31 October 2024
EMA/CHMP/285355/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Minutes for the meeting on 27-30 May 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

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

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

Participants were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. 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 27-30 May 2024

The CHMP adopted the agenda.

1.3. Adoption of the minutes

The CHMP adopted the minutes for the 22-25 April 2024 plenary.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 21 May 2024.

The CHMP adopted the minutes from the PROM meeting held on 21 May 2024.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

SIFI SPA; treatment of acanthamoeba keratitis

Scope: Oral explanation

Action: Oral explanation to be held on 28 May 2024 at 14:00

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

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

See 3.1

2.1.2. Epinephrine - EMEA/H/C/006139

Treatment of allergic reactions (anaphylaxis) and idiopathic or exercise induced anaphylaxis

Scope: Oral explanation

Action: Oral explanation to be held on 27 May 2024 at 16:00

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 23.02.2023.

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

See 3.2

2.1.3. Leniolisib - Orphan - EMEA/H/C/005927

Pharming Technologies B.V.; Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)

Scope: Oral explanation

Action: Oral explanation to be held on 28 May 2024 at 09:00

List of Outstanding Issues adopted on 25.01.2024, 09.11.2023, 20.07.2023. List of Questions adopted on 24.01.2023.

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

See 3.2.

2.1.4. 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 28 May 2024 at 16:00

Participation of patient representatives.

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

An oral explanation was held on 28 May 2024. The presentation by the applicant focused on the clinical data in support of the application.

See 3.2

2.2. Re-examination procedure oral explanations

2.2.1. Nezglyal - Leriglitazone - Orphan - EMEA/H/C/005757

Minoryx Therapeutics S.L.; the treatment of cerebral progression and myelopathy in male patients with adrenoleukodystrophy (ALD).

Scope: Oral explanation

Action: Oral explanation to be held on 28 May 2024 at 11:00

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

Opinion adopted on 25.01.2024. List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 15.12.2022.

An oral explanation was held on 28 May 2024. The presentation by the applicant focused on the clinical data in support of the application.

See 3.5

2.3. Post-authorisation procedure oral explanations

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

Boehringer Ingelheim International GmbH;

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

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (150 mg) and new route of administration (subcutaneous use), for the prevention of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age.

This line extension is grouped with a type II variation (C.I.6.a) to extend indication for Spevigo 450 mg concentrate for solution for infusion to include treatment of generalised pustular psoriasis (GPP) flares in adolescents (from 12 years of age), based on final results from study 1368-0027 (Effisayil 2) and extrapolation; this is a multi-center, randomized, parallel group, double blind, placebo controlled, phase IIb dose-finding study to evaluate efficacy and safety of BI 655130 (spesolimab) compared to placebo in preventing GPP flares in patients with history of GPP. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI and update the list of local representatives in the Package Leaflet."

Scope: Possible Oral Explanation

Action: Possible oral explanation to be held on 29 May 2024 at 16:00

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

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

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. ADZYNMA - rADAMTS13 - Orphan - EMEA/H/C/006198

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

Scope: Opinion

Action: For adoption

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

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

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

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

Furthermore, the CHMP considered that rADAMTS13 is a new active substance, as claimed by the applicant.

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

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

SIFI SPA; treatment of acanthamoeba keratitis

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 15.09.2022.

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 consensus together with the CHMP assessment report and translation timetable.

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

The summary of opinion was circulated for information.

3.1.3. Apexelsin - Paclitaxel - EMEA/H/C/005997

Whiteoak Pharmaceutical B.V.; treatment of metastatic breast cancer

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 13.10.2022. List of Questions adopted on 19.05.2022.

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.4. Avzivi - Bevacizumab - EMEA/H/C/005574

FGK Representative Service GmbH; treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer. First-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer. First-line treatment of patients with advanced and/or metastatic renal cell cancer.

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 24.02.2022. List of Questions adopted on 22.04.2021.

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.5. Cejemly - Sugemalimab - EMEA/H/C/006088

SFL Pharmaceuticals Deutschland GmbH; treatment of adults with metastatic non-small-cell lung cancer (NSCLC)

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 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.

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

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

The summary of opinion was circulated for information.

3.1.6. Dasatinib Accord Healthcare - Dasatinib - EMEA/H/C/006251

Accord Healthcare S.L.U.; Indicated for the treatment of chronic myelogenous leukaemia (CML)

Scope: Opinion

Action: For adoption

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

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

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.7. Durveqtix Fidanacogene elaparvovec - PRIME - ATMP - EMEA/H/C/004774

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

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 15.03.2024. List of Questions adopted on 08.09.2023.

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

Based on the draft opinion prepared by the CAT, the Committee adopted a positive opinion recommending the granting of a conditional marketing authorisation by majority (26 out of 30) together with the CHMP assessment report and translation timetable.

The divergent opinion (Jan Mueller-Berghaus, Simona Badoi, Outi Mäki-Ikola, Martina Weise, Hrefna Gudmundsdottir) was appended to the opinion.

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.8. Fluenz - Influenza vaccine (live attenuated, nasal) - EMEA/H/C/006514

AstraZeneca AB; Prophylaxis of influenza

Scope: Opinion scheduled for adoption at the May PROM Meeting

Action: For information

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

The Committee noted the positive opinion adopted by consensus at the PROM on May 21st recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

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

The summary of opinion was circulated for information.

3.1.9. GalliaPharm - Germanium (68Ge) chloride / Gallium (68Ga) chloride - EMEA/H/C/006053

Eckert & Ziegler Radiopharma GmbH; indicated for in vitro radiolabelling of specific carrier molecules to be used for positron emission tomography (PET) imaging

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 26.04.2023.

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.

3.1.10. IXCHIQ - Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated - PRIME – OPEN - EMEA/H/C/005797

Valneva Austria GmbH; prevention of disease caused by chikungunya (CHIKV) virus

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 23.04.2024. List of Questions adopted on 20.02.2024.

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 Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated is a new active substance, as claimed by the applicant.

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

The summary of opinion was circulated for information.

3.1.11. Pomalidomide Accord - Pomalidomide - EMEA/H/C/006273

Accord Healthcare S.L.U.; treatment of adult patients with multiple myeloma

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 25.01.2024.

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.12. Pomalidomide Krka - Pomalidomide - EMEA/H/C/006314

KRKA, d.d., Novo mesto; treatment of multiple myeloma

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 25.01.2024.

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.13. Pomalidomide Zentiva - Pomalidomide - EMEA/H/C/006294

Zentiva, k.s.; treatment of adults with multiple myeloma

Scope: Opinion

Action: For adoption

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

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 25.01.2024.

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

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

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

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report

3.1.14. Zegalogue - Dasiglucagon - EMEA/H/C/006214

Zealand Pharma A/S; treatment of severe hypoglycemia in patients with diabetes

Scope: Opinion

Action: For adoption

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

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

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

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

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

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

The summary of opinion was circulated for information.

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

3.2.1. Delgocitinib - EMEA/H/C/006109

treatment of moderate to severe chronic hand eczema (CHE)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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

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

3.2.2. Epinephrine - EMEA/H/C/006139

Treatment of allergic reactions (anaphylaxis) and idiopathic or exercise induced anaphylaxis

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 23.02.2023.

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

The CHMP agreed to consult the Methodology Working Party (MWP) and adopted a list of questions to this group.

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

3.2.3. Ustekinumab - EMEA/H/C/005805

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

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

The CHMP agreed to consult the Methodology Working Party (MWP) and adopted a list of questions to this group.

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

3.2.4. Trastuzumab - EMEA/H/C/006252

is indicated for the treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and HER2 positive early breast cancer (EBC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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

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

3.2.5. Elafibranor - Orphan - EMEA/H/C/006231

Ipsen Pharma; treatment of primary biliary cholangitis (PBC)

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.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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

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

3.2.7. Leniolisib - Orphan - EMEA/H/C/005927

Pharming Technologies B.V.; Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 25.01.2024, 09.11.2023, 20.07.2023. List of Questions adopted on 24.01.2023.

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

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

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

The Committee adopted a 4th list of outstanding issues with a specific timetable.

See 2.1.

3.2.8. Zapomeran – OPEN - EMEA/H/C/006207

active immunisation to prevent COVID-19

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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

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

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

3.2.9. Masitinib - Orphan - EMEA/H/C/005897

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

Scope: List of outstanding issues

Action: For adoption

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

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

The Committee adopted a 3rd list of outstanding issues with a specific timetable.

3.2.10. Ustekinumab - EMEA/H/C/006544

treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, Crohn's Disease.

Scope: List of outstanding issues

Action: For adoption

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

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

3.2.11. Lutetium (177Lu) chloride - EMEA/H/C/005882

radiolabelling of carrier molecules, which have been specifically developed for radiolabelling with this radionuclide

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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

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

3.2.12. Ciclosporin - EMEA/H/C/006250

Treatment of dry eye disease in adult patients

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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

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

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

3.3.1. 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 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. Trastuzumab - EMEA/H/C/006219

treatment of metastatic and early breast cancer

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.3. Diflunisal - Orphan - EMEA/H/C/006248

AO Pharma AB; Treatment of ATTR amyloidosis

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

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

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.5. Lazertinib - EMEA/H/C/006074

treatment of adult patients with advanced non-small cell lung cancer (NSCLC)

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.6. Linvoseltamab - EMEA/H/C/006370

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

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.7. Nemolizumab - EMEA/H/C/006149

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

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

treatment of neutropenia in paediatric patients

Scope: List of questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.9. 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 questions

Action: For adoption

The Committee discussed the issues identified in this application.

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

3.3.10. Trabectedin - EMEA/H/C/006433

treatment of soft tissue sarcoma and combination with PLD treatment of relapsed platinum-sensitive ovarian 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. Autologous cartilage-derived articular chondrocytes, in-vitro expanded - ATMP - EMEA/H/C/004594

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

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

Action: For adoption

List of Questions adopted on 19.04.2024.

Postponed to the June 2024 CAT and CHMP plenary meetings.

3.4.2. Catumaxomab - EMEA/H/C/005697

indicated for the treatment of malignant ascites

Scope: Correspondence by the applicant dated 24.05.2024 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in April 2024.

Action: For adoption

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

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 April 2024.

3.4.3. Zolbetuximab - Orphan - EMEA/H/C/005868

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

Scope: Change of timetable to respond to the list of outstanding issues adopted in March 2024

Action: For information

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

The CHMP noted the change of timetable to the list of outstanding issues adopted in March 2024.

3.4.4. insulin glargine - EMEA/H/C/006136

treatment of diabetes mellitus

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the List of Questions adopted in December 2023.

