1 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year

extension of the market protection."

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

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024, 30.05.2024.

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.

5.1.23. WS2717 OPDIVO - Nivolumab - EMEA/H/C/003985/WS2717/0146 Yervoy - Ipilimumab - EMEA/H/C/002213/WS2717/0115

Bristol-Myers Squibb Pharma EEIG

Lead Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Bianca Mulder

Scope: "A Worksharing application for OPDIVO and YERVOY, as follows:

Extension of indication to include a new indication for OPDIVO in combination with ipilimumab as first line treatment of adult patients with unresectable or advanced hepatocellular carcinoma (HCC) based on study CA2099DW. This is a phase 3 randomised, multi-centre, open label study of Nivolumab in combination with Ipilimumab compared to Sorafenib or Lenvatinib as first-line treatment in participants with advanced HCC. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 41.0 of the RMP has also been submitted.

Extension of indication to include a new indication for YERVOY in combination with ipilimumab as first line treatment of adult patients with unresectable or advanced hepatocellular carcinoma (HCC) based on study CA2099DW. This is a phase 3 randomised, multi-centre, open label study of Nivolumab in combination with Ipilimumab compared to Sorafenib or Lenvatinib as first-line treatment in participants with advanced HCC. 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 44.0 of the RMP has also been submitted."

Action: For adoption

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

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

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

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

Advanced Accelerator Applications

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "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)

Letter by the applicant dated 08.10.2024 requesting an extension to the clock stop to respond to the RSI adopted in September 2024.

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in September 2024.

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

6.1.1. Human albumin solution - EMEA/H/D/006410

vitrification of human MII-phase oocytes and embryos for assisted reproductive technology (ART).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.05.2024.

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

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

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006587

To detect G719X substitution mutations in exon 18, deletion mutations in exon 19, T790M and S768I substitution mutations in exon 20, insertion mutations in exon 20, and L858R and L861Q substitution mutations in exon 21.

Scope: Opinion

Action: For adoption

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

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

6.4. 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

No items

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. FILSPARI - Sparsentan - EMEA/H/C/005783/II/0002, Orphan

Vifor France

Rapporteur: Vilma Petrikaite, PRAC Rapporteur: Martin Huber

Scope: "Update of sections 4.8, and 5.1 of the SmPC in order to amend the frequency of the adverse drug reactions (ADRs) based on final results from study 021IGAN17001 (PROTECT) listed as a specific obligation in the Annex II; this is a randomized, multicentre, double-blind parallel-group, active control study of the efficacy and safety of sparsentan for the treatment of immunoglobulin A nephropathy. The Package Leaflet is updated accordingly. The RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II and to bring the PI in line with the latest QRD template version 10.4. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation."

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

Infai GmbH

Rapporteur: Christian Gartner

Scope: "Update of sections 4.2, 4.3 and 5.1 of the SmPC in order to modify administration instructions and to add a new contraindication based on final results from study HPT30/J/17; this is a single-group, observer-blind, multi-centre study to quantify the sensitivity and specificity of the 13C-UBT using the new test meal for Hp in patients with dyspepsia and GERD taking PPI. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 6.6 of the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024.

The Committee discussed the issues identified in this application.

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

9.1.3. Memantine LEK (SRD) – Memantine hydrochloride – EMEA/H/C/002630

Pharmathen S.A.; treatment of Alzheimer's disease

Rapporteur: Janet Koenig

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

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

PTC Therapeutics International Limited

Scope: Opinion, third-party interventions

Action: For adoption

Opinion adopted on 27.06.2024. Request for Supplementary Information adopted on 25.05.2023.

An oral explanation was held on 16 October 2024. The presentation by the applicant focused on the clinical data in support of the application.

The Committee adopted a negative opinion by consensus recommending not to renew the conditional marketing authorisation. The CHMP assessment report was adopted.

The CHMP noted the third-party interventions.

The CHMP noted the public health communication.

See 2.2

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

Orexigen Therapeutics Ireland Limited

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

Questions to AHEG and re-examination timetable.

Action: For adoption

Opinion adopted on 25.07.2024. Request for Supplementary Information adopted on 16.05.2024, 09.02.2024, 31.08.2023.

The CHMP endorsed the AHEG questions and adopted the re-examination timetable.

9.1.6. Mimpara – Cinacalcet – EMEA/H/C/000570

Amgen Europe B.V.

Rapporteur: Kristina Dunder, Co-Rapporteur: Christian Gartner

Action: For information

The CHMP noted the information.

9.1.7. Kisqali - Ribociclib - EMEA/H/C/004213/II/0054/G

Novartis Europharm Limited

Rapporteur: Filip JosephsonScope: Quality variation, DHPC and communication plan

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024.

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

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

9.1.8. Pegasys - Peginterferon alfa-2a – EMEA/H/C/000395

Pharmaand GmbH

Rapporteur: Filip Josephson, Co-Rapporteur: Antonio Gomez-Outes

Scope: DHPC

Action: For adoption

The CHMP adopted the DHPC.

10. Referral procedures

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

No items

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

No items

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

No items

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

No items

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

No items

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

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

MAH various (NAPs only)

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

Scope: List of outstanding issues

Action: For adoption

Need to re-evaluate the benefit-risk ratio of the approved indications considering the current scientific knowledge, the increasing resistance rate, the consumption data suggesting overuse and the different indications in the EU Member States. Furthermore, the appropriate dose and duration of administration for both oral and intravenous formulations need to be discussed as well as the adequacy of safety relevant information, information on pregnancy and breastfeeding and pharmacological properties.
The German National Competent Authority triggered a referral under Article 31 of Directive

2001/83 based on interest of the Union, requesting an opinion to CHMP on the benefit-risk of azithromycin-containing products and whether marketing authorisations of azithromycin-containing products for systemic use should be maintained, varied, suspended, or revoked.

List of outstanding issues adopted on 25.04.2024.

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

CHMP list of outstanding issues: October 2024 CHMP

Submission of responses: 09 January 2025

Re-start of the procedure: 30 January 2025

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 06 February 2025

Comments: 13 February 2025

Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 19 February 2025

CHMP list of outstanding issues / CHMP opinion: February 2025 CHMP

10.7. Re-examination Procedure under Article 32(4) of Directive 2001/83/EC

No items

10.8. Procedure under Article 107(2) of Directive 2001/83/EC

No items

10.9. Disagreement between Member States on Type II variation– Arbitration procedure initiated by MAH under Article 6(13) of Commission Regulation (EC) No 1084/2003

No items

10.10. Procedure under Article 29 of Regulation (EC) 1901/2006

No items

10.11. Referral under Article 13 Disagreement between Member States on Type II variation– Arbitration procedure initiated by Member State under Article 13 (EC) of Commission Regulation No 1234/2008

No items

11. Pharmacovigilance issue

11.1. Early Notification System

October 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. Election of CHMP Vice-Chairperson

Action: For adoption

The mandate of the CHMP Vice-Chair, Bruno Sepodes, will expire on 19 October 2024.

The election of the new vice-chair took place in accordance with the CHMP rules of procedure.

The nominations received were presented to the Committee. The CHMP elected Outi Mäki-Ikola as CHMP Vice-Chair for a three-year mandate starting on 18 October 2024. The CHMP and the Agency congratulated Outi Mäki-Ikola on her election and wished her all the best in her new role as Vice-Chair of the Committee.

14.1.2. Vote by proxy

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

Simona Badoi (RO) gave a proxy to Carla Torre (Co-opted member) for the entire duration of the meeting.

Robert Porszasz (HU) gave a proxy to Outi Mäki-Ikola (FI) for the entire duration of the meeting.

Janet Koenig (DE) gave a proxy to Jan Mueller-Berghaus (Co-opted member) for the entire duration of the meeting.

14.1.3. CHMP membership

The Chair welcomed Boje Kvorning Pires Ehmsen, as the new alternate for Denmark.

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 October 2024.

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at October 2024 PDCO

Action: For information

Agenda for the PDCO meeting held on 15-18 October 2024

Action: For information

The CHMP noted the information.

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Reports from the BWP meeting for CHMP adoption.

Action: For adoption

The CHMP adopted the reports.

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meetings held on 24-25 September 2024 and 09 October 2024.

Action: For adoption

The CHMP adopted the table of decisions.

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 30 September - 03 October 2024. Table of conclusions

Action: For information

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

The CHMP noted the update.

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

14.6. Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

14.9.1. CHMP Learnings

CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

Action: For information

The CHMP noted the information.

14.9.2. CHMP Revamp

CHMP adoption of the new Revamp Overview template.

CHMP: Daniela Philadelphy

Action: For adoption

The CHMP adopted the new Revamp Overview template.

15. Any other business

15.1. AOB topic

15.1.1. Health Threats and ETF Update

Action: For information

The CHMP noted the update.

15.1.2. GIREX rules

Clock-stop extensions and feedback from GIREX

Action: For information

The CHMP noted the information and supported the end of the transition period in December 2024.

15.1.3. CHMP meetings in Teams and new tool for voting

Training and next steps.

Action: For discussion

The CHMP discussed the new tools and transition to the new systems.

15.1.4. IRIS training plan

Action: For discussion

The CHMP discussed the training plan.

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 14-17 October 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
Bruno Sepodes	Chair	Portugal	No interests declared	
Daniela Philadelphy	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
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	
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	
Janet Koenig	Member	Germany	No interests declared	
Martin Mengel	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	
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	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martine Trauffler	Member	Luxembourg	No interests declared	
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	
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	
Andreja Kranjc	Alternate	Slovenia	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	
Umberto Casalegno	Expert	France	No interests declared	
Anissa Benlazar	Expert	France	No interests declared	
Laura Andreoli	Expert	France	No interests declared	
Nicolas Beix	Expert	France	No interests declared	
Sandra Bright	Expert	Ireland	No interests declared	
Sinead Harrington	Expert	Ireland	No interests declared	
Liam McDonough	Expert	Ireland	No interests declared	
Elma O'Reilly	Expert	Ireland	No interests declared	
Joseph De Courcey	Expert	Ireland	No interests declared	
Melanie Ramberger	Expert	Austria	No interests declared	
Lisa Nika	Expert	Austria	No participation in final deliberations and voting on:	4.3.1. Adempas - Riociguat - EMEA/H/C/002737/X/0041
Angelika Geroldinger	Expert	Austria	No interests declared	
Elisabeth Fuerst	Expert	Austria	No interests declared	
Mirjam Hinterleitner	Expert	Austria	No interests declared	
Silke Dorner	Expert	Austria	No interests declared	
Christine Vaculik	Expert	Austria	No interests declared	
Karin Erika Svedlund	Expert	Sweden	No interests declared	
Sandra Holt	Expert	Sweden	No interests declared	
Maria Grünewald	Expert	Sweden	No interests declared	
Adam Strömstedt	Expert	Sweden	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Knut Almgren	Expert	Sweden	No interests declared	
Charlotta Löfberg	Expert	Sweden	No restrictions applicable to this meeting	
Maja Lusina Kregar	Expert	Croatia	No restrictions applicable to this meeting	
Ivona Jukić	Expert	Croatia	No interests declared	
Danica Juričić Nahal	Expert	Croatia	No interests declared	
Tihana Šlezak	Expert	Croatia	No interests declared	
Tereza Bažantová	Expert	Czech Republic	No interests declared	
Pavla Zemanová	Expert	Czech Republic	No interests declared	
Anna Kubandová	Expert	Slovakia	No interests declared	
Jana Schweigertová	Expert	Slovakia	No interests declared	
Alicia Perez Gonzalez	Expert	Spain	No interests declared	
Mario Coelho da Silva Rosa	Expert	Portugal	No interests declared	
Irene Nowotny	Expert	Germany	No interests declared	
Robert Pollmann	Expert	Germany	No interests declared	
Katja Findeisen	Expert	Germany	No restrictions applicable to this meeting	
Julia Katharina Maier	Expert	Germany	No interests declared	
Clara Dingert	Expert	Germany	No restrictions applicable to this meeting	
Ute Friedel	Expert	Germany	No participation in final deliberations and voting on:	4.3.5. Taltz - Ixekizumab - EMEA/H/C/003943 /X/0051 5.1.12. Mounjaro - Tirzepatide - EMEA/H/C/005620 /II/0027
Susanne Müller-Egert	Expert	Germany	No interests declared	
Frank Holtkamp	Expert	Netherlands	No interests declared	
Adrian Post	Expert	Netherlands	No interests declared	
Cristina Migali	Expert	Italy	No interests declared	
Antonella Isgrò	Expert	Italy	No interests declared	
Irene Bachmann	Expert	Germany	No interests declared	
Gabriele Schlosser-Weber	Expert	Germany	No interests declared	
Clemens Mittmann	Expert	Germany	No interests declared	
Miriam Fürst-Wilmes	Expert	Germany	No interests declared	
Bruna Dekic	Expert	Germany	No interests declared	
Susanna Hausmann	Expert	Germany	No interests declared	
Franziska Brandt	Expert	Germany	No interests declared	
Ellen Pantke	Expert	Germany	No restrictions applicable to this meeting	
Anne Isabel Roth	Expert	Germany	No interests declared	
Jörg Zinserling	Expert	Germany	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dina Apele-Freimane	Expert	Latvia	No restrictions applicable to this meeting	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Ole Weis Bjerrum	Expert	Denmark	No interests declared	
Gabriella Passacquale	Expert	Italy	No interests declared	
Elina Rönnemaa	Expert	Sweden	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Viktoriia Starokozhko	Expert	Netherlands	No restrictions applicable to this meeting	
Kinga Nowicka-Matus	Expert	Denmark	No interests declared	
Hendrik Harms	Expert	Germany	No interests declared	
Carmen Purdel	Expert	Romania	No interests declared	
Fabienne Gaugaz	Expert	Sweden	No interests declared	
Francesco Nonino	Expert	Italy	No interests declared	
Violaine Closson Carella	Expert	France	No interests declared	
Celine Jumeau	Expert	France	No interests declared	
Lena Edström	Expert	Sweden	No interests declared	
Katrien Oude Rengerink	Expert	Netherlands	No interests declared	
Valeria Di Muzio	Expert	Italy	No interests declared	
Barbara Stommel	Expert	Germany	No interests declared	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Christoph Furtmann	Expert	Germany	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Beatriz Gutiérrez Eugenio	Expert	Spain	No interests declared	
Velma Capote	Expert	WHO	No interests declared	
Bramuel Tongola	Expert	WHO	No interests declared	
Nelson Otieno	Expert	WHO	No interests declared	
Tigist Dires	Expert	WHO	No interests declared	
A representative from the European Commission attended the meeting.				
Meeting run with the help of EMA staff.				