Action: For adoption

List of Questions adopted on 14.12.2023.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions issues adopted in December 2023.

3.4.5. Insulin lispro - EMEA/H/C/006158

treatment of diabetes mellitus

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the List of Questions adopted in January 2024.

Action: For adoption

List of Questions adopted on 25.01.2024.

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

3.4.6. Insulin aspart - EMEA/H/C/006187

treatment of diabetes mellitus

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the List of Questions adopted in January 2024.

Action: For adoption

List of Questions adopted on 25.01.2024.

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

3.4.7. Troriluzole - Orphan - EMEA/H/C/006068

Biohaven Bioscience Ireland Limited; is indicated for the treatment of adult patients with spinocerebellar ataxia genotype 3 (SCA3)

Scope: Letter by the applicant requesting an extension to the clock stop to respond to the List of Questions adopted in February 2024.

Action: For adoption

List of Questions adopted on 22.02.2024.

The CHMP agreed to the request the applicant for an extension to the clock stop to respond to the List of Questions adopted in February 2024.

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

3.5.1. Nezglyal - Leriglitazone - Orphan - EMEA/H/C/005757

Minoryx Therapeutics S.L.; the treatment of cerebral progression and myelopathy in male patients with adrenoleukodystrophy (ALD).

Scope: Re-examination opinion

Action: For adoption

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

Opinion adopted on 25.01.2024. List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 15.12.2022.

See 2.2

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

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

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. KINHARTO - Omecamtiv mecarbil - EMEA/H/C/006112

Cytokinetics (Ireland) Limited; treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction less than 30%

Scope: Withdrawal of initial marketing authorisation application

Action: For information

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

List of Outstanding Issues adopted on 21.03.2024, 14.12.2023. List of Questions adopted on 26.04.2023.

The CHMP noted the withdrawal of the marketing authorisation application.

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

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

4.1.1. Bimzelx - Bimekizumab - EMEA/H/C/005316/X/0021

UCB Pharma S.A.;

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to add a new strength of 320 mg (160 mg/ml) for bimekizumab solution for injection in pre-filled syringe or pre-filled pen, for subcutaneous (SC) administration."

Action: For adoption

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 25.01.2024.

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

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

The summary of opinion was circulated for information.

4.1.2. Eliquis - Apixaban - EMEA/H/C/002148/X/0089/G

Bristol-Myers Squibb / Pfizer EEIG;

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to:
1) Introduce a new pharmaceutical form (granules in single-dose container) associated with a new strength (0.15 mg).
2) Introduce a new pharmaceutical form (coated granules in sachet) associated with 3 new strengths (0.5 mg, 1.5 mg and 2 mg).
The above two line extensions are grouped with a type II - C.I.6.a variation:
Extension of indication to include the treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to less than 18 years of age

for Eliquis (all strengths), based on a pre-specified interim analysis from Study CV185325; this is an open-label, multi-centre, randomized, active controlled trial to provide PK data and data on anti-Xa activity to support the extrapolation of efficacy to children, to evaluate safety and efficacy of apixaban in children who require anticoagulation for a venous thromboembolism; As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPCs are updated. The Package Leaflet and Annex II are updated in accordance. Version 21.3 of the RMP has also been submitted."

Action: For adoption

List of Questions adopted on 14.12.2023.

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

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

The summary of opinion was circulated for information.

4.1.3. Reagila - Cariprazine - EMEA/H/C/002770/X/0033

Gedeon Richter Plc.;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension application to introduce a new pharmaceutical form (orodispersible tablets).
The RMP (version 3.0) is updated in accordance."

Action: For adoption

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

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

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

The summary of opinion was circulated for information.

4.1.4. Rybelsus - Semaglutide - EMEA/H/C/004953/X/0038

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt

Scope: "Extension application to introduce three new strengths of tablets (1.5 mg, 4 mg and 9 mg) for semaglutide."

Action: For adoption

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 22.02.2024.

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

addressed.

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

The summary of opinion was circulated for information.

4.1.5. Skyrizi - Risankizumab - EMEA/H/C/004759/X/0043/G

AbbVie Deutschland GmbH & Co. KG;

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new strength of 180 mg of risankizumab (solution for injection in cartridge), grouped with a type II variation extension of indication (C.I.6.a) to add a new indication (treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy). As a consequence of the extension of indication, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 5.3, 6.5 and 6.6 of the SmPC are updated. The Annex II, Labelling and Package Leaflets are updated in accordance. In addition, the marketing authorisation holder has taken the opportunity to update the list of local representatives in the PL. The RMP version 5.3 is adopted.

Action: For adoption

List of Outstanding Issues adopted on 25.04.2024. List of Questions adopted on 25.01.2024.

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

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

The summary of opinion was circulated for information.

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

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

Janssen-Cilag International N.V.;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (2.5 mg dispersible tablets). The new presentation is indicated, in combination with other antiretroviral medicinal products, for the treatment of HIV-1 infection in patients ≥2 to <18 years of age and weighing at least 10 kg to less than 25 kg. The PI and RMP have been updated in accordance.

Type II variation (C.I.6.a) to modify the approved therapeutic indication of the already authorised 25 mg film-coated tablets presentation to include, in combination with other antiretroviral medicinal products, treatment of human immunodeficiency virus type 1 (HIV-

1) infection in antiretroviral treatment-naïve and virologically suppressed (HIV-1 RNA less than 50 copies per ml) paediatric patients from 2 to less than 12 years weighing at least 25 kg, based on final results from study studies TMC278-TiDP38-C213 Cohort 2. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. The updated RMP version 10.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to Annex II and to update the list of local representatives in the Package Leaflet."

Action: For adoption

List of Questions adopted on 14.12.2023

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

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

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

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt

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

Action: For adoption

List of Questions adopted on 22.02.2024.

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

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

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

Boehringer Ingelheim International GmbH;

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

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (150 mg) and new route of administration (subcutaneous use), for the prevention of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age.
This line extension is grouped with a type II variation (C.I.6.a) to extend indication for Spevigo 450 mg concentrate for solution for infusion to include treatment of generalised pustular psoriasis (GPP) flares in adolescents (from 12 years of age), based on final results from study 1368-0027 (Effisayil 2) and extrapolation; this is a multi-center, randomized, parallel group, double blind, placebo controlled, phase IIb dose-finding study to evaluate efficacy and safety of BI 655130 (spesolimab) compared to placebo in preventing GPP flares in patients with history of GPP. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI and

update the list of local representatives in the Package Leaflet."

Action: For adoption

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

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

The Committee adopted the CHMP recommendation and scientific discussion together with a 2nd 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. Lyrica - Pregabalin - EMEA/H/C/000546/X/0127

Upjohn EESV;

Rapporteur: Peter Mol, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new pharmaceutical form (orodispersible tablet)"

Action: For adoption

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

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

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

No items

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

No items

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

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

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

Sanofi Winthrop Industrie;

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

Scope: "Extension of indication to include treatment of children up to 24 months of age who remain vulnerable to severe Respiratory Syncytial Virus (RSV) disease through their second RSV season for BEYFORTUS, based on interim results from studies D5290C00005 and D5290C00008.
Study D5290C00005 (MEDLEY) is a Phase II/III, randomized, double-blind, placebo-controlled study to evaluate the safety of Beyfortus in high-risk children. Study D5290C00008 (MUSIC) is a Phase II, open-label, uncontrolled, single-dose study to evaluate the safety and tolerability, pharmacokinetics, and occurrence of antidrug antibody for Beyfortus in immunocompromised children ≤ 24 Months of Age.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 2.1 of the RMP has also been submitted.
In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

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

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

The Committee adopted a 5th 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

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

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

5.1.3. Dupixent - Dupilumab - EMEA/H/C/004390/II/0079

Sanofi Winthrop Industrie;

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication for DUPIXENT to include treatment of adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterised by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate, based on final results from study EFC15804 (BOREAS) and interim results from study EFC15805 (NOTUS); this is a phase 3, randomized, double blind, placebo-controlled, multi-center, parallel group, 52-week study to assess the efficacy, safety and tolerability of dupilumab in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD) with type 2 inflammation. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet is updated in accordance. Version 10.3 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

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

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

The summary of opinion was circulated for information.

5.1.4. Dupixent - Dupilumab - EMEA/H/C/004390/II/0083

Sanofi Winthrop Industrie;

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

Scope: "Extension of indication to include treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents 12 years and older, who are symptomatic despite treatment with H1 antihistamines and who are intolerant to or inadequately controlled by anti-IgE therapy for Dupixent, based on the results from studies EFC16461 (CUPID) study B (pivotal) and study A (supportive); EFC16461 Study B was a 24-week, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of dupilumab in adult and adolescent participants with CSU who remained symptomatic despite the use of H1-antihistamine and who were intolerant or incomplete responders to omalizumab and EFC16461 Study A was a 24-week, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of dupilumab in participants with CSU

who remained symptomatic despite the use of H1-antihistamine and who were naïve to omalizumab. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11.0 of the RMP has also been submitted."

Action: For adoption

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

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

5.1.5. Kinpeygo - Budesonide - Orphan - EMEA/H/C/005653/II/0008

STADA Arzneimittel AG;

Rapporteur: Christian Gartner, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: "Extension of indication to slow kidney function decline in adults with primary immunoglobulin A (IgA) nephropathy (IgAN) for KINPEYGO, based on Part B of study NefIgArd (NEF-301), listed as the final specific obligation in the Annex II in the initial MA; this is a Phase 3, randomised, double-blind, placebo-controlled, multicenter study to evaluate the efficacy, safety, and tolerability of oral Nefecon compared to matching placebo in patients with primary IgAN on a background of optimized RAS inhibitor therapy. 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 1.3 of the RMP has been agreed.
In addition, the CHMP, having considered the application as set out in the appended assessment report and having reviewed the data submitted by the marketing authorisation holder including the evidence concerning compliance with specific obligations, is of the opinion that the risk-benefit balance of the above mentioned medicinal product remains favourable, that all specific obligations laid down in Annex II have been fulfilled and that comprehensive data supports a favourable benefit-risk balance of the above mentioned medicinal product. Therefore, pursuant to Article 14-a(8) of Regulation (EC) No 726/2004, the CHMP recommends by consensus the granting of a marketing authorisation in accordance with Article 14(1) of Regulation (EC) No 726/2004 for the above mentioned medicinal product for which the draft Summary of Product Characteristics is set out in Annex I."

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

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

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

The summary of opinion was circulated for information.

5.1.6. LIVMARLI - Maralixibat - Orphan - EMEA/H/C/005857/II/0003/G

Mirum Pharmaceuticals International B.V.;

Rapporteur: Martina Weise, PRAC Rapporteur: Adam Przybylkowski

Scope: "Grouped variation consisting of:

1) Extension of indication to include treatment of Progressive Familial Intrahepatic Cholestasis (PFIC) in patients 3 months of age and older for LIVMARLI, based on results from studies MRX-502, LUM001-501, MRX-503, MRX-800 and MRX-801; MRX-502 is an international, multicenter, randomized, double-blind, placebo-controlled, parallel group Phase 3 study that evaluated the efficacy and safety of maralixibat in PFIC participants aged >12 months to <18 years on a proposed dosage of up to 600 µg/kg BID over 6 months. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Annex II are updated in accordance. Version 4.1 of the RMP is agreed. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the labelling.

2) B.I.b.1.b – Quality

The group of variations leads to amendments to the Summary of Product Characteristics, Annex II, Labelling, Package Leaflet and to the Risk Management Plan (RMP)."

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, 14.12.2023, 20.07.2023.

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

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

The summary of opinion was circulated for information.

5.1.7. Palforzia - Defatted powder of *Arachis hypogaea L.,* semen (peanuts) - EMEA/H/C/004917/II/0014/G

Aimmune Therapeutics Ireland Limited;

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kirsti Villikka

Scope: "Grouped variation consisting of:
C.I.6.a (Extension of indication): Extension of indication to include treatment of patients 1 to 3 years old for PALFORZIA, based on final results from study ARC005; this is a Phase 3 randomized, double-blind, placebo-controlled Peanut Oral Immunotherapy Study of Early Intervention for Desensitization (POSEIDON) to evaluate the safety and efficacy of peanut powder in terms of superiority of placebo in children of 1 year to less than 4 years of age with peanut allergy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 6.5 and 8 of the SmPC are updated. The Package Leaflet and Labelling were updated accordingly. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC 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.

B.II.e.5.a: Introduction of a new pack-size for PALFORZIA, 1 mg, oral powder in capsules for opening.

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 14.12.2023.

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

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

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

Pharmaand GmbH;

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Grouped application consisting of:
Extension of indication to include treatment of Polycythaemia Vera (PV) and Essential thrombocytopenia (ET) for PEGASYS, based on published data of clinical studies conducted in support of the efficacy and safety of Pegasys for the treatment of ET and PV. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 22.02.2024.

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

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

5.1.9. Ronapreve - Casirivimab / Imdevimab - EMEA/H/C/005814/II/0017

Roche Registration GmbH;

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indication to include treatment of paediatric patients from 2 to less than 12 years old, weighing at least 10kg, who do not require supplemental oxygen and who are at increased risk of progression to severe COVID-19 for Ronapreve, based on final results from study COV-2067; this was a seamless, adaptive, Phase 3, randomized, double-blinded, placebo-controlled, multi-centre study to evaluate the efficacy, safety, and tolerability of casirivimab+imdevimab combination therapy in paediatric and adult outpatients with mild to moderate COVID-19. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."

Action: For adoption

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

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

5.1.10. RYBREVANT - Amivantamab - EMEA/H/C/005454/II/0013

Janssen-Cilag International N.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include amivantamab in combination with lazertinib for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 L858R substitution mutations (EGFRm NSCLC), based on results from study 73841937NSC3003 (MARIPOSA). This is a randomized, open-label, Phase 3 study that compares the efficacy and safety of the combination of amivantamab and lazertinib (Arm A) versus osimertinib monotherapy (Arm B) and lazertinib monotherapy (Arm C) in participants with EGFRm NSCLC. The primary objective of the MARIPOSA study was to assess the efficacy of the combination of amivantamab and lazertinib (Arm A), compared with osimertinib (Arm B), as measured by PFS assessed by BICR in adult participants with EGFRm NSCLC.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1, 5.2, 6.6 and 9 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.3 of the EU 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

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

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

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

Proveca Pharma Limited;

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

Scope: "Extension of indication to include treatment of children aged from 2 years and older for SIALANAR, based on the interim results from study PRO/GLY/005. This is a retrospective analysis of real-world data from children aged under 3 years treated with glycopyrronium for severe drooling. As a consequence, sections 4.1, 4.2, and 4.4 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

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.

5.1.12. Synjardy - Empagliflozin / Metformin - EMEA/H/C/003770/II/0078

Boehringer Ingelheim International GmbH;

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

Scope: "Extension of indication to include the treatment of children aged 10 years and above with type 2 diabetes for Synjardy, based on the final results from study 1218-0091 (DINAMO) - A double-blind, randomised, placebo-controlled, parallel group trial to evaluate the efficacy and safety of empagliflozin and linagliptin over 26 weeks, with a double-blind active treatment safety extension period up to 52 weeks, in children and adolescents with type 2 diabetes mellitus. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 16.0 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."

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. TAGRISSO - Osimertinib - EMEA/H/C/004124/II/0053

AstraZeneca AB;

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include TAGRISSO in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations, based on final results from study FLAURA2 (D5169C00001); this is a Phase III, open-label, randomized study of osimertinib with or without platinum plus pemetrexed chemotherapy, multicentre study to assess the efficacy and safety of TAGRISSO as first-line treatment in patients with EGFR mutation-positive, locally advanced or metastatic NSCLC. 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 16.2 of the RMP has also been agreed."

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024, 14.12.2023.

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

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

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

The summary of opinion was circulated for information.

5.1.14. Tepkinly - Epcoritamab - Orphan - EMEA/H/C/005985/II/0001

AbbVie Deutschland GmbH & Co. KG;

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

Scope: "Extension of indication to include treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy for TEPKINLY, based on results from the indolent Non-Hodgkins Lymphoma (iNHL) expansion cohort of Study GCT3013-01, the First In Human (FIH) Phase 1/2 study in R/R B-NHL, with key supportive data from the Phase 1b/2 Study GCT3013-04 in Japanese subjects. Study GCT3013-01 is an ongoing global, single-arm, Phase 1/2 study designed to evaluate epcoritamab as monotherapy in R/R B-NHL. As a consequence, sections 1, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3, 6.4, 6.5 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 22.02.2024.

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

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

5.1.15. 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 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 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

Action: For adoption

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

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

5.1.16. Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0008

Beigene Ireland Limited;

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

Scope: "Extension of indication to include treatment of adult patients with non-small cell lung cancer (NSCLC) in combination and as monotherapy for TEVIMBRA, based on results from studies BGB-A317-303, BGB-A317-304, BGB-A317-307 and BGB A317-206. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

Action: For adoption

The Committee 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.

5.1.17. Valdoxan - Agomelatine - EMEA/H/C/000915/II/0051

Les Laboratoires Servier;

Rapporteur: Eva Skovlund, PRAC Rapporteur: Pernille Harg

Scope: "Update of sections 4.2, 4.4, 4.8, 5.1 5.2 of the SmPC to reflect the results of the phase 2 (CL2-20098-075) and phase 3 (CL3-20098-076) paediatric clinical studies. The PL has been updated accordingly. In addition, section 6.6 of the SmPC was updated to reflect the Safety Working Party position."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024, 14.12.2023, 22.06.2023, 26.01.2023.

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.

5.1.18. 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

The Committee discussed the issues identified in this application, relating to clinical aspects and the request for 1 year of market protection.

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

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

Pierre Fabre Medicament;

Lead Rapporteur: Janet Koenig, PRAC Rapporteur: Rugile Pilviniene

Scope: "Extension of indication to include binimetinib in combination with encorafenib for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with a BRAF V600 mutation for MEKTOVI and BRAFTOVI based on results from study PHAROS (Study ARRAY-818-202) at the primary completion date; this is a Phase II, open-label, multicentre, non-comparative study (interventional). As a consequence, sections 4.1, 4.4, 4.8, 5.1, 5.2, 9 and 10 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection for MEKTOVI.", 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 25.01.2024.

The Committee discussed the issues identified in this application, relating to clinical aspects and the request for 1 year of market protection.

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

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

Vertex Pharmaceuticals (Ireland) Limited;

Lead Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

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

The Package Leaflet is updated in accordance. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 22.02.2024.

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

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

The CHMP agreed to consult an ad-hoc expert group (AHEG) and adopted a list of question to this group.

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

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

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

Scope: List of Questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted a request for supplementary information 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/006530

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

Scope: Request for supplementary information

Action: For adoption

The Committee discussed the issues identified in this application.

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

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. Belantamab mafodotin - Orphan - H0006511

Glaxosmithkline (Ireland) Limited; product is indicated for the treatment of multiple myeloma:
• in combination with bortezomib and dexamethasone in adult patients, who have received at least one prior therapy
• in combination with pomalidomide and dexamethasone in adult patients, who have received at least one prior therapy including lenalidomide

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

Action: For adoption

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

8.1.2. lifileucel - H0004741

Patients with unresectable or metastatic melanoma who have previously been treated with at least one systemic therapy, including a PD-1 blocking antibody and if BRAF V600 mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor

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

Action: For adoption

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

8.1.3. sipavibart - H0006291

Pre-exposure prophylaxis of COVID-19

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

Action: For adoption

The CHMP agreed to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

8.2. Priority Medicines (PRIME)

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

The CHMP adopted the recommendations for PRIME eligibility.

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. 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

The Committee discussed the issues identified in this application.

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

9.1.2. Lymphoseek – tilmanocept – EMEA/H/C/002085

Navidea Biopharmaceuticals Europe Ltd.; used in the delineation and localisation of lymph nodes

Rapporteur: Finbarr Leacy, Co-Rapporteur: Larisa Gorobets

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of marketing authorisation.

9.1.3. Remsima - Infliximab - EMEA/H/C/002576/II/0133/G

Celltrion Healthcare Hungary Kft.

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

Scope: Update of section 4.2, 4.8 and 5.1 of the SmPC in order to add 3-IV induction dosing regimen based on Week 54 data from studies CT-P13 3.7 (ulcerative colitis) and CT-P13 3.8 (Crohn's disease), listed as a category 3 study in the RMP.

Study CT-P13 3.7 is a Randomized, Placebo Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis and study CT-P13 3.8 is a Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Crohn's Disease.

The RMP version 16.2 was agreed. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce minor updates to the PI.

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024, 21.03.2024 and 09.11.2023.

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

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

The summary of opinion was circulated for information. The Committee also agreed to publish the full CHMP assessment report in the interest to the public.

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

PTC Therapeutics International Limited

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

Scope: Update on procedure, re-adoption of SAG questions, adoption of ad-hoc timetable

Action: For adoption

Negative Opinion adopted on 25.01.2024. Opinion adopted on 14.09.2023. Request for Supplementary Information adopted on 25.05.2023.