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

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

Explanatory notes

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

Oral explanations *(section 2)*

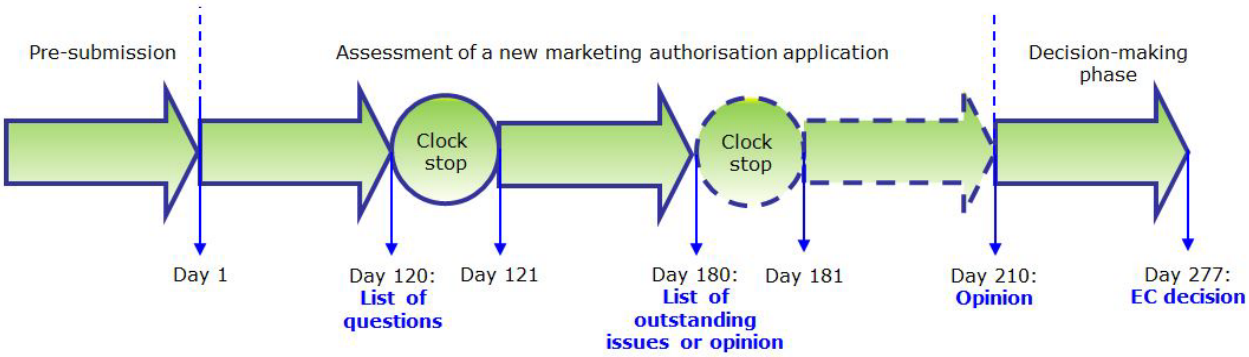
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

Extensions of marketing authorisations are applications for the change or addition of new strengths,

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 October 2024
EMA/CHMP/488404/2024

Annex to 14-17 October 2024 CHMP Minutes

Pre-submission and post-authorisations issues

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

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for October 2024: **For adoption**	Adopted

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

Final Outcome of Rapporteurship allocation for October 2024: **For adoption**	Adopted

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

MVABEA - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343/S/0022 Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances.
Qarziba - Dinutuximab beta - EMEA/H/C/003918/S/0063, Orphan Recordati Netherlands B.V., Rapporteur: Peter Mol, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances.
Zabdeno - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337/S/0020 Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. 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

Arsenic trioxide Mylan - Arsenic trioxide - EMEA/H/C/005235/R/0012 Mylan Ireland Limited, Generic of TRISENOX, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Tiphaine Vaillant Request for Supplementary Information adopted on 17.10.2024.	Request for supplementary information adopted with a specific timetable.
Azacitidine betapharm - Azacitidine - EMEA/H/C/005075/R/0020 betapharm Arzneimittel GmbH, Generic of Vidaza, Rapporteur: Petr Vrbata, 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.
Cinacalcet Accordpharma - Cinacalcet - EMEA/H/C/005236/R/0013 Accord Healthcare S.L.U., Generic of Mimpara, Rapporteur: Christian Gartner, PRAC Rapporteur: Mari Thorn	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.
Fetcroja - Cefiderocol - EMEA/H/C/004829/R/0022 Shionogi B.V., Rapporteur: Filip Josephson, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 17.10.2024.	Request for supplementary information adopted with a specific timetable.
Fluad Tetra - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/R/0055 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné	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.
GoResp Digihaler - Budesonide / Formoterol fumarate dihydrate - EMEA/H/C/004882/R/0016 Teva Pharma B.V., Duplicate of DuoResp Spiromax, Rapporteur: John Joseph Borg, Co-	Request for supplementary information adopted with a specific timetable.

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Marie Louise Schougaard Christiansen Request for Supplementary Information adopted on 17.10.2024.	
Tigecycline Accord - Tigecycline - EMEA/H/C/005114/R/0007 Accord Healthcare S.L.U., Generic of Tygacil, Rapporteur: Daniela Philadelphy, 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.
Trepulmix - Treprostinil sodium - EMEA/H/C/005207/R/0020, Orphan SciPharm Sarl, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Zane Neikena Request for Supplementary Information adopted on 19.09.2024.	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.
Vaxchora - Cholera vaccine, oral, live - EMEA/H/C/003876/R/0024 Bavarian Nordic A/S, Rapporteur: Ingrid Wang, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Jean-Michel Dogné Request for Supplementary Information adopted on 17.10.2024.	Request for supplementary information adopted with a specific timetable.

B.2.3. Renewals of Conditional Marketing Authorisations

Casgevy - Exagamglogene autotemcel - EMEA/H/C/005763/R/0006, Orphan, ATMP Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Heli Suila, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder Request for Supplementary Information adopted on 11.10.2024.	Request for supplementary information adopted with a specific timetable.
Hemgenix - Etranacogene dezaparvovec - EMEA/H/C/004827/R/0020, Orphan, ATMP CSL Behring GmbH, Rapporteur: Silke Dorner, Co-Rapporteur: Heli Suila, CHMP Coordinator: Daniela Philadelphy, PRAC Rapporteur: Bianca Mulder	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.
Retsevmo - Selpercatinib - EMEA/H/C/005375/R/0035 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Bianca Mulder Request for Supplementary Information adopted on 17.10.2024.	Request for supplementary information adopted with a specific timetable.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection PRAC recommendations on signals adopted at the PRAC meeting held on 30 September - 03 October 2024 PRAC:	
PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its October 2024 meeting:	
EMEA/H/C/PSUSA/00000071/202402 (agomelatine) CAPS: **Valdoxan** (EMEA/H/C/000915) (Agomelatine), Les Laboratoires Servier, Rapporteur: Eva Skovlund, PRAC Rapporteur: Pernille Harg, "20/02/2021 To: 19/02/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of Annex II.D to delete the additional risk minimisation measures regarding hepatotoxicity risk and interactions with potent CYP1A2 inhibitors. In addition, the MAH took the opportunity to align the Product Information to the QRD template 10.4 including deletion of the Northern Ireland local representative in the Package Leaflet.

EMEA/H/C/PSUSA/00000107/202403 (epcoritamab) CAPS: **Tepkinly** (EMEA/H/C/005985) (Epcoritamab), AbbVie Deutschland GmbH & Co. KG, Rapporteur: Peter Mol, PRAC Rapporteur: Monica Martinez Redondo, "22/09/2023 To: 21/03/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to add a warning regarding PML, an update of the information regarding ICANs in sections 4.4, 4.7 and inclusion of the frequency for ICANs grade ≥ 3 in section 4.8 of the SmPC. The PL has been updated accordingly.
EMEA/H/C/PSUSA/00000116/202403 (cabotegravir (for pre-exposure prophylaxis of HIV-1 infection)) CAPS: **Apretude** (EMEA/H/C/005756) (Cabotegravir), ViiV Healthcare B.V., Rapporteur: Fátima Ventura, PRAC Rapporteur: Martin Huber, "18/09/2023 To: 17/03/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section(s) 4.4 and 4.8 of the SmPC to add the adverse reaction Stevens-Johnsons Syndrome/Toxic Epidermal Necrolysis (SJS/TEN) with a frequency very rare and a warning/precaution regarding Severe Cutaneous Adverse Reactions (SCARs). The Package leaflet is updated accordingly. Update of section(s) 4.8 of the SmPC to add the adverse reaction gait disturbance with a frequency rare. The Package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00000232/202403 (gadopiclenol) CAPS: **Elucirem** (EMEA/H/C/005626) (Gadopiclenol), Guerbet, Rapporteur: Patrick Vrijlandt **Vueway** (EMEA/H/C/006172) (Gadopiclenol), Bracco Imaging S.p.A., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "21/09/2023 To: 20/03/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to add a warning/precaution regarding intrathecal administration of gadopiclenol. Update of section 4.6 of the SmPC to amend the statements regarding data from use of gadopiclenol in pregnant women and anticipated effects on the infant. The Package leaflet should be updated accordingly.
EMEA/H/C/PSUSA/00000787/202402 (cladribine (apart from products with multiple sclerosis indication)) CAPS: **Litak** (EMEA/H/C/000504) (Cladribine), Lipomed GmbH, Rapporteur: Thalia Marie Estrup Blicher NAPS: **NAPs** - EU PRAC Rapporteur: Marie Louise Schougaard Christiansen, "25/02/2021 To: 25/02/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.6 of the SmPC to amend the wording regarding breastfeeding. No update of the Package leaflet is considered warranted as the current information is considered sufficient.

EMEA/H/C/PSUSA/00002330/202402 (pemetrexed) CAPS: **Alimta** (EMEA/H/C/000564) (Pemetrexed), Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau **Armisarte** (EMEA/H/C/004109) (Pemetrexed), Actavis Group PTC ehf., Rapporteur: Alar Irs **Pemetrexed Accord** (EMEA/H/C/004072) (Pemetrexed), Accord Healthcare S.L.U., Rapporteur: John Joseph Borg **Pemetrexed Fresenius Kabi** (EMEA/H/C/003895) (Pemetrexed), Fresenius Kabi Deutschland GmbH, Rapporteur: Eva Skovlund NAPS: **NAPs** - EU PRAC Rapporteur: Tiphaine Vaillant, "05/02/2021 To: 04/02/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.5 of the SmPC to add an interaction between proton pump inhibitors and pemetrexed. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00002654/202401 (rivastigmine) CAPS: **Exelon** (EMEA/H/C/000169) (Rivastigmine), Novartis Europharm Limited, Rapporteur: Alexandre Moreau **Prometax** (EMEA/H/C/000255) (Rivastigmine), Almirall S.A., Rapporteur: Alexandre Moreau **Rivastigmine 1A Pharma** (EMEA/H/C/001181) (Rivastigmine), 1 A Pharma GmbH, Rapporteur: Alexandre Moreau **Rivastigmine HEXAL** (EMEA/H/C/001182) (Rivastigmine), Hexal AG, Rapporteur: Alexandre Moreau **Rivastigmine Sandoz** (EMEA/H/C/001183) (Rivastigmine), Sandoz GmbH, Rapporteur: Alexandre Moreau NAPS: **NAPs** - EU PRAC Rapporteur: Tiphaine Vaillant, "01/02/2019 To: 31/01/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reaction Pleurothotonus (Pisa syndrome) with a frequency "not known" under the SOC Nervous system disorders. The Package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00002799/202401 (sugammadex) CAPS: **Bridion** (EMEA/H/C/000885) (Sugammadex), Merck Sharp & Dohme B.V., Rapporteur: Outi Mäki-Ikola NAPS: **NAPs** - EU PRAC Rapporteur: Terhi Lehtinen, "31/01/2019 To: 31/01/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.8 of the SmPC to add information on hypersensitivity reactions for sugammadex-rocuronium complex.
EMEA/H/C/PSUSA/00010825/202403 (esketamine (for centrally authorised product only)) CAPS: **Spravato** (EMEA/H/C/004535) (Esketamine), Janssen-Cilag International N.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Terhi Lehtinen, "05/03/2023 To: 04/03/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reaction bradycardia with a frequency uncommon and the adverse reaction seizure with a frequency rare. The package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00010900/202403 (cabotegravir (for treatment of human immunodeficiency virus type 1 (HIV-1)) CAPS: **Vocabria** (EMEA/H/C/004976) (Cabotegravir), ViiV Healthcare B.V., Rapporteur: Jean-Michel Race, PRAC Rapporteur: Martin Huber, "18/03/2023 To: 17/03/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of sections 4.4 and 4.8 of the SmPC to add the severe cutaneous adverse reactions Stevens-Johnson syndrome/ Toxic epidermal necrolysis (SJS/TEN) with a frequency very rare and a warning/precaution regarding severe cutaneous adverse reactions. The Package leaflet is updated accordingly. Update of section 4.8 of the SmPC to add the adverse reaction gait disturbance with a frequency rare. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010969/202402 (lonapegsomatropin) CAPS: **Skytrofa** (EMEA/H/C/005367) (Lonapegsomatropin), Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "26/08/2023 To: 25/02/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to add a warning/precaution regarding the risk of osteonecrosis. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00011018/202403 (nivolumab / relatlimab) CAPS: **Opdualag** (EMEA/H/C/005481) (Nivolumab / Relatlimab), Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, "18/09/2023 To: 17/03/2024"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reactions Serositis and Pleural effusion. The Package leaflet is updated accordingly.