The CHMP has restarted the evaluation of the application.

The CHMP adopted the list of question to SAG with a specific timetable.

See the Meeting highlights from May 2024 CHMP meeting.

10. Referral procedures

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

10.1.1. Mysimba - naltrexone hydrochloride / bupropion hydrochloride - EMEA/H/C/003687/A20/0065

Orexigen Therapeutics Ireland Limited

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

Scope: Revised timetable

Action: For adoption

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Mysimba (naltrexone/bupropion), taking into account any consequences from the failure to comply with the obligations laid down in the marketing authorisation.
This review of all available data on the potential long-term cardiovascular risk and its impact on the benefit-risk balance of Mysimba in its approved indication was considered needed in view of the remaining concern and lack of adequate study plan to address the uncertainty about this risk.

CHMP list of outstanding issues adopted on 25.04.2024 and 14.12.2023. List of Questions adopted on 14.09.2023.

The CHMP noted that the Rapporteur stepped down and appointed Kristina Dunder as a new referral Rapporteur .

The CHMP adopted the LoQ with the timetable.

List of questions: 30 May 2024

Submission of responses: 19 August 2024

Re-start of the procedure: 12 September 2024

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 24 September 2024

Comments: 02 October 2024

Updated rapporteur/co-rapporteur assessment reports circulated to CHMP: 08 October 2024

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

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

Advanz Pharma Limited

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

Scope: List of experts for AHEG, updated timetable

Action: For adoption

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

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

The CHMP adopted the list of experts for the AHEG on 12 June 2024 and an updated timetable reflecting the date of the AHEG.

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

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

Action: For information

The CHMP noted the information.

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

such inspections

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by proxy

Bruno Delafont gave a proxy to Jean-Michel Race from Monday to Wednesday, and to Alexandre Moreau for Thursday of the CHMP meeting.

Blanka Hirschlerova gave a proxy to Tomas Radimersky for Tuesday afternoon.

14.1.2. Strategic review and learning meeting (SRLM) under Belgian EU presidency

Agenda for the SRLM, to be held 03 – 05 June 2024 in Brussels

CHMP: Christophe Focke

Action: For information

The CHMP noted the agenda for the strategic review and learning meeting.

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

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

Action: For adoption

The CHMP adopted the EURD list.

14.2.2. Paediatric Committee (PDCO)

Agenda of the May 2024 PDCO plenary meeting.

Action: For information

The CHMP noted the PDCO agenda.

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Reports from the BWP meeting for CHMP adoption

Action: For adoption

The CHMP adopted the BWP reports.

14.3.2. Name Review Group (NRG)

No items

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 13-16 May 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.

14.3.4. Ad-hoc Influenza Working Group

Scope: EU Strain selection for the Influenza Vaccines for the Season 2024/2025: Amended Report from the Ad Hoc Influenza working group to the BWP

Action: For adoption

Scope: Amended EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2024/2025

The CHMP adopted the revised report on EU Strain selection.

14.3.5. Methodology Working Party (MWP)

Chairs: Christian B. Roes, Kristin Karlsson MWP response to the request from CHMP to draft some text for requesting tipping point sensitivity analysis for survival endpoints.

CHMP: Bruno Delafont

Action: For adoption

The CHMP adopted the MWP response.

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.

15. Any other business

15.1. AOB topic

No items

16. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 27-30 May 2024 CHMP meeting, which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Daniela Philadelphy	Member	Austria	No interests declared	
Christian Gartner	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Lyubina Racheva Todorova	Member	Bulgaria	No interests declared	
Gergana Lazarova	Alternate	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Emilia Mavrokordatou	Alternate	Cyprus	No interests declared	
Tomas Radimersky	Member	Czechia	No interests declared	
Petr Vrbata	Alternate	Czechia	No interests declared	
Thalia Marie Estrup Blicher	Member	Denmark	No interests declared	
Aaron Sosa Mejia	Alternate	Denmark	No participation in discussion, final deliberations and voting on:	Rybelsus - Semaglutide - EMEA/H/C/004953/X/0038 Rybelsus - Semaglutide - EMEA/H/C/004953/X/0039
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No participation in discussion, final deliberations and voting on:	KINHARTO - Omecamtiv mecarbil - EMEA/H/C/006112

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Beata Maria Jakline Ullrich	Alternate	Hungary	No interests declared	
Hrefna Gudmundsdottir	Member	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Finbarr Leacy	Alternate	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Vilma Petrikaite	Member	Lithuania	No interests declared	
Larisa Gorobets	Alternate	Lithuania	No restrictions applicable to this meeting	
Martine Trauffler	Member	Luxembourg	No interests declared	
Alexandra Branchu	Alternate	Luxembourg	No participation in discussion, final deliberations and voting on:	Beyfortus - Nirsevimab - EMEA/H/C/005304 /II/0005 Dupixent - Dupilumab - EMEA/H/C/004390 /II/0079 Dupixent - Dupilumab - EMEA/H/C/004390 /II/0083
John Joseph Borg	Member	Malta	No interests declared	
Peter Mol	Member	Netherlands	No interests declared	
Patrick Vrijlandt	Alternate	Netherlands	No interests declared	
Ingrid Wang	Member	Norway	No interests declared	
Eva Skovlund	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No restrictions applicable to this meeting	
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Jana Klimasová	Alternate	Slovakia	No restrictions applicable to this meeting	
Andreja Kranjc	Alternate	Slovenia	No interests declared	
Carolina Prieto Fernandez	Member	Spain	No interests declared	
Antonio Gomez Outes	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Bruno Delafont	Co-opted member	France	No interests declared	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sol Ruiz	Co-opted member	Spain	No interests declared	
Trine Jensen	Expert	Denmark	No restrictions applicable to this meeting	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Susan Uiterwaal	Expert	Netherlands	No interests declared	
Carolien Versantvoort	Expert	Netherlands	No interests declared	
Karin Kundler	Expert	Austria	No interests declared	
Johannes Blumel	Expert	Germany	No interests declared	
Nienke Rodenhuis	Expert	Netherlands	No interests declared	
Susanne Brendler-Schwaab	Expert	Germany	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Pierre Demolis	Expert	France	No interests declared	
Deirdre Mannion	Expert	Ireland	No restrictions applicable to this meeting	
Christoph Furtmann	Expert	Germany	No interests declared	
Hanne Lomholt Larsen	Expert	Denmark	No interests declared	
Violette Dirix	Expert	Belgium	No interests declared	
Marta Romano	Expert	Belgium	No interests declared	
Ingrid Bourges	Expert	Belgium	No interests declared	
Nicolas Nyssen	Expert	Belgium	No interests declared	
Edwige Haelterman	Expert	Belgium	No interests declared	
Ilona G. Reischl	Expert	Austria	No interests declared	
Sofia Persson	Expert	Sweden	No interests declared	
Umberto Casalegno	Expert	France	No interests declared	
Laura Andreoli	Expert	France	No interests declared	
Anissa Benlazar	Expert	France	No interests declared	
Yseult Brun	Expert	France	No interests declared	
Sandrine Chiappini	Expert	France	No interests declared	
Lidija Prka	Expert	Croatia	No interests declared	
Danica Juričić Nahal	Expert	Croatia	No interests declared	
Kersti Oselin	Expert	Estonia	No part in discussions, final deliberations and voting on:	RYBREVANT - Amivantamab - EMEA/H/C/005454 /II/0013 TAGRISSO - Osimertinib - EMEA/H/C/004124 /II/0053
Silke Dorner	Expert	Austria	No interests declared	
Philipp Janesch	Expert	Austria	No interests declared	
Brigitte Müller	Expert	Austria	No interests declared	
Walter-Johannes Beiersdorf	Expert	Austria	No restrictions applicable to this meeting	
Elisabeth Strutzmann	Expert	Austria	No interests declared	
Tereza Bažantová	Expert	Czech Republic	No interests declared	
Pavla Zemanová	Expert	Czech Republic	No interests declared	
Pavlína Chladová	Expert	Czech Republic	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Lenka Králová	Expert	Czech Republic	No interests declared	
Michaela Dlouhá	Expert	Czech Republic	No interests declared	
Jana Žižkovská	Expert	Czech Republic	No interests declared	
Jitka Soukupová	Expert	Czech Republic	No interests declared	
Janne Komi	Expert	Finland	No restrictions applicable to this meeting	
Antero Kallio	Expert	Finland	No restrictions applicable to this meeting	
Sinead Harrington	Expert	Ireland	No interests declared	
Catherine Byrne	Expert	Ireland	No interests declared	
Larissa Higgins	Expert	Ireland	No interests declared	
Sandra Bright	Expert	Ireland	No interests declared	
Brian Aylward	Expert	Ireland	No interests declared	
Ailise Carleton	Expert	Ireland	No interests declared	
Maura O'Donovan	Expert	Ireland	No interests declared	
Monika Jarzabek	Expert	Ireland	No interests declared	
Iftekhar Khan	Expert	Ireland	No interests declared	
Alicia Pérez González	Expert	Spain	No interests declared	
Ana Sagredo	Expert	Spain	No interests declared	
Maria Chamorro Somoza Díaz-Sarmiento	Expert	Spain	No interests declared	
Mette Linnert Jensen	Expert	Denmark	No interests declared	
Kinga Nowicka-Matus	Expert	Denmark	No interests declared	
Martin Bronislaw Oleksiewicz	Expert	Denmark	No interests declared	
Céline Jumeau	Expert	France	No interests declared	
Olga Kholmanskikh	Expert	Belgium	No interests declared	
Violette Dirix	Expert	Belgium	No interests declared	
Edwige Haelterman	Expert	Belgium	No interests declared	
Marta Romano	Expert	Belgium	No interests declared	
Ingrid Bourges	Expert	Belgium	No interests declared	
Stefan Bonné	Expert	Belgium	No interests declared	
Tom Lams	Expert	Belgium	No interests declared	
Marianne Depreter	Expert	Belgium	No interests declared	
Anna Mari Lone	Expert	Norway	No restrictions applicable to this meeting	
Elisabeth Fürst	Expert	Austria	No interests declared	
Hinterleitner Mirjam	Expert	Austria	No interests declared	
Odoardo Maria Olimpieri	Expert	Italy	No interests declared	
Antonella Isgrò	Expert	Italy	No interests declared	
Johanna de Groot	Expert	Netherlands	No interests declared	
Jacobus Johannes Christianus Maria Romme	Expert	Netherlands	No interests declared	
Hinke Johanna van der Woude	Expert	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Anne Torrez Flores-Lexmond	Expert	Netherlands	No part in discussions, final deliberations and voting on:	Epinephrine - EMEA/H/C/006139
Emmely de Vries	Expert	Netherlands	No interests declared	
Ingrid Schellens	Expert	Netherlands	No interests declared	
Sabine Mayrhofer	Expert	Germany	No interests declared	
Friederike Marei Feldmann	Expert	Germany	No interests declared	
Christoph Furtmann	Expert	Germany	No interests declared	
Martin Mengel	Expert	Germany	No interests declared	
Sofia Kapanadze	Expert	Germany	No interests declared	
Franziska Brandt	Expert	Germany	No interests declared	
Clemens Mittmann	Expert	Germany	No interests declared	
Daiana Vasilcanu	Expert	Sweden	No interests declared	
Jenny-Maria Jönsson	Expert	Sweden	No part in discussions, final deliberations and voting on:	Avzivi - Bevacizumab - EMEA/H/C/005574
Charlotte Anderberg	Expert	Sweden	No interests declared	
Juliane Rau	Expert	Germany	No interests declared	
Benjamin Hofner	Expert	Germany	No restrictions applicable to this meeting	
Steffen Groß	Expert	Germany	No interests declared	
Christina Reeb	Expert	Germany	No interests declared	
Katja Findeisen	Expert	Germany	No restrictions applicable to this meeting	
Susanne Müller-Egert	Expert	Germany	No interests declared	
Jörg Engelbergs	Expert	Germany	No interests declared	
Paolo Foggi	Expert	Italy	No interests declared	
Pierre Demolis	Expert	France	No interests declared	
Joerg Zinserling	Expert	Germany	No interests declared	
Flora Musuamba Tshinanu	Expert	Belgium	No restrictions applicable to this meeting	
Elina Rönnemaa	Expert	Sweden	No interests declared	
Mikael Andersson	Expert	Sweden	No interests declared	
Elmer Schabel	Expert	Germany	No interests declared	
Viktoriia Starokozhko	Expert	Netherlands	No restrictions applicable to this meeting	
Dace Peiseniece	Expert	Latvia	No interests declared	
Kristīne Ondrupe-Kirilova	Expert	Latvia	No interests declared	
Nicolas Beix	Expert	France	No interests declared	
Mario Miguel Coelho da Silva Rosa	Expert	Portugal	No interests declared	
Adriana Ammassari	Expert	Italy	No interests declared	
Angelo Molinaro	Expert	Italy	No interests declared	
Angela Garau	Expert	Italy	No interests declared	
Melanie Ramberger	Expert	Austria	No interests declared	
Sabine van der Putten-de Brouwer	Expert	Netherlands	No restrictions applicable to this meeting	
Lieke Sandberg-Smits	Expert	Netherlands	No interests declared	
Derk Reinders	Expert	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Observers from ANVISA (Brazil) and FDA (USA) 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)*

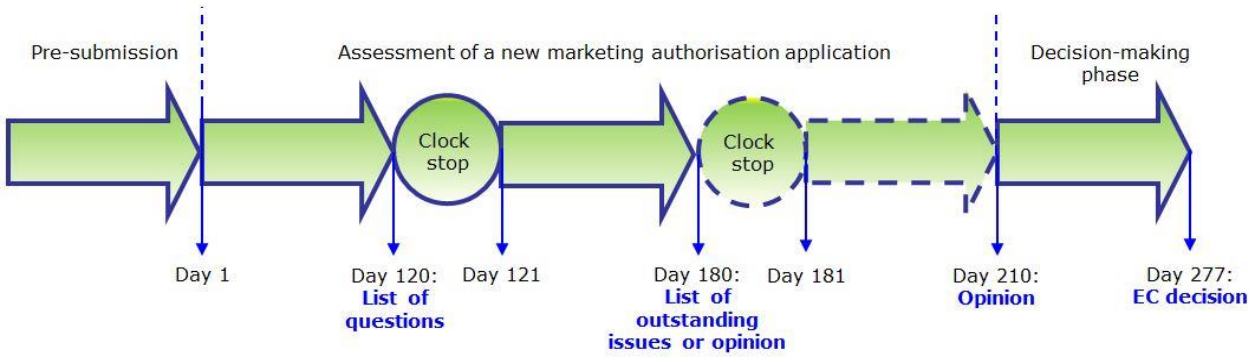
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

31 October 2024
EMA/CHMP/257275/2024

Annex to 27-30 May 2024 CHMP Minutes

Pre-submission and post-authorisations issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for May 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

Ceplene - Histamine dihydrochloride - EMEA/H/C/000796/S/0048 Laboratoires Delbert, Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu Request for Supplementary Information adopted on 25.04.2024.	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.
Ebvallo - Tabelecleucel - EMEA/H/C/004577/S/0008, Orphan, ATMP Pierre Fabre Medicament, Rapporteur: Egbert Flory, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Amelia Cupelli	Positive Opinion adopted by consensus together with the CAT(CHMP) assessment report. The Marketing Authorisation remains under exceptional circumstances.
ELZONRIS - Tagraxofusp - EMEA/H/C/005031/S/0025, Orphan Stemline Therapeutics B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder	Positive Opinion adopted by consensus together with the CHMP assessment report and translation timetable. The Marketing Authorisation remains under exceptional circumstances.
Obizur - Susoctocog alfa - EMEA/H/C/002792/S/0056 Baxalta Innovations GmbH, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Gabriele Maurer Request for Supplementary Information adopted on 30.05.2024.	Request for supplementary information adopted with a specific timetable.
Tecovirimat SIGA - Tecovirimat -	Positive Opinion adopted by consensus together

EMEA/H/C/005248/S/0010 SIGA Technologies Netherlands B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber	with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.
Voraxaze - Glucarpidase - EMEA/H/C/005467/S/0025, Orphan SERB S.A.S., Rapporteur: Petr Vrbata, PRAC Rapporteur: Martin Huber	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Arsenic trioxide Accord - Arsenic trioxide - EMEA/H/C/005175/R/0009 Accord Healthcare S.L.U., Generic of TRISENOX, Rapporteur: Alar Irs, PRAC Rapporteur: Tiphaine Vaillant	Request for supplementary information adopted with a specific timetable.
Bortezomib Fresenius Kabi - Bortezomib - EMEA/H/C/005074/R/0010 Fresenius Kabi Deutschland GmbH, Generic of VELCADE, Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Amelia Cupelli	Request for supplementary information adopted with a specific timetable.
Deferasirox Mylan - Deferasirox - EMEA/H/C/005014/R/0013 Mylan Pharmaceuticals Limited, Generic of EXJADE, Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Tiphaine Vaillant Request for Supplementary Information adopted on 21.03.2024.	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.
Epidyolex - Cannabidiol - EMEA/H/C/004675/R/0031, Orphan Jazz Pharmaceuticals Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Ana Sofia Diniz Martins Request for Supplementary Information adopted on 25.04.2024.	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.
RINVOQ - Upadacitinib - EMEA/H/C/004760/R/0051 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, Co-Rapporteur:	Request for supplementary information adopted with a specific timetable.

Outi Mäki-Ikola, PRAC Rapporteur: Petar Mas

B.2.3. Renewals of Conditional Marketing Authorisations

AYVAKYT - Avapritinib - EMEA/H/C/005208/R/0034, Orphan Blueprint Medicines (Netherlands) B.V., Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
Idefirix - Imlifidase - EMEA/H/C/004849/R/0020, Orphan Hansa Biopharma AB, Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder, PRAC Rapporteur: Bianca Mulder	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
MINJUVI - Tafasitamab - EMEA/H/C/005436/R/0015, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ulla Wändel Liminga	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
ROCTAVIAN - Valoctocogene roxaparvovec - EMEA/H/C/005830/R/0011, Orphan, ATMP BioMarin International Limited, Rapporteur: Violaine Closson Carella, Co-Rapporteur: Silke Dorner, CHMP Coordinator: Jean-Michel Race, PRAC Rapporteur: Bianca Mulder	Request for supplementary information adopted with a specific timetable.
Tepkinly - Epcoritamab - EMEA/H/C/005985/R/0004, Orphan AbbVie Deutschland GmbH & Co. KG, Rapporteur: Peter Mol, Co-Rapporteur: Ingrid Wang, PRAC Rapporteur: Monica Martinez Redondo	Positive Opinion adopted by consensus together with the CHMP assessment report. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional.
VITRAKVI - Larotrectinib - EMEA/H/C/004919/R/0035 Bayer AG, Rapporteur: Filip Josephson, PRAC Rapporteur: Rugile Pilviniene	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.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Post-authorisation safety studies	
PRAC recommendations on PASS results adopted at the PRAC meeting held on 13-16 May 2024	
Quinsair (CAP) – EMEA/H/C/PSR/S/0046 (levofloxacin) PRAC Rapporteur: Maria del Pilar Rayon, Scope: Annex II of the product information is updated to remove the PASS, as the study has been completed. Information about additional monitoring, including the black triangle, should also be removed from the SmPC and the package leaflet. In addition, the information in section 4.8 of the SmPC for haemoptysis has been updated. A revised RMP version 3.2 has been adopted. PRAC recommendation to CHMP **Action:** For adoption	Adopted
PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its May 2024 meeting:	

EMEA/H/C/PSUSA/00000459/202309 (buprenorphine (all formulations except implants)) CAPS: **Buvidal** (EMEA/H/C/004651) (Buprenorphine), Camurus AB, Rapporteur: Finbarr Leacy NAPS: **NAPs** - EU , PRAC Rapporteur: Tiphaine Vaillant, "30/09/2020 To: 30/09/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.5 of the SmPC to add interactions with gabapentinoids as well as with anticholinergics. The Package leaflet is updated accordingly. Update of Package Leaflet section 5 to reinforce information on the importance to store products in a safe and secure place to avoid intoxication. Update of Package Leaflet section 'Instructions for Use for Healthcare Professionals' and Labelling outer packaging to reinforce information on the use of injection only into the subcutaneous tissue. Update of sections 4.2, 4.4 and 4.8 of the SmPC to reinforce information about opioid use disorder. The Package leaflet is updated accordingly. Update of section 4.8 of the SmPC to add the adverse reaction dental caries with a frequency not known. The Package leaflet is updated accordingly.