B.4. EPARs / WPARs

Afqlir - Aflibercept - EMEA/H/C/006150 Sandoz GmbH, 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),, 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.
ELAHERE - Mirvetuximab soravtansine - EMEA/H/C/005036, Orphan AbbVie Deutschland GmbH & Co. KG, treatment of ovarian, fallopian tube, or primary peritoneal cancer, 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.
HETRONIFLY - Serplulimab - EMEA/H/C/006170, Orphan Henlius Europe GmbH, first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC), 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.
Hympavzi - Marstacimab - EMEA/H/C/006240, Orphan Pfizer Europe Ma EEIG, indicated for routine prophylaxis of bleeding episodes in patients with haemophilia A or 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.
Opuviz - Aflibercept - EMEA/H/C/006056 Samsung Bioepis NL B.V., treatment of age-related macular degeneration (AMD) and visual impairment, 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.
Penbraya - Meningococcal group A, B, C, W and Y vaccine - EMEA/H/C/006165 Pfizer Europe MA EEIG, indicated for active immunisation to prevent invasive disease caused by Neisseria meningitidis groups A, B, C, W, and Y, 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.
Pomalidomide Teva - Pomalidomide - EMEA/H/C/006302 Teva GmbH, in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM), Generic, Generic of	For information only. Comments can be sent to the PL in casie necessary.

Imnovid, , Generic application (Article 10(1) of Directive No 2001/83/EC)	
Ranibizumab Midas – Ranibizumab - EMEA/H/C/006528 MIDAS Pharma GmbH, treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to diabetic macular oedema (DME), proliferative diabetic retinopathy (PDR), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to choroidal neovascularisation (CNV), 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.
Theralugand - Lutetium (177Lu) chloride - EMEA/H/C/005882 Eckert & Ziegler Radiopharma GmbH, radiolabelling of carrier molecules, which have been specifically developed for radiolabelling with this radionuclide, 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.

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

Apidra - Insulin glulisine - EMEA/H/C/000557/II/0095 Sanofi-Aventis Deutschland GmbH, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 17.10.2024.	Positive Opinion adopted by consensus on 17.10.2024.
Azacitidine betapharm - Azacitidine - EMEA/H/C/005075/II/0015 betapharm Arzneimittel GmbH, Generic of Vidaza, Rapporteur: Petr Vrbata Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 15.06.2023.	Positive Opinion adopted by consensus on 17.10.2024.
Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0026/G Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 03.10.2024.	Positive Opinion adopted by consensus on 03.10.2024.
Briumvi - Ublituximab - EMEA/H/C/005914/II/0017/G	Request for supplementary information adopted with a specific timetable.

Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra Request for Supplementary Information adopted on 10.10.2024.	
Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan - Efavirenz / Emtricitabine / Tenofovir disoproxil - EMA/VR/0000225000 Mylan Pharmaceuticals Limited, Rapporteur: Fátima Ventura Request for Supplementary Information adopted on 17.10.2024.	Request for supplementary information adopted with a specific timetable.
Emtricitabine/Tenofovir disoproxil Mylan - Emtricitabine / Tenofovir disoproxil - EMA/VR/0000223057 Mylan Pharmaceuticals Limited, Rapporteur: Vilma Petrikaite Request for Supplementary Information adopted on 03.10.2024.	Request for supplementary information adopted with a specific timetable.
Empliciti - Elotuzumab - EMEA/H/C/003967/II/0040/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol Opinion adopted on 10.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 10.10.2024.
Eylea - Aflibercept - EMEA/H/C/002392/II/0093 Bayer AG, Rapporteur: Jean-Michel Race Opinion adopted on 03.10.2024.	Positive Opinion adopted by consensus on 03.10.2024.
Gardasil - Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed) - EMEA/H/C/000703/II/0107/G Merck Sharp & Dohme B.V., Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 10.10.2024.	Request for supplementary information adopted with a specific timetable.
HyQvia - Human normal immunoglobulin - EMEA/H/C/002491/II/0101 Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 10.10.2024.	Request for supplementary information adopted with a specific timetable.
Imfinzi - Durvalumab - EMEA/H/C/004771/II/0067/G AstraZeneca AB, Rapporteur: Thalia Marie Estrup Blicher	Positive Opinion adopted by consensus on 17.10.2024.

Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 25.07.2024.	
IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0106 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 26.09.2024.	Request for supplementary information adopted with a specific timetable.
Insulin aspart Sanofi - Insulin aspart - EMEA/H/C/005033/II/0018/G Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt Opinion adopted on 17.10.2024.	Positive Opinion adopted by consensus on 17.10.2024.
Insulin lispro Sanofi - Insulin lispro - EMEA/H/C/004303/II/0021 Sanofi Winthrop Industrie, Rapporteur: Outi Mäki-Ikola Opinion adopted on 17.10.2024.	Positive Opinion adopted by consensus on 17.10.2024.
Insuman - Insulin human - EMEA/H/C/000201/II/0152/G Sanofi-Aventis Deutschland GmbH, Rapporteur: Karin Janssen van Doorn Opinion adopted on 17.10.2024.	Positive Opinion adopted by consensus on 17.10.2024.
Kauliv - Teriparatide - EMEA/H/C/004932/II/0004 Strides Pharma (Cyprus) Limited, Rapporteur: Janet Koenig Opinion adopted on 26.09.2024.	Positive Opinion adopted by consensus on 26.09.2024.
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0155 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini Opinion adopted on 10.10.2024. Request for Supplementary Information adopted on 04.07.2024.	Positive Opinion adopted by consensus on 10.10.2024.
KIMMTRAK - Tebentafusp - EMEA/H/C/004929/II/0007, Orphan Immunocore Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 17.10.2024.	Positive Opinion adopted by consensus on 17.10.2024.
Kisqali - Ribociclib - EMEA/H/C/004213/II/0054/G Novartis Europharm Limited, Rapporteur: Filip Josephson	Positive Opinion adopted by consensus on 17.10.2024. See 9.1

Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 19.09.2024.	
Menveo - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/001095/II/0122/G GSK Vaccines S.r.l, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 03.10.2024.	Request for supplementary information adopted with a specific timetable.
NexoBrid - Concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0069 MediWound Germany GmbH, Rapporteur: Janet Koenig Opinion adopted on 10.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 10.10.2024.
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0071/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt Opinion adopted on 07.10.2024. Request for Supplementary Information adopted on 05.09.2024, 11.07.2024.	Positive opinion adopted by consensus on 07.10.2024. See PROM minutes
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0078 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt Opinion adopted on 07.10.2024. Request for Supplementary Information adopted on 19.09.2024.	Positive Opinion adopted by consensus on 07.10.2024. See PROM minutes
Ogivri - Trastuzumab - EMEA/H/C/004916/II/0063 Biosimilar Collaborations Ireland Limited, Rapporteur: Karin Janssen van Doorn Opinion adopted on 03.10.2024.	Positive Opinion adopted by consensus on 03.10.2024.
Pergoveris - Follitropin alfa / Lutropin alfa - EMEA/H/C/000714/II/0095/G Merck Europe B.V., Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 03.10.2024.	Request for supplementary information adopted with a specific timetable.
Pombiliti - Cipaglucosidase alfa - EMEA/H/C/005703/II/0015 Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 10.10.2024.	
Praluent - Alirocumab - EMEA/H/C/003882/II/0091/G Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 18.07.2024.	Positive Opinion adopted by consensus on 17.10.2024.
PREVYMIS - Letermovir - EMEA/H/C/004536/II/0036, Orphan Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson Opinion adopted on 26.09.2024. Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.	Positive Opinion adopted by consensus on 26.09.2024.
Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0209 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 10.10.2024.	Positive Opinion adopted by consensus on 10.10.2024.
Puregon - Follitropin beta - EMA/VR/0000224916 Organon N.V., Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 17.10.2024.	Request for supplementary information adopted with a specific timetable.
Ryeqo - Relugolix / Estradiol / Norethisterone acetate - EMEA/H/C/005267/II/0025 Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 17.10.2024.
Semglee - Insulin glargine - EMEA/H/C/004280/II/0050 Biosimilar Collaborations Ireland Limited, Rapporteur: Janet Koenig Request for Supplementary Information adopted on 10.10.2024, 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Silapo - Epoetin zeta - EMEA/H/C/000760/II/0074 STADA Arzneimittel AG, Rapporteur: Janet Koenig Opinion adopted on 10.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 10.10.2024.

Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0132/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 03.10.2024. Request for Supplementary Information adopted on 20.06.2024.	Positive Opinion adopted by consensus on 03.10.2024.
Spinraza - Nusinersen - EMEA/H/C/004312/II/0035, Orphan Biogen Netherlands B.V., Rapporteur: Fátima Ventura Opinion adopted on 26.09.2024.	Positive Opinion adopted by consensus on 26.09.2024.
Stimufend - Pegfilgrastim - EMEA/H/C/004780/II/0007 Fresenius Kabi Deutschland GmbH, Rapporteur: Christian Gartner Opinion adopted on 10.10.2024. Request for Supplementary Information adopted on 05.09.2024, 20.06.2024, 16.05.2024.	Positive Opinion adopted by consensus on 10.10.2024.
Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0015/G Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 03.10.2024, 06.06.2024, 08.02.2024.	Request for supplementary information adopted with a specific timetable.
TALVEY - Talquetamab - EMEA/H/C/005864/II/0012/G, Orphan Janssen-Cilag International N.V., Rapporteur: Alexandre Moreau Opinion adopted on 03.10.2024.	Positive Opinion adopted by consensus on 03.10.2024.
Tecvayli - Teclistamab - EMEA/H/C/005865/II/0015 Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo Opinion adopted on 03.10.2024.	Positive Opinion adopted by consensus on 03.10.2024.
Tenofovir disoproxil Viatris- Tenofovir disoproxil - EMA/VR/0000224509 Mylan Pharmaceuticals Limited, Rapporteur: Vilma Petrikaite Request for Supplementary Information adopted on 17.10.2024.	Request for supplementary information adopted with a specific timetable.
Tyenne - Tocilizumab - EMEA/H/C/005781/II/0005 Fresenius Kabi Deutschland GmbH, Rapporteur: Kristina Dunder Opinion adopted on 17.10.2024.	Positive Opinion adopted by consensus on 17.10.2024.
WEZENLA - Ustekinumab -	Request for supplementary information adopted

EMEA/H/C/006132/II/0001 Amgen Technology (Ireland) Unlimited Company, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 03.10.2024.	with a specific timetable.
Zynlonta - Loncastuximab tesirine - EMEA/H/C/005685/II/0015/G Swedish Orphan Biovitrum AB (publ), Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 10.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 10.10.2024.
WS2529 **Keppra-EMEA/H/C/000277/WS2529/0200** UCB Pharma S.A., Lead Rapporteur: Karin Janssen van Doorn, Lead PRAC Rapporteur: Jo Robays Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 11.07.2024.	Positive Opinion adopted by consensus on 17.10.2024.
WS2692/G **Hexacima-EMEA/H/C/002702/WS2692/0157/G** **Hexyon-EMEA/H/C/002796/WS2692/0161/G** Sanofi Pasteur Europe Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 10.10.2024. Request for Supplementary Information adopted on 25.07.2024.	Positive Opinion adopted by consensus on 10.10.2024.
WS2732 **Lantus-EMEA/H/C/000284/WS2732/0135** **Suliqua-EMEA/H/C/004243/WS2732/0043** **Toujeo-EMEA/H/C/000309/WS2732/0132** Sanofi-Aventis Deutschland GmbH, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 17.10.2024.	Positive Opinion adopted by consensus on 17.10.2024.

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

Alecensa - Alectinib - EMEA/H/C/004164/II/0048 Roche Registration GmbH, Rapporteur: Filip Josephson, "To update sections 4.4 and 4.6 of the SmPC to update the safety information to amend the duration of the period for which female patients of child-bearing potential must use highly effective contraceptive methods	Positive Opinion adopted by consensus on 17.10.2024.

following the last dose of Alecensa, and must be informed of potential harm to the foetus in the event of pregnancy, from 3 months to 5 weeks based on the latest guidelines on contraception requirements for drugs with aneugenic potential. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 19.09.2024, 25.07.2024.	
AQUIPTA - Atogepant - EMEA/H/C/005871/II/0006 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC based on final results from study ELEVATE (3101-304-002). This is a phase 3, 12 weeks, randomized, double-blind, placebo-controlled, parallel-group study that evaluated the efficacy, safety, and tolerability of atogepant 60 mg once daily (QD) for the prophylaxis of migraine in participants with episodic migraine who had previously failed 2 to 4 classes of oral prophylactic treatments. In addition, the MAH took the opportunity to implement editorial changes to the SmPC." Opinion adopted on 10.10.2024.	Positive Opinion adopted by consensus on 10.10.2024.
Arixtra - Fondaparinux sodium - EMEA/H/C/000403/II/0092 Viatris 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." Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 13.06.2024.	Positive Opinion adopted by consensus on 17.10.2024.
Cablivi - Caplacizumab - EMEA/H/C/004426/II/0048, Orphan	Request for supplementary information adopted with a specific timetable.