EMEA/H/C/PSUSA/00001837/202309 (leflunomide) CAPS: **Arava** (EMEA/H/C/000235) (Leflunomide), Sanofi-Aventis Deutschland GmbH, Rapporteur: Peter Mol **Leflunomide medac** (EMEA/H/C/001227) (Leflunomide), medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Janet Koenig **Leflunomide Zentiva** (EMEA/H/C/001129) (Leflunomide), Zentiva, k.s., Rapporteur: Peter Mol NAPS: **NAPs** - EU , PRAC Rapporteur: Liana Martirosyan, "11/09/2020 To: 10/09/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.4 of the SmPC to add a warning about impaired wound healing after surgery. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00002113/202309 (buprenorphine / naloxone) CAPS: **Suboxone** (EMEA/H/C/000697) (Buprenorphine / Naloxone), Indivior Europe Limited, Rapporteur: Janet Koenig **Zubsolv** (EMEA/H/C/004407) (Buprenorphine / Naloxone), Accord Healthcare S.L.U., Rapporteur: Finbarr Leacy NAPS: **NAPs** - EU , PRAC Rapporteur: Martin Huber, "25/09/2019 To: 25/09/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of sections 4.5 and 4.8 of the SmPC to add interactions with gabapentinoids and to add the adverse reaction dental caries with a frequency not known. The Package leaflet is updated accordingly. Update of Package Leaflet section 5 to reinforce information on the importance to store products in a safe and secure place to avoid intoxication.

EMEA/H/C/PSUSA/00002480/202310 (posaconazole) CAPS: **Noxafil** (EMEA/H/C/000610) (Posaconazole), Merck Sharp & Dohme B.V., Rapporteur: Alexandre Moreau NAPS: **NAPs** - EU , PRAC Rapporteur: Nathalie Gault, "25/10/2022 To: 25/10/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): 1. Update of sections 4.4 and 4.5 of the SmPC to a warning/precaution regarding the interaction with flucloxacillin. The Package leaflet is updated accordingly. 2. Update of sections 4.4 and 4.8 to add the adverse reaction "Photosensitivity reaction" with a frequency "not known" and a warning/precaution. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00002999/202309 (toremifene) CAPS: **Fareston** (EMEA/H/C/000091) (Toremifene), Orion Corporation, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "01/10/2020 To: 30/09/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add the adverse reaction hypertriglyceridaemia with a frequency "not known". The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010029/202310 (dapagliflozin) CAPS: **Edistride** (EMEA/H/C/004161) (Dapagliflozin), AstraZeneca AB, Rapporteur: Kristina Dunder **Forxiga** (EMEA/H/C/002322) (Dapagliflozin), AstraZeneca AB, Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, "05/10/2022 To: 04/10/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 of the SmPC to add a warning/precaution regarding increased haematocrit.

EMEA/H/C/PSUSA/00010135/202309 (teriflunomide) CAPS: **AUBAGIO** (EMEA/H/C/002514) (Teriflunomide), Sanofi Winthrop Industrie, Rapporteur: Martina Weise **Teriflunomide Accord** (EMEA/H/C/005960) (Teriflunomide), Accord Healthcare S.L.U., Rapporteur: Kristina Nadrah **Teriflunomide Mylan** (EMEA/H/C/005962) (Teriflunomide), Mylan Pharmaceuticals Limited, Rapporteur: Alar Irs NAPS: **NAPs** - EU , PRAC Rapporteur: Martin Huber, "09/11/2022 To: 12/09/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of sections 4.4 and 4.8 of the SmPC to add a warning/precaution regarding occurrence of herpes virus infections and to add the adverse reaction herpes virus infections with a frequency common. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00011008/202310 (asciminib) CAPS: **Scemblix** (EMEA/H/C/005605) (Asciminib), Novartis Europharm Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová, "29/04/2023 To: 28/10/2023"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC to add Pancytopenia with a frequency uncommon (≥1/1 000 to <1/100). The PIL is updated accordingly.

B.4. EPARs / WPARs

ALTUVOCT - Efanesoctocog alfa - EMEA/H/C/005968, Orphan Swedish Orphan Biovitrum AB (publ), Treatment and prophylaxis of bleeding in patients with haemophilia A, 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.
Eribulin Baxter - Eribulin - EMEA/H/C/006191 Baxter Holding B.V., treatment of breast cancer and liposarcoma, Generic, Generic of Halaven, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
FRUZAQLA - Fruquintinib - EMEA/H/C/005979	For information only. Comments can be sent to

Takeda Pharmaceuticals International AG Ireland Branch, treatment of metastatic colorectal cancer, New active substance (Article 8(3) of Directive No 2001/83/EC)	the PL in case necessary.
JERAYGO - Aprocitentan - EMEA/H/C/006080 Idorsia Pharmaceuticals Deutschland GmbH, treatment of resistant hypertension, 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.
KINHARTO (WD) - Omecamtiv mecarbil - EMEA/H/C/006112 Cytokinetics (Ireland) Limited, treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction less than 30%, New active substance (Article 8(3) of Directive No 2001/83/EC) **WPAR**	For information only. Comments can be sent to the PL in case necessary.
Obgemsa - Vibegron - EMEA/H/C/005957 Pierre Fabre Medicament, symptomatic treatment of adult patients with overactive bladder (OAB) syndrome., 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.
Qalsody - Tofersen - EMEA/H/C/005493, Orphan Biogen Netherlands B.V., treatment of adults with amyotrophic lateral sclerosis (ALS), associated with a mutation in the superoxide dismutase 1 (SOD1) gene, 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.
Tofidence - Tocilizumab - EMEA/H/C/005984 Biogen Netherlands B.V., treatment of rheumatoid arthritis (RA), coronavirus disease 2019 (COVID-19), polyarticular juvenile idiopathic arthritis (pJIA), and systemic juvenile idiopathic arthritis (sJIA), 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.
Truqap - Capivasertib - EMEA/H/C/006017 AstraZeneca AB, is indicated in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative (defined as IHC 0 or 1+, or IHC 2+/ISH-) locally advanced or metastatic	For information only. Comments can be sent to the PL in case necessary.

breast cancer following recurrence or progression on or after an endocrine based regimen, New active substance (Article 8(3) of Directive No 2001/83/EC)	
WEZENLA - Ustekinumab - EMEA/H/C/006132 Amgen Technology (Ireland) Unlimited Company, treatment of moderate to severe plaque psoriasis in adults, children and adolescents, active psoriatic arthritis in adults, treatment of Crohn's Disease and Ulcerative colitis, 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.

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

Adenuric - Febuxostat - EMEA/H/C/000777/II/0071/G Menarini International Operations Luxembourg S.A., Rapporteur: Christian Gartner Opinion adopted on 02.05.2024. Request for Supplementary Information adopted on 11.01.2024.	Positive Opinion adopted by consensus on 02.05.2024.
Adtralza - Tralokinumab - EMEA/H/C/005255/II/0014/G LEO Pharma A/S, Rapporteur: Jayne Crowe Opinion adopted on 02.05.2024. Request for Supplementary Information adopted on 18.01.2024.	Positive Opinion adopted by consensus on 02.05.2024.
Advate - Octocog alfa - EMEA/H/C/000520/II/0122/G Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 04.04.2024.	Positive Opinion adopted by consensus on 30.05.2024.
AREXVY - Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E - EMEA/H/C/006054/II/0009/G GlaxoSmithkline Biologicals S.A., Rapporteur: Patrick Vrijlandt	Positive Opinion adopted by consensus on 02.05.2024.

Opinion adopted on 02.05.2024.	
Besremi - Ropeginterferon alfa-2b - EMEA/H/C/004128/II/0033/G AOP Orphan Pharmaceuticals GmbH, Rapporteur: Janet Koenig Request for Supplementary Information adopted on 30.05.2024.	Request for supplementary information adopted with a specific timetable.
Cancidas - Caspofungin - EMEA/H/C/000379/II/0083/G Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 04.04.2024, 11.01.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Clopidogrel Viatris - Clopidogrel - EMEA/H/C/001189/II/0049/G Viatris Limited, Generic of Plavix, Duplicate of Grepid, Rapporteur: Kristina Nadrah Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 11.01.2024.	Positive Opinion adopted by consensus on 16.05.2024.
COMIRNATY - COVID-19 mRNA vaccine - EMEA/H/C/005735/II/0212/G BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
DuoTrav - Travoprost / Timolol - EMEA/H/C/000665/II/0068/G Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 16.05.2024.	Request for supplementary information adopted with a specific timetable.
Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0002 Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau Opinion adopted on 02.05.2024. Request for Supplementary Information adopted on 08.02.2024.	Positive Opinion adopted by consensus on 02.05.2024.
Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0004/G Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau Opinion adopted on 23.05.2024. Request for Supplementary Information adopted on 04.04.2024.	Positive Opinion adopted by consensus on 23.05.2024.

Enrylaze - Crisantaspase - EMEA/H/C/005917/II/0003/G Jazz Pharmaceuticals Ireland Limited, Rapporteur: Peter Mol Opinion adopted on 23.05.2024. Request for Supplementary Information adopted on 14.03.2024.	Positive Opinion adopted by consensus on 23.05.2024.
Erbitux - Cetuximab - EMEA/H/C/000558/II/0098/G Merck Europe B.V., Rapporteur: Filip Josephson Opinion adopted on 23.05.2024.	Positive Opinion adopted by consensus on 23.05.2024.
Evenity - Romosozumab - EMEA/H/C/004465/II/0023 UCB Pharma S.A., Rapporteur: Kristina Dunder Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
Evenity - Romosozumab - EMEA/H/C/004465/II/0024 UCB Pharma S.A., Rapporteur: Kristina Dunder Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
Flixabi - Infliximab - EMEA/H/C/004020/II/0086 Samsung Bioepis NL B.V., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 30.05.2024.	Positive Opinion adopted by consensus on 30.05.2024.
GONAL-f - Follitropin alfa - EMEA/H/C/000071/II/0168/G Merck Europe B.V., Rapporteur: Patrick Vrijlandt Opinion adopted on 23.05.2024. Request for Supplementary Information adopted on 18.04.2024.	Positive Opinion adopted by consensus on 23.05.2024.
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0149 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini Opinion adopted on 02.05.2024. Request for Supplementary Information adopted on 07.03.2024.	Positive Opinion adopted by consensus on 02.05.2024.
Leqvio - Inclisiran - EMEA/H/C/005333/II/0027/G Novartis Europharm Limited, Rapporteur: Martina Weise Request for Supplementary Information adopted on 30.05.2024.	Request for supplementary information adopted with a specific timetable.
LUTATHERA - Lutetium (177Lu) oxodotreotide - EMEA/H/C/004123/II/0048, Orphan	Positive Opinion adopted by consensus on 02.05.2024.