Ablynx NV, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update efficacy and safety information on paediatric patients based on results from study OBS17325 - Retrospective Data Collection of Paediatric Patients with Immune Thrombotic Thrombocytopenic Purpura (iTTP) Treated with Caplacizumab. The primary objective of this study was to describe the effectiveness and safety of caplacizumab in paediatric patients with iTTP." Request for Supplementary Information adopted on 17.10.2024, 25.07.2024, 14.03.2024.	
Cablivi - Caplacizumab - EMEA/H/C/004426/II/0050, Orphan Ablynx NV, Rapporteur: Filip Josephson, "Update of section 4.2 of the SmPC in order to include further administration instructions in case the first intravenous dose of caplacizumab is missed and plasma exchange is already administered, based on final results from study ALX0681-C103; this is a Phase 1, single-centre, randomized, double-blind, placebo controlled, 2 part study that evaluated the safety, tolerability, PK/PD profile, and immunogenicity of single IV and SC doses (Part I) or multiple SC doses once daily for 7 days (Part II) of caplacizumab in Japanese and White healthy volunteers. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 25.07.2024.	Positive Opinion adopted by consensus on 17.10.2024.
COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000224683 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "A grouped application comprised of 3 Type II Variations as follows: C.I.4: Update of sections 4.6, 4.8 and 5.1 of the SmPC in order to update pregnancy related information based on final results from interventional study C4591015, listed as a category 3 study in the RMP. Study C4591015 is a phase 2/3, placebo controlled, randomized, observer-blinded study to evaluate the safety, tolerability, and immunogenicity of a SARS-CoV-2 RNA vaccine candidate (BNT162b2) against COVID-19 in healthy pregnant women 18 years of age and older. The Package Leaflet is updated	Request for supplementary information adopted with a specific timetable.

accordingly. C.I.4: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update information for immunocompromised individuals based on final results from interventional study C4591024, listed as a category 3 study in the RMP. Study C4591024 is a phase 2b, open-label study to evaluate the safety, tolerability, and immunogenicity of vaccine candidate BNT162b2 in immunocompromised participants ⩾2 years of age. The Package Leaflet is updated accordingly. C.I.13: Submission of the C4591030 (secondary BNT162b2 immunogenicity endpoint analysis) supplementary (post-final) clinical study report. This is a phase 3, randomized, observer-blind trial to evaluate the safety and immunogenicity of BNT162b2 when co-administered with seasonal inactivated influenza vaccine (SIIV) in adults 18 through 64 years of age. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 17.10.2024.	
Helicobacter Test INFAI - 13C-Urea - EMEA/H/C/000140/II/0028 Infai GmbH, Rapporteur: Christian Gartner, "Update of sections 4.2, 4.3 and 5.1 of the SmPC in order to modify administration instructions and to add a new contraindication based on final results from study HPT30/J/17; this is a single-group, observer-blind, multi-centre study to quantify the sensitivity and specificity of the 13C-UBT using the new test meal for Hp in patients with dyspepsia and GERD taking PPI. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 6.6 of the SmPC." Request for Supplementary Information adopted on 17.10.2024, 30.05.2024.	Request for supplementary information adopted with a specific timetable. See 9.1
IBRANCE - Palbociclib - EMEA/H/C/003853/II/0045 Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on final results from study A5481092. This is a Phase 1/2 Study	Positive Opinion adopted by consensus on 17.10.2024.

to Evaluate palbociclib in Combination with irinotecan and temozolomide or in Combination with topotecan and cyclophosphamide in Pediatric Patients with Recurrent or Refractory Solid Tumors. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4." Opinion adopted on 17.10.2024.	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0083 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from study 2019nCoV-301 (Adult population) listed as a category 3 study in the RMP. This is A Phase 3, Randomized, Observer-Blinded, Placebo Controlled Study To Evaluate The Efficacy, Safety, And Immunogenicity Of A Sars-Cov-2 Recombinant Spike Protein Nanoparticle Vaccine (Sars-Cov-2 Rs) With Matrix-M1 Adjuvant In Adult Participants ≥ 18 Years With A Paediatric Expansion In Adolescents (12 To < 18 Years)." Request for Supplementary Information adopted on 03.10.2024.	Request for supplementary information adopted with a specific timetable.
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0084 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-302 listed as a category 3 study in the RMP. This is a Phase 3, Randomised, Observer-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1TM Adjuvant in Adult Participants 18 – 84 Years of Age in the United Kingdom." Request for Supplementary Information adopted on 17.10.2024.	Request for supplementary information adopted with a specific timetable.
Ocrevus - Ocrelizumab - EMEA/H/C/004043/II/0040/G 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	Request for supplementary information adopted with a specific timetable.

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 26.09.2024, 06.06.2024.	
OZAWADE - Pitolisant - EMEA/H/C/005117/II/0010 Bioprojet Pharma, Rapporteur: Peter Mol, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a new posology regimen, change posology recommendations for patients with renal and hepatic impairment and to update the list of adverse drug reactions (ADRs) as well as efficacy information, based on the final results from study P15-13 (HAROSA III); this is a prospective, multicentre, randomized, double blind, placebo-controlled phase 3 study of the efficacy and safety of pitolisant in the treatment of excessive daytime sleepiness in patients with obstructive sleep apnoea (OSA). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information, 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." Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 19.09.2024, 30.05.2024.	Positive Opinion adopted by consensus on 17.10.2024.
Paxlovid - Nirmatrelvir / Ritonavir -	Positive Opinion adopted by consensus on

EMEA/H/C/005973/II/0056 Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Update of section 4.6 and 5.2 of the SmPC in order to update information on breastfeeding based on final results from study C4671039 listed as a category 3 study in the RMP (MEA/018.2); this is a Phase I, multiple dose, pharmacokinetic and safety study in healthy lactating adult women. The package leaflet is updated accordingly." Opinion adopted on 03.10.2024. Request for Supplementary Information adopted on 11.07.2024.	03.10.2024.
Prevenar 20 - Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0026 Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphy, "Update of sections 4.2 and 5.1 of the SmPC in order to introduce a vaccination schedule for children 12 months to 23 months of age transitioning from another pneumococcal conjugate vaccine and to update clinical information based on the final results from the paediatric study B7471027; this is a phase 3, randomized, partially double-blind trial to evaluate the safety and immunogenicity of 20-valent pneumococcal conjugate vaccine in healthy toddlers 12 through 23 months of age with 2 prior infant doses of Prevenar 13. The Package Leaflet is updated accordingly." Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 25.07.2024.	Positive Opinion adopted by consensus on 17.10.2024.
Remicade – Infliximab - EMA/VR/0000224494 Janssen Biologics B.V., Rapporteur: Kristina Dunder, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add post-procedural complications (including infectious and non-infections complications) to the list of adverse drug reactions (ADRs) with frequency not known and update treatment recommendations for patients with a planned surgical procedure based on a cumulative review of literature, clinical trial and registry data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 17.10.2024.	
Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0010, Orphan Biogen Netherlands B.V., Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.8 of the SmPC in order to add hypersensitivity, including urticaria and rash, to the list of adverse drug reactions (ADRs) with frequency not known based on post-marketing experience. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce corrections and minor changes to the PI and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 03.10.2024.	Request for supplementary information adopted with a specific timetable.
Soliris - Eculizumab - EMEA/H/C/000791/II/0131, Orphan Alexion Europe SAS, Rapporteur: Antonio Gomez-Outes, "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 ECU-MG-303; this is a Phase 3, open-label, multicentre study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of eculizumab in paediatric patients with refractory generalized myasthenia gravis (gMG). In addition, the MAH took the opportunity to introduce minor changes to the PI." Request for Supplementary Information adopted on 17.10.2024, 18.07.2024.	Request for supplementary information adopted with a specific timetable.
Ultomiris - Ravulizumab - EMEA/H/C/004954/II/0043/G Alexion Europe SAS, Rapporteur: Antonio Gomez-Outes, "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	Positive Opinion adopted by consensus on 26.09.2024.

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." Opinion adopted on 26.09.2024. Request for Supplementary Information adopted on 20.06.2024, 14.03.2024.	
Ultomiris - Ravulizumab - EMEA/H/C/004954/II/0045 Alexion Europe SAS, Rapporteur: Antonio Gomez-Outes, "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-center 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." Opinion adopted on 26.09.2024. Request for Supplementary Information adopted on 20.06.2024.	Positive Opinion adopted by consensus on 26.09.2024.
Veklury - Remdesivir - EMEA/H/C/005622/II/0061 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update sections 4.9 and 5.1 of the SmPC based on final results from study GS US 540 9053. This is a Phase 1, Partially Blinded, Randomized, Placebo- and Positive-Controlled Study to Evaluate the Effect of Remdesivir on the QT/QTc Interval in Healthy Participants." Opinion adopted on 17.10.2024.	Positive Opinion adopted by consensus on 17.10.2024.
Wegovy - Semaglutide - EMEA/H/C/005422/II/0021 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Update of section 5.1 of the SmPC in order to include new data generated in patients with knee osteoarthritis (OA), based on final results	Positive Opinion adopted by consensus on 10.10.2024.

from study NN9536-4578 (STEP 9); this is a phase 3b randomised, two-arm, double-blinded, multi-centre clinical trial comparing semaglutide s.c. 2.4 mg once-weekly with semaglutide placebo in subjects with moderate OA of one or both knees, pain due to knee OA, and obesity." Opinion adopted on 10.10.2024. Request for Supplementary Information adopted on 05.09.2024, 23.05.2024.	
Xtandi - Enzalutamide - EMEA/H/C/002639/II/0068/G Astellas Pharma Europe B.V., Rapporteur: Antonio Gomez-Outes, "Grouped application comprising two type II variations as follows: C.I.4 - Update of sections 4.2, 4.4 and 4.8 in order to add a new warning on Dysphagia related to product size and to add dysphagia to the list of adverse drug reactions (ADRs) with frequency Not known based on the cumulative review of the MAH safety database and literature search. C.I.4 – Update of section 4.8 of the SmPC in order to add decreased appetite to the list of adverse drug reactions (ADRs) with frequency Not known based on the cumulative review of the MAH safety database and literature search. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 26.09.2024.	Request for supplementary information adopted with a specific timetable.
Xultophy - Insulin degludec / Liraglutide - EMEA/H/C/002647/II/0052 Novo Nordisk A/S, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add 'intestinal obstruction' to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI in order to align with the latest QRD requirements." Opinion adopted on 26.09.2024. Request for Supplementary Information adopted on 18.07.2024.	Positive Opinion adopted by consensus on 26.09.2024.

B.5.3. CHMP-PRAC assessed procedures

Beovu - Brolucizumab - EMEA/H/C/004913/II/0029 Novartis Europharm Limited, Rapporteur:	Positive Opinion adopted by consensus on 17.10.2024.