Advanced Accelerator Applications, Rapporteur: Janet Koenig Opinion adopted on 02.05.2024.	
Mircera - Methoxy polyethylene glycol-epoetin beta - EMEA/H/C/000739/II/0099/G Roche Registration GmbH, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 16.05.2024.	Request for supplementary information adopted with a specific timetable.
Nucala - Mepolizumab - EMEA/H/C/003860/II/0066/G GlaxoSmithKline Trading Services Limited, Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 02.05.2024.	Request for supplementary information adopted with a specific timetable.
Opzelura - Ruxolitinib - EMEA/H/C/005843/II/0002/G Incyte Biosciences Distribution B.V., Rapporteur: Peter Mol Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 30.11.2023, 31.08.2023.	Positive Opinion adopted by consensus on 30.05.2024.
Orencia - Abatacept - EMEA/H/C/000701/II/0166/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 16.05.2024.	Request for supplementary information adopted with a specific timetable.
OXERVATE - Cenegermin - EMEA/H/C/004209/II/0059, Orphan Dompe farmaceutici S.p.A., Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 02.05.2024.	Request for supplementary information adopted with a specific timetable.
Qarziba - Dinutuximab beta - EMEA/H/C/003918/II/0056/G, Orphan Recordati Netherlands B.V., Rapporteur: Peter Mol Request for Supplementary Information adopted on 02.05.2024, 15.02.2024.	Request for supplementary information adopted with a specific timetable.
Rotarix - Rotavirus vaccine (live, oral) - EMEA/H/C/000639/II/0133/G GlaxoSmithKline Biologicals S.A., Rapporteur: Christophe Focke Opinion adopted on 02.05.2024.	Positive Opinion adopted by consensus on 02.05.2024.

Ruxience - Rituximab - EMEA/H/C/004696/II/0015 Pfizer Europe MA EEIG, Rapporteur: Peter Mol Request for Supplementary Information adopted on 23.05.2024, 04.04.2024.	Request for supplementary information adopted with a specific timetable.
Saxenda - Liraglutide - EMEA/H/C/003780/II/0038 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 11.04.2024.	Positive Opinion adopted by consensus on 16.05.2024.
Skytrofa - Lonapegsomatropin - EMEA/H/C/005367/II/0025/G, Orphan Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 04.04.2024, 08.02.2024.	Positive Opinion adopted by consensus on 16.05.2024.
SomaKit TOC - Edotreotide - EMEA/H/C/004140/II/0028, Orphan Advanced Accelerator Applications, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 16.05.2024.	Request for supplementary information adopted with a specific timetable.
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0124/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 02.05.2024.	Positive Opinion adopted by consensus on 02.05.2024.
Stimufend - Pegfilgrastim - EMEA/H/C/004780/II/0007 Fresenius Kabi Deutschland GmbH, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 20.06.2024, 16.05.2024.	Request for supplementary information adopted with a specific timetable.
Tabrecta - Capmatinib - EMEA/H/C/004845/II/0007/G Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez Request for Supplementary Information adopted on 16.05.2024, 18.01.2024.	Request for supplementary information adopted with a specific timetable.
Travatan - Travoprost - EMEA/H/C/000390/II/0071/G Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 16.05.2024.	
TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0033 Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 02.05.2024.	Request for supplementary information adopted with a specific timetable.
Tysabri - Natalizumab - EMEA/H/C/000603/II/0143/G Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 23.05.2024.	Request for supplementary information adopted with a specific timetable.
Vitrolife IVF media - Recombinant human albumin solution - EMEA/H/D/004693/II/0005 Vitrolife Sweden AB, Rapporteur: Maria Grazia Evandri Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 14.03.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Vyvgart - Efgartigimod alfa - EMEA/H/C/005849/II/0016, Orphan Argenx, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 04.04.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Vyvgart - Efgartigimod alfa - EMEA/H/C/005849/II/0017, Orphan Argenx, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 02.05.2024.	Request for supplementary information adopted with a specific timetable.
Xenpozyme - Olipudase alfa - EMEA/H/C/004850/II/0009, Orphan Sanofi B.V., Rapporteur: Patrick Vrijlandt Opinion adopted on 30.05.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Yellox - Bromfenac - EMEA/H/C/001198/II/0036/G Bausch + Lomb Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 30.05.2024, 25.01.2024.	Request for supplementary information adopted with a specific timetable.
Yuflyma - Adalimumab - EMEA/H/C/005188/II/0035/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola	Positive Opinion adopted by consensus on 30.05.2024.

Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 25.04.2024.	
Zebinix - Eslicarbazepine acetate - EMEA/H/C/000988/II/0089/G Bial - Portela & Cª, S.A., Rapporteur: Martina Weise Opinion adopted on 02.05.2024. Request for Supplementary Information adopted on 15.02.2024.	Positive Opinion adopted by consensus on 02.05.2024.
WS2550 **Aldara-EMEA/H/C/000179/WS2550/0089** **Zyclara-EMEA/H/C/002387/WS2550/0031** Viatris Healthcare Limited, Lead Rapporteur: Ewa Balkowiec Iskra Request for Supplementary Information adopted on 02.05.2024.	Request for supplementary information adopted with a specific timetable.
WS2634 **Hexacima-EMEA/H/C/002702/WS2634/0154** **Hexyon-EMEA/H/C/002796/WS2634/0158** Sanofi Pasteur Europe, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 30.05.2024, 04.04.2024.	Request for supplementary information adopted with a specific timetable.
WS2642/G **Riltrava Aerosphere-EMEA/H/C/005311/WS2642/0011/G** **Trixeo Aerosphere-EMEA/H/C/004983/WS2642/0018/G** AstraZeneca AB, Lead Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 16.05.2024.	Request for supplementary information adopted with a specific timetable.
WS2684 **Nuwiq-EMEA/H/C/002813/WS2684/0061** **Vihuma-EMEA/H/C/004459/WS2684/0043** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 30.05.2024.	Positive Opinion adopted by consensus on 30.05.2024.

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

Bimzelx - Bimekizumab -	Positive Opinion adopted by consensus on

EMEA/H/C/005316/II/0025 UCB Pharma S.A., Rapporteur: Finbarr Leacy, "Update of section 5.1 of the SmPC in order to add long-term efficacy data based on the interim results (week 144 data) from study PS0014 listed as a category 3 study in the RMP (MEA/005); this is an ongoing, multicentre, open-label extension (OLE) study to assess the long-term safety, tolerability, and efficacy of bimekizumab in adult study participants with moderate to severe plaque PSO who completed 1 of the 3 completed feeder studies (PS0008, PS0009, and PS0013)." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 21.03.2024, 25.01.2024.	16.05.2024.
Duavive - Estrogens conjugated / Bazedoxifene - EMEA/H/C/002314/II/0036 Pfizer Europe MA EEIG, Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC in order to update the wording regarding interactions with other medicinal products and to align with the updated CMDh Core SmPC. 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 bring the PI in line with the latest QRD template version 10.4." Opinion adopted on 02.05.2024. Request for Supplementary Information adopted on 14.03.2024.	Positive Opinion adopted by consensus on 02.05.2024.
EVUSHELD - Tixagevimab / Cilgavimab - EMEA/H/C/005788/II/0018 AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2, 4.4 and 5.1 of the SmPC in order to update the warning on antiviral resistance, based on the latest neutralisation data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the Product Information." Opinion adopted on 30.05.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Gazyvaro - Obinutuzumab - EMEA/H/C/002799/II/0054/G, Orphan Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, "Grouped application comprising two variations as follows: C.I.4 - Update of section 4.4 of the SmPC in	Request for supplementary information adopted with a specific timetable.

order to amend the cytokine release syndrome (CRS) statement based on the cumulative review of the MAH safety database, clinical trials and literature. 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 10.3. A.6 - To change the ATC Code of Obinutuzumab from L01XC15 to L01FA03." Request for Supplementary Information adopted on 02.05.2024, 11.01.2024.	
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 30.05.2024.	Request for supplementary information adopted with a specific timetable.
Imfinzi - Durvalumab - EMEA/H/C/004771/II/0066 AstraZeneca AB, Rapporteur: Aaron Sosa Mejia, "Update of sections 4.2, 4.4, and 4.8 of the SmPC in order to include rhabdomyolysis as an extension of the myositis and polymyositis medical concept based on post marketing data and literature." Opinion adopted on 30.05.2024.	Positive Opinion adopted by consensus on 30.05.2024.
JEMPERLI - Dostarlimab - EMEA/H/C/005204/II/0031 GlaxoSmithKline (Ireland) Limited, Rapporteur: Carolina Prieto Fernandez, "Type II (C.I.4) - To update section 6.6 of the SmPC for the addition of a maximum dilution volume for infusion solution (250 mL) for the 500 mg and 1000 mg doses and to update the corresponding minimum concentration for the 1000 mg dose (from 2 mg/mL to 4mg/mL). The Package Leaflet is updated accordingly. In addition,	Positive Opinion adopted by consensus on 30.05.2024.

Annex II was updated to remove the PSUR 6 monthly submission requirement wording to align with the updated EURD list, as a result of the conversion of the conditional marketing authorization to full approval (EC decision on 07-Dec-2023). The MAH also took the opportunity to introduce minor editorial changes to the Product Information." Opinion adopted on 30.05.2024.	
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0152 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, "Update of section 5.1 of the SmPC in order to update efficacy information based on interim results from study KEYNOTE-564; this is a phase 3, randomized, double-blind, placebo-controlled clinical trial of pembrolizumab as monotherapy in the adjuvant treatment of renal cell carcinoma post nephrectomy." Opinion adopted on 02.05.2024.	Positive Opinion adopted by consensus on 02.05.2024.
NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0066 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-101 Part 2 listed as a category 3 study in the RMP (MEA 010.2). This is a 2-part, phase 1/2, randomized, observer-blinded study to evaluate the safety and immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with or without Matrix-M adjuvant in healthy participants." Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
Olumiant - Baricitinib - EMEA/H/C/004085/II/0046 Eli Lilly Nederland B.V., Rapporteur: Peter Mol, "Update of section 5.1 of the SmPC in order to add information on JIA-associated uveitis or chronic anterior antibody positive uveitis based on interim results from study I4VMC-JAHW; this is an open-label, active-controlled, safety, and efficacy study of oral baricitinib in patients from 2 years to less than 18 years old with active juvenile idiopathic arthritis-associated uveitis or chronic anterior antinuclear antibody-positive uveitis." Opinion adopted on 30.05.2024. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 30.05.2024.