Alexandre Moreau, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2 and 5.1 of the SmPC in order to include information on maintenance treatment and to update efficacy and safety information based on final results from studies CRTH258A2303 (TALON) and CRTH258A2303E1 (TALON Extension). TALON is a 64-week, two-arm, randomized, double-masked, phase IIIb study assessing the efficacy and safety of brolucizumab 6 mg compared to aflibercept 2 mg in a treat-to-control regimen in patients with neovascular age-related macular degeneration. TALON Extension is a 56-week phase IIIb/IV, open-label, one-arm extension study to assess the efficacy and safety of brolucizumab 6 mg in a Treat-to-Control regimen with maximum treatment intervals up to 20 weeks for the treatment of subjects with neovascular age-related macular degeneration who have completed the CRTH258A2303 (TALON) study. The Package Leaflet is updated accordingly. The RMP version 12.1 has also been submitted." Opinion adopted on 17.10.2024. Request for Supplementary Information adopted on 30.05.2024.	
Byooviz - Ranibizumab - EMEA/H/C/005545/II/0016/G Samsung Bioepis NL B.V., Rapporteur: Christian Gartner, PRAC Rapporteur: Karin Bolin, Quality variation Request for Supplementary Information adopted on 03.10.2024, 13.06.2024. Clock stop extension requested by the applicant to respond to the RSI adopted on 03.10.2024.	Request for supplementary information adopted with a specific timetable.
FILSPARI - Sparsentan - EMEA/H/C/005783/II/0002, Orphan Vifor France, Rapporteur: Vilma Petrikaite, PRAC Rapporteur: Martin Huber, "Update of sections 4.8, and 5.1 of the SmPC in order to amend the frequency of the adverse drug reactions (ADRs) based on final results from study 021IGAN17001 (PROTECT) listed as a specific obligation in the Annex II; this is a randomized, multicentre, double-blind parallel-group, active control study of the efficacy and safety of sparsentan for the treatment of immunoglobulin A nephropathy. The Package Leaflet is updated accordingly. The RMP version 1.0 has also been submitted. In addition, the MAH took the	Request for supplementary information adopted with a specific timetable. See 9.1

opportunity to update Annex II and to bring the PI in line with the latest QRD template version 10.4. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation." Request for Supplementary Information adopted on 17.10.2024.	
Inrebic - Fedratinib - EMEA/H/C/005026/II/0020, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, PRAC Rapporteur: Sonja Hrabcik, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update information regarding thiamine levels based on a review of the primary results of the study FEDR-MF-002. This is a Phase 3, multicentre, open-label, randomized study to evaluate the efficacy and safety of fedratinib compared with BAT in subjects with DIPSS intermediate-2 or high-risk primary MF, post-PV MF, or post-ET MF and previously treated with ruxolitinib. The RMP version 3 has also been submitted." Request for Supplementary Information adopted on 17.10.2024, 25.04.2024.	Request for supplementary information adopted with a specific timetable.
Rybelsus - Semaglutide - EMEA/H/C/004953/II/0041 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Mari Thorn, "Update of section 4.6 of the SmPC in order to update information on breast-feeding based on final results from study NN9924-4669. This was an open-label, single-armed, multiple-dose, multi-centre study evaluating the semaglutide and SNAC concentrations in breastmilk from healthy lactating women dosed once daily with oral semaglutide for 10 days (3 mg for 5 days followed by 7 mg for 5 days). The primary endpoints were evaluated during a 24 hours pharmacokinetic (PK) sampling period after the 10th dose. The package leaflet is updated accordingly. The RMP version 9.0 has also been submitted." Opinion adopted on 03.10.2024. Request for Supplementary Information adopted on 11.07.2024.	Positive Opinion adopted by consensus on 03.10.2024.
TAKHZYRO - Lanadelumab - EMEA/H/C/004806/II/0040, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder,	Request for supplementary information adopted with a specific timetable.

PRAC Rapporteur: Terhi Lehtinen, "Update of section 4.4 of the SmPC in order to remove the information related to non-availability of clinical data on the use of lanadelumab in HAE patients with normal C1-INH activity, based on results from studies CASPIAN (SHP643-303) and CASPIAN OLE (TAK-743-3001). CASPIAN (SHP643-303) is a Phase 3, multicentre, randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of lanadelumab for prevention against acute attacks of NONHISTAMINERGIC ANGIOEDEMA with Normal C1 Inhibitor (C1-INH); and CASPIAN OLE (TAK-743-3001) is an open-label study to evaluate the long term safety and efficacy of lanadelumab for prevention against acute attacks of Nonhistaminergic Angioedema with Normal C1-Inhibitor (C1-INH). The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and the Package Leaflet." Request for Supplementary Information adopted on 17.10.2024, 11.04.2024.	
WS2738 **Entresto-** **EMEA/H/C/004062/WS2738/0065** **Neparvis-** **EMEA/H/C/004343/WS2738/0062** Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt, Lead PRAC Rapporteur: Karin Erneholm, "Update of sections 4.8 and 5.3 of the SmPC in order to update information on long-term data in paediatric patients, based on final results from study CLCZ696B2319E1(PANAROMA-HF OLE) listed as a category 3 study in the RMP (MEA/009); this is a phase 3, multicentre, uncontrolled study to evaluate long-term safety and tolerability of open label sacubitril/valsartan in paediatric patients with heart failure due to systemic left ventricle systolic dysfunction who have completed study CLCZ696B2319 (PANORAMA-HF); the RMP version 8 has also been submitted." Request for Supplementary Information adopted on 03.10.2024.	Request for supplementary information adopted with a specific timetable.

B.5.4. PRAC assessed procedures

PRAC Led **CRYSVITA - Burosumab - EMEA/H/C/004275/II/0040, Orphan** Kyowa Kirin Holdings B.V, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of an updated RMP version 8.0 in order to remove hyperphosphataemia as an important potential risk and to add a specific adverse drug reaction follow-up form/questionnaire for increased parathyroid hormone levels as a routine pharmacovigilance activity." Request for Supplementary Information adopted on 03.10.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **JCOVDEN - COVID-19 Vaccine Janssen (Ad26.COV2.S) - EMEA/H/C/005737/II/0078/G** Janssen-Cilag International N.V., PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "A grouped application consisting of three Type II variations, as follows: C.I.13: Submission of the final report from study COV3003 listed as a category 3 study in the RMP. This is a randomized, double-blind, phase 3 study to evaluate 6 dose levels of Ad26.COV2.S administered as a two-dose schedule in healthy adults. The RMP version 8.3 has also been submitted. C.I.13: Submission of the final report from study COV3009 listed as a category 3 study in the RMP. This is a randomized, double-blind, placebo controlled phase 3 study to assess the efficacy and safety ofAd26.COV2.S for the prevention of SARS-CoV-2-mediated COVID-19 in adults aged 18 years and older. C.I.13: Submission of the final report from study RSV2008 listed as a category 3 study in the RMP. This is a randomized, observer-blind, phase 1 study to evaluate innate and pro-inflammatory responses of an Ad26.RSV.preF-based vaccine, Ad26.COV2.S vaccine and Ad26.ZEBOV vaccine in adults aged 18 to 59 years." Opinion adopted on 03.10.2024.	Positive Opinion adopted by consensus on 03.10.2024.

PRAC Led **Lenvima - Lenvatinib - EMEA/H/C/003727/II/0056** Eisai GmbH, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Update of section 5.1 of the SmPC in order to update the safety and efficacy information for the current HCC indication based on final results from study E7080-M000-508 (STELLAR), listed as a category 3 PASS in the RMP; this is a multicentre non-interventional, observational Phase 4 study to evaluate the safety and tolerability of lenvatinib in patients with advanced or unresectable HCC. The RMP version 17.0 has also been submitted." Request for Supplementary Information adopted on 03.10.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Moventig - Naloxegol - EMEA/H/C/002810/II/0043** Gruenenthal GmbH, PRAC Rapporteur: Eamon O Murchu, PRAC-CHMP liaison: Finbarr Leacy, "Submission of the final report from the PASS study D3820R0008 listed as a category 3 study in the RMP. This is a US post-marketing, comparative, observational study to evaluate the cardiovascular safety of Naloxegol in patients with non-cancer pain in comparison to other treatments for opioid induced constipation. The RMP version 9.0 has also been submitted." Request for Supplementary Information adopted on 03.10.2024, 16.05.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0082** Novavax CZ a.s., PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission an updated RMP version 5.1 in order to include the safety and effectiveness data available from the non-clinical studies and post-authorization usage regarding the JN.1 variant strain." Opinion adopted on 03.10.2024.	Positive Opinion adopted by consensus on 03.10.2024.
PRAC Led **Prolia - Denosumab - EMEA/H/C/001120/II/0100** Amgen Europe B.V., PRAC Rapporteur: Mari	Positive Opinion adopted by consensus on 03.10.2024.

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." Opinion adopted on 03.10.2024. Request for Supplementary Information adopted on 13.06.2024, 11.04.2024, 11.01.2024.	
PRAC Led **RAYVOW - Lasmiditan - EMEA/H/C/005332/II/0007** Eli Lilly Nederland B.V., PRAC Rapporteur: Anna Mareková, PRAC-CHMP liaison: Frantisek Drafi, "Submission of the final report from study H8H-MC-B005, listed as a category 3 study in the RMP (MEA/003). This is a Real-World Observational Study to Assess Drug Utilisation Patterns in the US Among Migraine Patients Treated with Lasmiditan. The RMP version 2.1 is submitted alongside the final study report." Opinion adopted on 03.10.2024. Request for Supplementary Information adopted on 11.04.2024.	Positive Opinion adopted by consensus on 03.10.2024.
PRAC Led **Rotarix - Rotavirus vaccine (live, oral) - EMEA/H/C/000639/II/0135** GlaxoSmithKline Biologicals S.A., PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of an updated RMP version 24.0 in order to remove missing information related to long term genetic stability of the vaccine virus strain." Opinion adopted on 03.10.2024.	Positive Opinion adopted by consensus on 03.10.2024.
PRAC Led **Ruconest - Conestat alfa - EMEA/H/C/001223/II/0088/G** Pharming Group N.V, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Daniela Philadelphy, "Submission of an updated RMP version 19.3 in order to request the early termination of the EU registry study C1 1412, as well as to update safety information based on cumulative data from clinical trials, the EU registry data, post-marketing data and literature. A request for the extension of the due	Request for supplementary information adopted with a specific timetable.

date for the European survey of educational materials for Ruconest is also included." Request for Supplementary Information adopted on 03.10.2024.	
PRAC Led **Uptravi - Selexipag - EMEA/H/C/003774/II/0045** Janssen-Cilag International N.V., PRAC Rapporteur: Tiphaine Vaillant, 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 on 03.10.2024, 13.06.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Vyndaqel - Tafamidis - EMEA/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 AATR-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	Request for supplementary information adopted with a specific timetable.

on 03.10.2024, 13.06.2024, 11.04.2024.	
PRAC Led **WS2620** **Dovato-EMEA/H/C/004909/WS2620/0047** **Juluca-EMEA/H/C/004427/WS2620/0056** **Tivicay-EMEA/H/C/002753/WS2620/0092** **Triumeq-EMEA/H/C/002754/WS2620/0118** ViiV Healthcare B.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of section 4.6 of the SmPC in order to update information about the use of DTG-containing regimens in pregnancy and at conception based on final results from non-interventional Tsepamo study and the Eswatini Birth Outcomes Surveillance study. In addition, data from other cohort studies and pregnancy registries, including the APR, DOLOMITE-EPPICC (Study 208613) and DOLOMITE-NEAT-ID Network study (Study 208759) both listed as category 3 studies in the RMP; and the US Chart Review (Study 212976) as well as data from literature are included. DOLOMITE-EPPICC (Study 208613) is a s a non-interventional study to Assess "real-world" maternal and foetal outcomes following DTG use during pregnancy and to describe patterns of DTG utilization; DOLOMITE NEAT ID Network Study (208759) is a non-interventional, multi-site observational study to define the safety and effectiveness of Dolutegravir use in HIV positive pregnant women. The Package Leaflet is updated accordingly. The RMP version 19 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to sections 4.4 and 4.5 of the SmPC." Request for Supplementary Information adopted on 03.10.2024, 16.05.2024, 08.02.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2743** **Komboglyze-EMEA/H/C/002059/WS2743/0060** **Onglyza-EMEA/H/C/001039/WS2743/0061** AstraZeneca AB, Lead PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 18.1 in order to remove the previously classified important potential risk serious cutaneous adverse reactions (SCAR)."	Positive Opinion adopted by consensus on 03.10.2024.

Opinion adopted on 03.10.2024.	

B.5.5. CHMP-CAT assessed procedures

Kymriah - Tisagenlecleucel - EMEA/H/C/004090/II/0086/G, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, , "A grouped application consisting of: C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on cytokine release syndrome based on literature. C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on neurological adverse reaction based on literature. The Package Leaflet is updated accordingly. C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on hypersensitivity reactions based on post marketing data and 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 and to implement editorial changes to the PI." Request for Supplementary Information adopted on 11.10.2024.	Request for supplementary information adopted with a specific timetable.
Upstaza - Eladocagene exuparvovec - EMEA/H/C/005352/II/0023/G, Orphan, ATMP PTC Therapeutics International Limited, Rapporteur: Joseph DeCourcey, CHMP Coordinator: Finbarr Leacy, Quality variation Request for Supplementary Information adopted on 11.10.2024.	Request for supplementary information adopted with a specific timetable.
Zolgensma - Onasemnogene abeparvovec - EMEA/H/C/004750/II/0052, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Emmely de Vries, CHMP Coordinator: Peter Mol, "Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and vector shedding data following request in procedure EMA/H/C/004750/P46/022 and based on data from study COAV101A12306. In addition, a reference to section 5.2 is added to section 4.4, as requested in final Assessment report of procedure EMA/H/C/004750/P46/022."	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 11.10.2024.	
WS2500 **Tecartus-** **EMEA/H/C/005102/WS2500/0040** **Yescarta-** **EMEA/H/C/004480/WS2500/0068** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, Quality variation Request for Supplementary Information adopted on 11.10.2024, 24.05.2024, 16.02.2024.	Request for supplementary information adopted with a specific timetable.

B.5.6. CHMP-PRAC-CAT assessed procedures

Yescarta - Axicabtagene ciloleucel - EMEA/H/C/004480/II/0075/G, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: 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 Multicenter 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-Center 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 11.0 has also been submitted." Opinion adopted on 17.10.2024, 11.10.2024. Request for Supplementary Information adopted on 21.06.2024.	Positive Opinion adopted by consensus on 17.10.2024.

B.5.7. PRAC assessed ATMP procedures

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

WS2740/G **Alkindi-** **EMEA/H/C/004416/WS2740/0023/G** **Efmody-**	Positive Opinion adopted by consensus on 03.10.2024.

EMEA/H/C/005105/WS2740/0010/G Diurnal Europe BV, Lead Rapporteur: Karin Janssen van Doorn, Quality variationOpinion adopted on 03.10.2024.	
WS2745 **Entresto-** **EMEA/H/C/004062/WS2745/0067** **Neparvis-** **EMEA/H/C/004343/WS2745/0064** Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt, Quality variationOpinion adopted on 26.09.2024.	Positive Opinion adopted by consensus on 26.09.2024.
WS2750 **Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-** **EMEA/H/W/005362/WS2750/0018** **Qdenga-** **EMEA/H/C/005155/WS2750/0019** Takeda GmbH, Lead Rapporteur: Sol Ruiz, Quality variation Opinion adopted on 03.10.2024.	Positive Opinion adopted by consensus on 03.10.2024.
WS2757/G **Aerius-** **EMEA/H/C/000313/WS2757/0107/G** **Azomyr-** **EMEA/H/C/000310/WS2757/0111/G** **Neoclarityn-** **EMEA/H/C/000314/WS2757/0105/G** Organon N.V., Lead Rapporteur: Christophe Focke, Quality variation Opinion adopted on 03.10.2024.	Positive Opinion adopted by consensus on 03.10.2024.
WS2759/G **Mirapexin-** **EMEA/H/C/000134/WS2759/0109/G** **Sifrol-** **EMEA/H/C/000133/WS2759/0100/G** Boehringer Ingelheim International GmbH, Lead Rapporteur: Thalia Marie Estrup Blicher, Quality variation	Positive Opinion adopted by consensus on 03.10.2024.

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

Torisel - Temsirolimus - EMEA/H/C/000799/II/0092 Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, "Update of sections 4.4 and 4.5 of the SmPC in order to update the warnings and drug-drug interaction information with newly marketed drug substances. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	The MAH withdrew the procedure on 09.10.2024.
Cystadrops - Mercaptamine - EMEA/H/C/003769/II/0030, Orphan Recordati Rare Diseases, Rapporteur: Kristina Dunder	The MAH withdrew the procedure on 04.10.2024.

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

Erbitux - Cetuximab - EMEA/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.	Change of timetable requested by the applicant to respond to the RSI adopted in June 2024.

Xevudy - Sotrovimab - EMEA/H/C/005676/II/0029/G Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "A grouped application comprised of 5 Type II Variations, as follows: C.I.4: Update of section 5.1 of the SmPC based on final results from study 218407 (LUNAR); this is a Phase 4 single-arm prospective cohort genomic surveillance study to describe changes in the SARS-CoV-2 spike protein observed in immunocompromised non-hospitalized patients receiving sotrovimab in Great Britain to monitor the emergence of viral variants. 4 x (C.I.13): To submit the final reports from the following studies: COMET-TAIL Safety Substudy (217114); this is a Phase 3 randomized, multi-centre, open label study to assess the efficacy, safety, and tolerability of monoclonal antibody VIR-7831 (sotrovimab) given intramuscularly versus intravenously for the treatment of mild/moderate coronavirus disease 2019 (COVID-19) in high- risk non-hospitalized patients; Safety Substudy assessing the safety and tolerability of single ascending dose monoclonal antibody VIR-7831. AGILE (215337); this is a randomized, multicentre, seamless, adaptive, Phase 1/2 platform study to determine the Phase 2a dose of VIR-7832, and evaluate the safety and efficacy of VIR-7831 and VIR-7832 for the treatment of COVID-19. COSMIC (218128); this is a Phase 1, open-label, randomized, parallel group, single-dose clinical pharmacology study to investigate the relative bioavailability, safety, and tolerability of two different concentrations of sotrovimab administered at different injection sites, in male or female healthy participants aged 18 to 65 years. And from a clinical pharmacology study evaluating SARS-CoV-2 specific T cells responses in participants receiving 500 mg IV sotrovimab in COMET-ICE (PC-22-0123)."	Request by the applicant for an extension to the clock stop to respond to the RSI adopted in September 2024.

Request for Supplementary Information adopted on 12.09.2024.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

Denosumab - EMEA/H/C/006490
Treatment of osteoporosis in postmenopausal women and in men, treatment of bone loss associated with hormone ablation in men with prostate cancer and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients.

Human serum albumin - EMEA/H/D/006611
use in Assisted Reproductive Technologies (ART)

Nipocalimab - EMEA/H/C/006379
treatment of generalised Myasthenia Gravis

Denosumab - EMEA/H/C/006238
treatment of osteoporosis and bone loss

Belumosudil - EMEA/H/C/006421, Orphan
Sanofi Winthrop Industrie, Treatment of chronic graft-versus host disease (cGVHD) after failure of at least two prior lines of systemic therapy.

Rilonacept - EMEA/H/C/006537, Orphan
FGK Representative Service GmbH, treatment of idiopathic pericarditis

Denosumab - EMEA/H/C/006552
Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults and treatment of adults and skeletally mature adolescents with giant cell tumour of bone

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

Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/X/0033/G
Bayer AG, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Bianca Mulder, "Extension application to add a new strength of Jivi 4000 UI powder and solvent for solution for injection for treatment and prophylaxis of bleeding in previously treated patients ≥ 12 years of age with haemophilia A (congenital

factor VIII deficiency).

Version 3.1 of the RMP has also been submitted.

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

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

Bosulif - Bosutinib - EMEA/H/C/002373/X/0058/G

Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Extension application to introduce a new pharmaceutical form (hard capsules) associated with two new strengths (50 mg and 100 mg) grouped with an extension of indication (C.I.6.a) to include treatment of paediatric patients greater than or equal to 1 year of age with newly-diagnosed (ND) chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukaemia (Ph+ CML) for BOSULIF, based on interim results from study ITCC-054/AAML1921 (BCHILD); this is a phase 1/2, multicentre, international, single-arm, open-label study of bosutinib in paediatric patients with newly diagnosed chronic phase or resistant/intolerant Ph+ chronic myeloid leukaemia. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 7.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."
List of Questions adopted on 25.07.2024.

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

for active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae
List of Questions adopted on 25.07.2024.

In vitro diagnostic medical device - EMEA/H/D/006587

To detect G719X substitution mutations in exon 18, deletion mutations in exon 19, T790M and S768I substitution mutations in exon 20,

insertion mutations in exon 20, and L858R and L861Q substitution mutations in exon 21
Request for Supplementary Information adopted on 19.09.2024.

Human normal immunoglobulin - EMEA/H/C/006423
replacement therapy (primary immunodeficiency syndromes and secondary hypogammaglobulinemia), immunomodulation (in primary immune thrombocytopenic purpura, Guillain Barré syndrome, Kawasaki disease and Multifocal Motor Neuropathy)
List of Questions adopted on 25.07.2024.

Eltrombopag - EMEA/H/C/006459
treatment of primary immune thrombocytopenia (ITP), chronic hepatitis C virus (HCV) and acquired severe aplastic anaemia (SAA),
List of Questions adopted on 25.07.2024.

Sipavibart - EMEA/H/C/006291
indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older
List of Questions adopted on 17.09.2024.

Lyrica - Pregabalin - EMEA/H/C/000546/X/0127
Upjohn EESV, Rapporteur: Peter Mol, PRAC Rapporteur: Liana Martirosyan, "Extension application to introduce a new pharmaceutical form (orodispersible tablet)"
List of Questions adopted on 30.05.2024.

Nirogacestat - EMEA/H/C/006071, Orphan
Springworks Therapeutics Ireland Limited, treatment of desmoid tumours
List of Questions adopted on 27.06.2024.

Omvoh - Mirikizumab - EMEA/H/C/005122/X/0006/G
Eli Lilly Nederland B.V., Rapporteur: Finbarr Leacy, PRAC Rapporteur: Sonja Hrabcik"Extension application to add a new strength of 200 mg grouped with an extension of indication (C.I.6) to include treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment, for Omvoh, based mainly on final results from study I6T-MC-AMAM; this is

a phase 3, multicenter, randomized, double-blind, placebo- and active-controlled, treat-through study to evaluate the efficacy and safety of mirikizumab in patients with moderately to severely active Crohn's disease. As a consequence, sections 1, 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.1, 6.5, 6.6 and 8 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. Version 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and to update the list of local representatives in the Package Leaflet. As part of the application, the MAH is requesting a 1-year extension of the market protection. List of Questions adopted on 19.09.2024. Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
PREVYMIS - Letermovir - EMEA/H/C/004536/X/0037/G, Orphan Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Terhi Lehtinen, "Extension applications to introduce a new pharmaceutical form (granules in sachet) associated with new strengths (20 and 120 mg) grouped with a type II variation (C.I.6.a) to include treatment of paediatric patients from birth up to 18 years old based on the final results from studies P030 and P031. Study P030 was a Phase 2b, open-label, single-arm study to evaluate PK, efficacy, safety, and tolerability of LET when used for CMV prophylaxis in paediatric participants from birth to <18 years of age who are at risk of developing CS-CMVi following an allogeneic HSCT. Study P031 was an open-label, single-dose, four-period, seven-treatment, crossover study designed to evaluate the bioavailability of 2 paediatric formulations of MK-8228 (Formulations A and B) administered alone or in soft food (applesauce and vanilla pudding) compared to a currently marketed tablet formulation. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted.	

In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes."
List of Questions adopted on 25.07.2024.

Retsevmo - Selpercatinib - EMEA/H/C/005375/X/0031
Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder, "Extension application to introduce a new pharmaceutical form (film-coated tablets) associated with new strengths (40 mg, 80 mg, 120 mg and 160 mg).
The RMP (version 7.1) is updated in accordance."
List of Questions adopted on 25.07.2024.

Atropine - EMEA/H/C/006324
treatment of progression of myopia in children aged 3 to 18 years
List of Questions adopted on 25.07.2024.

Sargramostim - EMEA/H/C/006411
treatment for exposure to myelosuppressive doses of radiation
List of Questions adopted on 23.07.2024.

Tremfya - Guselkumab - EMEA/H/C/004271/X/0043/G
Janssen-Cilag International N.V., Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Gabriele Maurer, "Extension application to:
- introduce a new pharmaceutical form (concentrate for solution for infusion), a new strength (200 mg) and a new route of administration (intravenous use)
- add a new strength of 200 mg for solution for injection (in pre-filled syringe / pre-filled pen) for subcutaneous use
This application is grouped with a type II variation (C.I.6.a) to include the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor for Tremfya, based on results of a Phase 2b/3 clinical development programme (CNTO1959UCO3001) consisting of 3 separate studies, an Induction dose finding Study 1 Phase 2b, an Induction Study 2 Phase 3 and a Phase 3 Maintenance Study. These studies were

randomized, double-blind, placebo-controlled, parallel-group, multicentre studies that evaluated the efficacy and safety of guselkumab in participants with moderately to severely active UC. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC of the already approved form 100 mg solution for injection are updated. The Package Leaflet and Labelling are 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 and to introduce editorial changes to the PI."
List of Questions adopted on 19.09.2024.

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

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

FILSPARI - Sparsentan -
EMEA/H/C/005783/R/0004, Orphan
Vifor France, Rapporteur: Vilma Petrikaite, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber

Natpar - Parathyroid hormone -
EMEA/H/C/003861/R/0058, Orphan
Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Rhea Fitzgerald

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

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Busulfan Fresenius Kabi – Busulfan -
EMA/VR/0000228648
Fresenius Kabi Deutschland GmbH, Rapporteur: John Joseph Borg,

COMIRNATY – COVID-19 mRNA vaccine -
EMA/VR/0000228506
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

Dupixent - Dupilumab -
EMEA/H/C/004390/II/0090/G
Sanofi Winthrop Industrie, Rapporteur: Jan Mueller-Berghaus

Enhertu - Trastuzumab -
EMEA/H/C/005124/II/0051
Daiichi Sankyo Europe GmbH, Rapporteur: Thalia Marie Estrup Blicher

Fluad Tetra - Influenza vaccine (surface antigen, inactivated, adjuvanted) -
EMEA/H/C/004993/II/0056/G
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

IDELVION - Albutrepenonacog alfa -
EMEA/H/C/003955/II/0074, Orphan
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

JEMPERLI - Dostarlimab -
EMEA/H/C/005204/II/0038/G
GlaxoSmithKline (Ireland) Limited, Rapporteur: Antonio Gomez-Outes

Kanuma - Sebelipase alfa -
EMEA/H/C/004004/II/0050/G, Orphan
Alexion Europe SAS, Rapporteur: Karin Janssen van Doorn

Keytruda - Pembrolizumab -
EMEA/H/C/003820/II/0162
Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini

Lonquex - Lipegfilgrastim -
EMEA/H/C/002556/II/0096/G
Teva B.V., Rapporteur: Outi Mäki-Ikola

Orgovyx - Relugolix -
EMEA/H/C/005353/II/0023
Accord Healthcare S.L.U., Rapporteur: Patrick Vrijlandt

OZAWADE - Pitolisant -
EMEA/H/C/005117/II/0011/G
Bioprojet Pharma, Rapporteur: Peter Mol

Padcev - Enfortumab vedotin -
EMEA/H/C/005392/II/0021/G
Astellas Pharma Europe B.V., Rapporteur: Aaron Sosa Mejia

Pifeltro - Doravirine -
EMEA/H/C/004747/II/0031/G
Merck Sharp & Dohme B.V., Rapporteur: Filip

Josephson

Revolade - Eltrombopag -
EMEA/H/C/001110/II/0078/G
Novartis Europharm Limited, Rapporteur:
Antonio Gomez-Outes

Rybrevant - Amivantamab -
EMEA/H/C/005454/II/0018/G
Janssen-Cilag International N.V., Rapporteur:
Filip Josephson

Soliris - Eculizumab -
EMEA/H/C/000791/II/0134/G, Orphan
Alexion Europe SAS, Rapporteur: Antonio
Gomez-Outes

VEYVONDI - Vonicog alfa -
EMEA/H/C/004454/II/0036/G
Baxalta Innovations GmbH, Rapporteur: Jan
Mueller-Berghaus

Yuflyma - Adalimumab -
EMEA/H/C/005188/II/0042/G
Celltrion Healthcare Hungary Kft., Rapporteur:
Outi Mäki-Ikola

WS2752
Infanrix hexa-
EMEA/H/C/000296/WS2752/0349
GlaxoSmithkline Biologicals SA, Lead
Rapporteur: Christophe Focke

WS2756
Hexacima-
EMEA/H/C/002702/WS2756/0160
Hexyon-
EMEA/H/C/002796/WS2756/0164
Sanofi Pasteur Europe Lead Rapporteur: Jan
Mueller-Berghaus

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

Abraxane - Paclitaxel -
EMEA/H/C/000778/II/0115
Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Peter Mol, "Update section 4.6 of the SmPC
based on the Reproductive Toxicity Testing and
Labeling recommendations, Food and Drug
Administration Guidance (May 2019) and the
Non-clinical Working Party/Non-clinical Working
Party (S/Nc), European Medicines Agency
recommendations (March 2023) on the duration
of contraception following the end of treatment

with a genotoxic drug. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”	
Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0012 Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe, “Update of section 5.1 of the SmPC in order to update information based on end-of-season 2 data from clinical study C3671013. This is an ongoing Phase 3, randomized, double-blind, placebo controlled to evaluate safety immunogenicity, and efficacy of Abrysvo in prevention of lower respiratory tract disease in adults 60 years of age and older during the first respiratory syncytial virus (RSV) season and the long-term immunogenicity and efficacy of Abrysvo in the second RSV season and across 2 RSV seasons. In addition, the MAH took the opportunity to introduce minor changes to the PI based on the already submitted clinical study report C3671008.”	
Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0014 Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe, “Update of section 4.5 of the SmPC in order to add information regarding coadministration of Abrysvo and COVID-19 mRNA vaccines, with or without a high dose influenza vaccine following Phase 1/2 study C5481001 Substudy A - a Study to Evaluate the Safety, Tolerability, and Immunogenicity of Combined Vaccine Candidate(s) Against Infectious Respiratory Illnesses, Including COVID 19 and RSV, in healthy participants ≥65 years of age; the Package Leaflet is updated accordingly.”	
Amvuttra - Vutrisiran - EMEA/H/C/005852/II/0013/G, Orphan Alnylam Netherlands B.V., Rapporteur: Janet Koenig, “Update of section 5.3 of the SmPC in order to update non-clinical information on the carcinogenicity of vutrisiran, based on final results from studies NCS-21-00440 and TTRSC02-GLP18-003; these are 2-year carcinogenicity studies in CD-1 mice and	

Sprague Dawley rats, respectively. In addition, the MAH took the opportunity to submit Amended Report 1 of study TTRSC02-GLP18-013."

Amvuttra - Vutrisiran - EMEA/H/C/005852/II/0014, Orphan

Alnylam Netherlands B.V., Rapporteur: Janet Koenig, "Update of section 4.2 of the SmPC in order to add the option for administration by patient and/or caregiver, based on an updated Notified Body Opinion report. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to make editorial changes in the PI."

Balversa - Erdafitinib - EMEA/H/C/006050/II/0001

Janssen-Cilag International N.V., Rapporteur: Janet Koenig, "Update of section 4.8 of the SmPC in order to add cataract as a new ADR with frequency common based on a review of new information observed in clinical studies and in the post marketing setting. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of the most common ADRs in the SmPC section 4.8 and to make editorial corrections in the SmPC and Package Leaflet."

Bosulif - Bosutinib - EMEA/H/C/002373/II/0061

Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, "Update of section 4.5 of the SmPC in order to update the drug-drug interaction information to include substances based on the impact analysis of the French Drug Interaction Thesaurus 2023 on Bosulif. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes and update the list of local representatives in the Package Leaflet to bring the PI in line with the latest QRD template v10.4."

Braftovi - Encorafenib - EMEA/H/C/004580/II/0041

Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4 and 5.2 of the SmPC to include a dose recommendation for patients with moderate hepatic impairment based on the results of a modelling and

simulation study and post-marketing data The Package Leaflet is updated accordingly."

Erbitux - Cetuximab - EMEA/H/C/000558/II/0102
Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Mari Thorn, "Update of section 5.1 of the SmPC based on results from study CALGB/SWOG 80405; this is a phase 3 trial of irinotecan/5-fu/leucovorin or oxaliplatin/5-fu/leucovorin with bevacizumab, or cetuximab (C225), or with the combination of bevacizumab and cetuximab for patients with KRAS wild-type untreated metastatic adenocarcinoma of the colon or rectum, with efficacy as primary objective."

Fluenz - Influenza vaccine (live attenuated, nasal) - EMEA/H/C/006514/II/0002
AstraZeneca AB, Rapporteur: Christophe Focke, "Update of section 4.2 of the SmPC, upon request by the CHMP, to include an adequate age range for children that should be vaccinated with a 2-dose schedule, and section 4.4 of the SmPC to include a statement regarding the postponement of vaccinations in individuals with symptoms of an acute infection. In addition, the MAH took the opportunity to implement editorial changes in the SmPC, labelling and Package Leaflet, as well as a rearrangement of existing text for increased clarity."

Kesimpta - Ofatumumab - EMEA/H/C/005410/II/0022
Novartis Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC in order to include information from pre-planned analyses of serum neurofilament light chain (NfL) concentration based on data from phase III studies COMB157G2301 (ASCLEPIOS I) and COMB157G2302 (ASCLEPIOS II), and from the open-label extension study COMB157G2399 (ALITHIOS). The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to make editorial changes."

Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0160
Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, "Update of section 5.1 of the SmPC in order to update information based on the Interim Analysis 7 (IA7) results from the

P522V05MK3475 (KEYNOTE-522) study. This is a Phase 3 randomized, double-blind study to evaluate pembrolizumab plus chemotherapy vs placebo plus chemotherapy as neoadjuvant therapy and pembrolizumab vs placebo as adjuvant therapy for triple negative breast cancer (TNBC)."

Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0161

Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, "Update of sections 4.4 and 4.8 of the SmPC in order to update information on pericarditis and include the risk of pericarditis under the section "Other immune-mediated adverse reactions" based on post-marketing data and literature. The Package Leaflet is updated accordingly."

Mayzent - Siponimod - EMEA/H/C/004712/II/0032

Novartis Europharm Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC in order to update efficacy and safety information from study CBAF312A2304 (EXPAND) listed as a category 3 study in the RMP. This is a phase III study and is comprised of two parts: a Core Part and an Extension Part. The Core Part was a multicentre, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of siponimod in SPMS patients. This was followed by an open-label Extension Part, collecting long-term efficacy and safety data on siponimod for up to 7 years. In addition, the MAH took the opportunity to add editorial changes to the PI."

Mektovi - Binimetinib - EMEA/H/C/004579/II/0034

Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4 and 5.2 of the SmPC to include a dose recommendation for patients with moderate hepatic impairment based on the results of a modelling and simulation study and post-marketing data. The Package Leaflet is updated accordingly."

Mosquirix - Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0086

GlaxoSmithkline Biologicals SA, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2, 4.5,

4.8 and 5.1 of the SmPC in order to update posology, efficacy and safety information based on final results from study MALARIA-094 and literature. This is a Phase 2b, randomized, open-label, controlled, multi-centre study of the efficacy, safety and immunogenicity of RTS,S/AS01E evaluating schedules with or without fractional doses, early dose 4 and yearly doses, in children living in sub-Saharan Africa. The Package Leaflet and Labelling are 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, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI."

Olumiant - Baricitinib - EMEA/H/C/004085/II/0050/G

Eli Lilly Nederland B.V., Rapporteur: Peter Mol, "A grouped application comprised of two type II variations, as follows:

C.I.4: Update of section 5.1 of the SmPC in order to update information based on final long-term efficacy data from study I4V-MC-JAHN (BREEZE-AD3); this is a phase 3, double-blind study to evaluate the long-term safety and efficacy of baricitinib in adult patients with atopic dermatitis.

C.I.13: Submission of the final long-term data from study I4V-MC-JAIN (BREEZE-AD4); this is a phase 3, double-blind, randomized, placebo-controlled study to evaluate the safety and efficacy of baricitinib in combination with topical corticosteroids in adult patients with moderate-to-severe atopic dermatitis."

Ontozry - Cenobamate - EMEA/H/C/005377/II/0029

Angelini S.p.A., Rapporteur: Fátima Ventura, "Update of sections 4.2 and 5.2 of the SmPC to include the crushed tablets method of administration and section 4.5 of the SmPC in order to present the existing information on DDI in a tabular format. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement an editorial correction of the contact details of the manufacturer ACRAF SPA in Annex II and

Package Leaflet."

Padcev - Enfortumab vedotin - EMEA/H/C/005392/II/0020

Astellas Pharma Europe B.V., Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.8 of the SmPC in order to add 'skin hyperpigmentation' with frequency 'not known' based on available clinical, post marketing, and preclinical data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Remicade – Infliximab - EMA/VR/0000229576

Janssen Biologics B.V., Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add 'paradoxical drug-induced immune disorders' to the list of adverse drug reactions (ADRs) with frequency uncommon, based on the results of a cumulative review for paradoxical reactions. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to delete the reference to the core Patient Reminder Card messages from the Annex II in accordance with GVP XVI, to add information about polysorbates in line with revision 4 of the Annex to the EU Excipients Guideline, as well as to introduce minor editorial changes, update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template."

RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0059

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, "Update of section 4.4 of the SmPC in order to include a precaution regarding medication residue in stool based on post marketing data and 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."

Xenpozyme - Olipudase alfa - EMEA/H/C/004850/II/0013/G, Orphan

Sanofi B.V., Rapporteur: Patrick Vrijlandt, "A grouped application consisting of:
C.I.4: Update of section 4.2 of the SmPC in order to update the 'Missed Doses' section to facilitate the appropriate clinical management of

patients based on pre-existing data from the clinical trials.

C.I.4: Update of section 4.2 of the SmPC in order to include a clarification of the infusion rate during the home infusion based on pre-existing data from the clinical trials."

Zykadia - Ceritinib - EMEA/H/C/003819/II/0057

Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes, "Submission of the final report from study CLDK378A2301; a phase III multicentre, randomized study evaluating oral LDK378 against standard chemotherapy in previously untreated adults with ALK rearranged (ALK-positive), stage IIIB or IV, non- squamous non-small cell lung cancer."

WS2762
Finlee-EMEA/H/C/005885/WS2762/0010
Spexotras-EMEA/H/C/005886/WS2762/0009

Novartis Europharm Limited, Lead Rapporteur: Filip Josephson, "Update of sections 4.2 and 5.2 of the SmPC in order to modify administration instructions and pharmacokinetic properties on food effect based on final results from study CDRB436G2401. This is a randomized, open-label, two independent part, 2 x 2 cross-over study to investigate the relative bioavailability of trametinib and dabrafenib liquid formulations under fasted vs. low-fat low-calorie meal conditions in adult healthy participants. In addition, the MAH took the opportunity to implement editorial changes to the PI."

B.6.10. CHMP-PRAC assessed procedures

BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/II/0017

Hipra Human Health S.L., Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Zane Neikena, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update safety information and remove the warning for immunocompromised individuals, based on final results from study HIPRA-HH-4 listed as a category 3 study in the RMP; this is a Phase IIb/III, open label, single

arm, multi-centre trial to assess the immunogenicity and safety of an additional dose vaccination with a recombinant protein RBD fusion heterodimer candidate (PHH-1V) against SARS-CoV-2, in adults with pre-existing immunosuppressive conditions vaccinated against COVID-19. The Package Leaflet is updated accordingly. The RMP version 1.5 has also been submitted. In addition, the MAH took the opportunity to include information on excipient polysorbate 80, to introduce minor editorial changes to the PI and to bring the PI in line with QRD template version 10.4."

Cufence - Trientine - EMEA/H/C/004111/II/0020

Univar Solutions BV, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Ana Sofia Diniz Martins, "Submission of the PK/PD sub-study report for study UNV-TR-004 (UNITED) listed as a PAES in the Annex II of the Product Information. This is an open label, prospective study to characterize the pharmacokinetics and pharmacodynamics of Cufence and to investigate the efficacy and safety in Wilson's disease. The Annex II and the RMP (version 5.0) are updated accordingly."

ELREXFIO - Elranatamab - EMEA/H/C/005908/II/0005

Pfizer Europe Ma EEIG, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Barbara Kovacic Bytyqi, "Update of section 4.2 of the SmPC to add every four-week dosing schedule after at least 24 weeks of every two-week dosing and to update the recommendations for restarting therapy following dose delay, and update of sections 4.8, 5.1 and 5.2 of the SmPC with long-term efficacy, safety, and clinical pharmacology results (≥2 years of follow-up after the last participant initial dose), based on the final study report of Study C1071003; a Phase 2, open-label, multicentre, non-randomised study of elranatamab monotherapy in participants with MM who are refractory to at least one PI, one IMiD, and one anti-CD38 Ab. The Package Leaflet has been updated in accordance. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to update the list of local representatives in the Package Leaflet. Further, the provision of the final study report addresses

SOB 001, and Annex II has been updated accordingly. A revised RMP version 1.2 was provided as part of the application."

Krazati - Adagrasib - EMEA/H/C/006013/II/0010/G

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Kimmo Jaakkola, "A grouped application consisting of:

C.I.4: Update of section 5.1 of the SmPC based on final results from study 849-012 (KRYSTAL-12) listed as a specific obligation in the Annex II. This is a Randomized Phase 3 Study of MRTX849 versus Docetaxel in Patients with Previously Treated Non-Small Cell Lung Cancer with KRAS G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex IIE of the PI.

C.I.4: Update of section 4.8 of the SmPC in order to update safety information based on an integrated analysis of data from interventional studies 849-012 (KRYSTAL-12), 849-007 (KRYSTAL-7) and 849-001 (KRYSTAL-1)."

LysaKare - L-lysine hydrochloride / L-arginine hydrochloride - EMEA/H/C/004541/II/0018

Advanced Accelerator Applications, Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Update of sections 4.2, 4.3, 4.4, 4.8 and 5.1 of the SmPC in order to remove the contraindication and update the warning on 'Hyperkalaemia' as well as on 'Metabolic acidosis' and to update safety information based on final results from study CAAA001A12401 listed as a category 3 study in the RMP. This is a multicentre, open-label post authorization safety study to evaluate the effect of LysaKare infusion on serum potassium levels in GEP-NET patients eligible for Lutathera treatment. The RMP version 3.0 has also been submitted."

Scemblix - Asciminib - EMEA/H/C/005605/II/0017, Orphan

Novartis Europharm Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová, "Submission of a comprehensive final analysis of the data from study CABL001X2101, listed as a

category 3 study in the RMP. This is a phase I, multicentre, open-label study of oral asciminib in patients with chronic myelogenous leukaemia or Philadelphia Chromosome-positive acute lymphoblastic leukaemia. The RMP version 2.0 has also been submitted."

Tivicay - Dolutegravir - EMEA/H/C/002753/II/0093
ViiV Healthcare B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber, "Submission of the final study report for Study ING112578 (IMPAACT P1093) (Category 3 PASS); an open-label, Phase 1/2 study designed to select a DTG dose for chronic dosing of infants, children, and adolescents based on PK, safety, and tolerability. As a consequence, a revised RMP version 20 has been provided and the MAH proposes to remove long-term safety data as an area of missing information."

Zejula - Niraparib - EMEA/H/C/004249/II/0056, Orphan
GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang, PRAC Rapporteur: Jan Neuhauser, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from PRIMA study (PR-30-5017-C) listed as a PAES in the Annex II; this is a Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Niraparib Maintenance Treatment in Patients with Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy. The RMP version 9.0 has also been submitted. In addition, the MAH took the opportunity to update section D of Annex II, and to implement editorial changes to the PI."

B.6.11. PRAC assessed procedures

PRAC Led
Dengvaxia - Dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0032
Sanofi Pasteur, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik, PRAC-CHMP liaison: Daniela Philadelphy, "Submission of the final study report for DNG16 (category 3 PASS); a non-interventional Pregnancy Registry for DENGVAXIA, CYD-TDV Dengue Vaccine used to

evaluate the safety of CYD-TDV in pregnant women and their offsprings inadvertently exposed during pregnancy or up to 30 days preceding their last menstrual period with regards to maternal, pregnancy, birth, neonatal, and infant outcomes. This submission fulfils MEA/FSR 002."

PRAC Led

Entyvio - Vedolizumab - EMEA/H/C/002782/II/0086

Takeda Pharma A/S, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Submission of amendment 2 (version 3) to the final clinical study report (CSR) for the post authorisation safety study MLN0002-401, listed as a category 3 study in the RMP. This was a prospective, observational, international, multicentre, cohort study comparing vedolizumab with other biologic agents in patients with UC or CD. The final CSR (versions 1 and 2) was submitted and assessed in procedure EMEA/H/C/002782/II/0073. Further review and additional inconsistencies were identified in the analyses and reporting of safety, which are addressed in CSR amendment 2 (version 3)."

PRAC Led

EXJADE - Deferasirox - EMEA/H/C/000670/II/0090

Novartis Europharm Limited, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Update of section 4.2 of the SmPC in order to update information on posology based on the non-interventional study CICL670A2429 listed as a category 3 study in the RMP. This is a survey to assess physicians' knowledge of Exjade posology and biological monitoring recommendations as described in the Educational Materials (EMs)."

PRAC Led

Farydak - Panobinostat - EMEA/H/C/003725/II/0030, Orphan

Pharmaand GmbH, Rapporteur: Peter Mol, PRAC Rapporteur: Sofia Trantza, PRAC-CHMP liaison: Konstantina Alexopoulou, "Submission of an updated RMP version 7.0 in order to align the RMP with GVP V and GVP XVII. As a consequence, the MAH proposes to remove severe haemorrhage and severe infections

(including sepsis/pneumonia/reactivation of hepatitis B infection) as important identified risks, and developmental toxicity, carcinogenicity/second primary malignancy (SPM), and medication error as important potential risks. In addition, the MAH proposes to revise the Annex II to reflect the removal of the Patient Card and educational programme as additional risk minimisation measures."

PRAC Led

Gazyvaro - Obinutuzumab - EMEA/H/C/002799/II/0059, Orphan

Roche Registration GmbH, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 10.0 in order to remove the guided questionnaires (GQ) for secondary malignancies, progressive multifocal leukoencephalopathy and hepatitis B reactivation as well as to update the ATC code and to introduce additional updates."

PRAC Led

Mosquirix - Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0085/G

GlaxoSmithkline Biologicals SA, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "A grouped application comprised of two type II variations, as follows:

C.I.4: Update of sections 4.4 and 5.1 of the SmPC in order to remove meningitis from the list of important potential risks and add effectiveness data based on EPI-MAL-003 study listed as a category 3 study in the RMP. This is a prospective study to evaluate the safety, effectiveness and impact of the RTS,S/AS01E vaccine in young children in sub-Saharan Africa countries. The Package Leaflet is updated accordingly.
The RMP version 6.0 has also been submitted.

C.I.13: Submission of the final report from study MVPE (Malaria Vaccine Pilot Evaluation) listed as a category 3 study in the RMP. This is a observational study in the context of a cluster-randomized pilot implementation in order to assess the feasibility of delivery, safety, and

impact on mortality of the RTS,S/AS01E malaria vaccine delivered through the routine immunization services in Kenya, Malawi, and Ghana over 4 years."

PRAC Led

Nucala - Mepolizumab - EMEA/H/C/003860/II/0071

GlaxoSmithKline Trading Services Limited, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report from the Mepolizumab (Nucala) Pregnancy Exposure Study 200870: a VAMPSS post marketing surveillance study of Mepolizumab safety in pregnancy, listed as a category 3 study in the RMP. This is a non-interventional study to monitor planned and unplanned pregnancies exposed to mepolizumab and to evaluate the possible teratogenic effect of this medication relative to the pregnancy outcomes of major birth defects, preterm delivery, small for gestational age infants and spontaneous abortion or stillbirth. The RMP version 13.0 has also been submitted."

PRAC Led

Orgovyx - Relugolix - EMEA/H/C/005353/II/0024

Accord Healthcare S.L.U., PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Update of section 4.8 of the SmPC in order to amend the frequency of an existing adverse drug reactions (ADRs) 'Myocardial infarction' from 'rare' to 'uncommon' following PSUSA 00010994/202401 procedure and based on the current available clinical trial data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to add editorial changes."

PRAC Led

POTELIGEO - Mogamulizumab - EMEA/H/C/004232/II/0026, Orphan

Kyowa Kirin Holdings B.V., Rapporteur: Peter Mol, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Update of section 4.8 of the SmPC in order to add 'granuloma' to the list of adverse drug reactions (ADRs) with frequency 'unknown', based on post marketing data; the Package Leaflet is updated accordingly."

PRAC Led

Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0142

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-P920 – US PASS (Post Authorization Safety Study in the US) listed as a category 3 study in the RMP; this is a post-marketing safety of elasomeran/davesomeran and andusomeran vaccines in the United States."

PRAC Led

TachoSil - Human thrombin / Human fibrinogen - EMEA/H/C/000505/II/0131

Corza Medical GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 4.2 of the SmPC to emphasise correct product handling and section 4.8 of the SmPC to reflect the fact that cases of product non-adhesion issues have been reported, upon request by PRAC following the outcome of the PSUR procedure EMEA/H/C/PSUSA/00010297/202306. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC."

PRAC Led

WS2125

Soliris-EMEA/H/C/000791/WS2125/0133

Ultomiris-EMEA/H/C/004954/WS2125/0047

Alexion Europe SAS, Lead PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gomez-Outes, "Submission of an updated RMP version 21.0 for SOLIRIS and RMP version 9.0 for ULTOMIRIS in order to revise the controlled distribution additional risk minimisation measures and to add a new post-authorisation safety study (PASS) intended to evaluate the effectiveness of the revised additional risk minimisation measures for minimising the risk of meningococcal infections in the EU, following the PRAC outcome for PSUSA/00001198/202310 for SOLIRIS. The Annex II is updated accordingly. In addition, the MAH introduced minor updates to the SmPC to

align the wording with the updated Annex II.”

B.6.12. CHMP-CAT assessed procedures

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

PRAC Led

Tecartus - Brexucabtagene autoleucel - EMEA/H/C/005102/II/0051, Orphan, ATMP

Kite Pharma EU B.V, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Peter Mol, “Submission of the final study report for the non-interventional study KT-EU-472-5966 titled "Quantitative Testing of Health Care Professional Knowledge About Tecartus Risk Minimisation Measures'' listed as a category 3 study in the RMP.”

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

WS2751/G
Dovato- EMEA/H/C/004909/WS2751/0051/G
Juluca- EMEA/H/C/004427/WS2751/0060/G
Tivicay- EMEA/H/C/002753/WS2751/0094/G
Triumeq- EMEA/H/C/002754/WS2751/0123/G

ViiV Healthcare B.V., Lead Rapporteur: Filip Josephson, Quality variation

WS2755
Hexacima- EMEA/H/C/002702/WS2755/0161
Hexyon- EMEA/H/C/002796/WS2755/0165

Sanofi Pasteur Europe, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus, Quality variation

WS2764/G
Hefiya- EMEA/H/C/004865/WS2764/0054/G
Hyrimoz- EMEA/H/C/004320/WS2764/0053/G

Sandoz GmbH, Lead Rapporteur: Christian Gartner"C.I.2.a - To update section 4.8 of the SmPC to clarify that the malignancy reported rates come from the spontaneously reported date, following assessment and approval of the same changes in the reference product, Humira. C.I.z - To update section 2 ("What you need to know before you use Hefiya") to be in line with the reference product, Humira. Furthermore, the Marketing Authorisation Holder has also taken the opportunity to: -Update the local representative details for Luxembourg, Denmark, Slovakia, and Cyprus. -Implement editorial changes in the following translations: CS, DA, DE, EL, ET, FI, FR, HU, LT, MT, NO, PT, RO, SV, SK, and SL."	
WS2765/G **Aflunov-** **EMEA/H/C/002094/WS2765/0087/G** **Foclivia-** **EMEA/H/C/001208/WS2765/0090/G** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2765/0006/G** Seqirus S.r.l., Informed Consent of Aflunov, Lead Rapporteur: Maria Grazia Evandri, Quality variation	
WS2772 **Jubbonti-** **EMEA/H/C/005964/WS2772/0004** **Wyost-EMEA/H/C/006378/WS2772/0003** Sandoz GmbH, Lead Rapporteur: Christian Gartner, Quality variation	
WS2775/G **Aflunov-** **EMEA/H/C/002094/WS2775/0088/G** **Foclivia-** **EMEA/H/C/001208/WS2775/0091/G** Seqirus S.r.l, Lead Rapporteur: Maria Grazia Evandri, Quality variation	
WS2779 **Aflunov-** **EMEA/H/C/002094/WS2779/0089** **Foclivia-** **EMEA/H/C/001208/WS2779/0092** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2779/0007** Seqirus S.r.l, Lead Rapporteur: Maria Grazia	

Evandri, Quality variation
WS2785 **Aflunov-** **EMEA/H/C/002094/WS2785/0090** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2785/0008** Seqirus S.r.l, Lead Rapporteur: Maria Grazia Evandri, 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.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