on 04.04.2024, 08.02.2024.	
Oncaspar - Pegaspargase - EMEA/H/C/003789/II/0053/G Les Laboratoires Servier, Rapporteur: Alexandre Moreau, "A grouped application comprised of a Type II variation and a Type IB variation, as follows: - Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to add 'Hepatic veno-occlusive disease (VOD)' as a warning and new safety risk with 'not known' frequency, following an internal signal evaluation. The Package Leaflet is updated accordingly. - Type IB (C.I.3.z): Update of sections 4.4 and 4.8 of the SmPC in order to add 'Antithrombin III decreased' to the list of adverse drug reactions with frequency 'Very common' and to update the frequency of 'Neutrophil count decreased' from 'Not known' to 'Very common', following the outcome of the PAM procedure P46/008. The Package Leaflet is updated accordingly." Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
Onivyde pegylated liposomal - Irinotecan hydrochloride trihydrate - EMEA/H/C/004125/II/0035, Orphan Les Laboratoires Servier, Rapporteur: Filip Josephson, "Update of section 4.8 of the SmPC in order to add "Interstitial lung disease (including pneumonitis)" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on post-marketing data and literature. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 16.05.2024.	Request for supplementary information adopted with a specific timetable.
Opfolda - Miglustat - EMEA/H/C/005695/II/0010/G Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, "A grouped application comprised of two Type II Variations, as follows: C.I.4: Update of section 5.2 of the SmPC in order to update drug metabolism information based on the final report of the in vitro transporter study 8496647 as well as the population PK study AMC0206. Study 8496647	Request for supplementary information adopted with a specific timetable.

was for the evaluation of miglustat as a substrate and inhibitor of a panel of human drug transporters. C.I.4: Update of sections 4.6 and 5.3 of the SmPC in order to update reproductive and developmental toxicology information based on reassessment of non-clinical data. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information." Request for Supplementary Information adopted on 02.05.2024.	
Orgovyx - Relugolix - EMEA/H/C/005353/II/0020 Accord Healthcare S.L.U., Rapporteur: Patrick Vrijlandt, "Update of sections 4.2 and 4.5 of the SmPC in order to add information on "Combination with other medicines for advanced hormone-sensitive prostate cancer" based on clinical studies and literature. In addition, the MAH took the opportunity to update section 5.1 of the SmPC." Request for Supplementary Information adopted on 23.05.2024.	Request for supplementary information adopted with a specific timetable.
Orladeyo - Berotralstat - EMEA/H/C/005138/II/0017/G BioCryst Ireland Limited, Rapporteur: Finbarr Leacy, "A grouped application comprised of two type II variations, as follows: C.I.4: Update of section 4.5 of the SmPC in order to remove the recommendation for close monitoring for adverse events with concomitant use of P-gp and BCRP inhibitors based on final safety results from the drug-drug interaction study BCX7353-119, as well as to update the effects of cyclosporine on berotralstat. Study BCX7353-119 is a phase 1 drug-drug interaction study to evaluate the effect of cyclosporine on the pharmacokinetics of berotralstat in healthy subjects. C.I.13: Submission of the final reports from parts 2 and 3 of study BCX7353-301; this is a phase 3, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of two dose levels of	Request for supplementary information adopted with a specific timetable.

BCX7353 as an oral treatment for the suppression of events in subjects with hereditary angioedema. In addition, the MAH took the opportunity to add additional wording for patients with severely reduced kidney function in the Package Leaflet and to introduce minor editorial changes to the PI, as per previous guidance." Request for Supplementary Information adopted on 30.05.2024, 21.03.2024.	
OZAWADE - Pitolisant - EMEA/H/C/005117/II/0007 Bioprojet Pharma, Rapporteur: Peter Mol, "Submission of the final report from study P21-03. This is an open label, single centre, drug-drug interaction study to evaluate the effect of a combination of itraconazole and paroxetine treatment on the pitolisant pharmacokinetics at steady-state in eighteen healthy male Caucasian subjects." Request for Supplementary Information adopted on 02.05.2024, 01.02.2024.	Request for supplementary information adopted with a specific timetable.
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." Request for Supplementary Information adopted on 30.05.2024.	Request for supplementary information adopted with a specific timetable.
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0051/G	Request for supplementary information adopted with a specific timetable.

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Grouped application comprising of the following variations: Type II (C.I.4): Update of section 4.2 of the SmPC in order to add clarifying language to the posology section to distinguish between symptom severity and baseline disease severity. Type II (C.I.4): Update of section 4.4 of the SmPC in order to add information on severe, life-threatening, and fatal drug reactions associated with DDIs. Type II (C.I.4): Update of section 4.6 of the SmPC in order to clarify that there is limited human data on the use of Paxlovid during pregnancy. Type II (C.I.4): Update of section 5.1 of the SmPC in order to update information on antiviral activity." Request for Supplementary Information adopted on 30.05.2024, 25.01.2024.	
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0052/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "A grouped application comprised of 2 Type II Variations, as follows: C.I.4: Update of section 4.5 of the SmPC in order to include more detailed dosing information within the clinical comments for the drug-drug interactions (DDIs) related to venetoclax, apixaban, saxagliptin and cariprazine and to remove the reference to the dabigatran SmPC in the dabigatran DDI clinical comments. C.I.4: Update of section 5.2 of the SmPC in order to include additional information related to the rosuvastatin DDI, based on the final results from study C4671052; this is a phase 1, randomized, fixed sequence, multiple dose, open-label study to estimate the effect of nirmatrelvir/ritonavir on rosuvastatin pharmacokinetics in healthy adult participants." Request for Supplementary Information adopted on 02.05.2024.	Request for supplementary information adopted with a specific timetable.
Remsima - Infliximab - EMEA/H/C/002576/II/0133/G Celltrion Healthcare Hungary Kft., Rapporteur:	Positive Opinion adopted by consensus on 30.05.2024.

Outi Mäki-Ikola, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising three type II variations (C.I.4) as follows: Update of section 4.2, 4.8 and 5.1 of the SmPC in order to add 3-IV induction dosing regimen based on Week 54 data from studies CT-P13 3.7 (ulcerative colitis) and CT-P13 3.8 (Crohn's disease), listed as a category 3 study in the RMP. Study CT-P13 3.7 is a Randomized, Placebo Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis and study CT-P13 3.8 is a Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Crohn's Disease. The RMP version 16.2 was agreed. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce minor updates to the PI." Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 25.04.2024, 21.03.2024, 09.11.2023.	
Retsevmo - Selpercatinib - EMEA/H/C/005375/II/0030 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Epiphysiolysis of the femoral head in Paediatric Patients" and to add it to the list of adverse drug reactions (ADRs) with frequency 'Common', based on a safety report. The Package Leaflet is updated accordingly." Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
Rivastigmine 1A Pharma - Rivastigmine - EMEA/H/C/001181/II/0042 1 A Pharma GmbH, Informed Consent of Exelon, Rapporteur: Alexandre Moreau, "Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on the risk of QT prolongation 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	Positive Opinion adopted by consensus on 23.05.2024.

representatives in the Package Leaflet." Opinion adopted on 23.05.2024. Request for Supplementary Information adopted on 21.03.2024.	
Rivastigmine HEXAL - Rivastigmine - EMEA/H/C/001182/II/0042 Hexal AG, Informed Consent of Exelon, Rapporteur: Alexandre Moreau, "Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on the risk of QT prolongation 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." Opinion adopted on 23.05.2024. Request for Supplementary Information adopted on 21.03.2024.	Positive Opinion adopted by consensus on 23.05.2024.
Rivastigmine Sandoz - Rivastigmine - EMEA/H/C/001183/II/0042 Sandoz GmbH, Informed Consent of Exelon, Rapporteur: Alexandre Moreau, "Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on the risk of QT prolongation 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." Opinion adopted on 23.05.2024. Request for Supplementary Information adopted on 21.03.2024.	Positive Opinion adopted by consensus on 23.05.2024.
Scemblix - Asciminib - EMEA/H/C/005605/II/0013/G, Orphan Novartis Europharm Limited, Rapporteur: Janet Koenig, "Grouped application comprising three type II variations as follows: C.I.4 - Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with P-gp Substrates based on the final results from studies 2301078, CABL001A2301 and CABL001X2101, listed as a category 3 study in the RMP. C.I.4 - Update of section 4.8 of the SmPC in order to update the Summary of the safety profile and safety information based on final results from study CABL001A2301 and CABL001X2101, listed as a category 3 study in the RMP.	Request for supplementary information adopted with a specific timetable.

C.I.4 - Update of section 5.1 of the SmPC in order to update safety information based on final results from study CABL001A2301. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 02.05.2024.	
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0121/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, "A grouped application consisting of three Type II variations, as follows: C.I.4: Update of section 4.5 of the SmPC to add information of co-administration of Spikevax (mRNA-1273), including its variant formulations with herpes zoster (shingles) vaccine, based on final results from Clinical Study 217670 (NCT05047770). This is a phase 3, randomised, open-label, controlled, multi-centre clinical study to evaluate the immune response and safety of both herpes zoster subunit vaccine in healthy adults aged 50 years and older, and the quadrivalent seasonal influenza vaccine in healthy adults aged 18 years and older, when administered sequentially or co-administered with mRNA-1273 booster vaccination. C.I.4: Update of section 4.5 of the SmPC to add information of co-administration of Spikevax (mRNA-1273), including its variant formulations with influenza vaccines (standard), based on final results from Clinical Study 217670 (NCT05047770). This is a phase 3, randomised, open-label, controlled, multi-centre clinical study to evaluate the immune response and safety of both herpes zoster subunit vaccine in healthy adults aged 50 years and older, and the quadrivalent seasonal influenza vaccine in healthy adults aged 18 years and older, when administered sequentially or co-administered with mRNA-1273 booster vaccination. C.I.4: Update of sections 4.5 of the SmPC to add information of co-administration of Spikevax (mRNA-1273) with influenza (high-dose) vaccines, based on final results from Clinical Study QHD00028 (NCT04969276). This is a Phase II, open-label study, to 'Assess the Safety and Immunogenicity of Fluzone High-Dose Quadrivalent (Influenza Vaccine), 2021-2022 Formulation and a Third Dose of Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)	Positive Opinion adopted by consensus on 16.05.2024.

Administered Either Concomitantly or Singly in Adults 65 Years of Age and Older Previously Vaccinated With a 2-dose Schedule of Moderna COVID-19 Vaccine'." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 21.03.2024.	
Spinraza - Nusinersen - EMEA/H/C/004312/II/0032, Orphan Biogen Netherlands B.V., Rapporteur: Bruno Sepodes, "Update of sections 4.4 and 4.8 of the SmPC in order to amend a warning on lumbar puncture procedure to inform about the risk of arachnoiditis, the need to confirm the diagnosis using an MRI as well as the impact of arachnoiditis on the subsequent drug administration and in order to add 'Arachnoiditis' to the list of adverse drug reactions (ADRs) with frequency not known, based on post marketing review. The Package Leaflet is updated accordingly. The MAH took the opportunity to update the list of local representatives." Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 08.02.2024.	Positive Opinion adopted by consensus on 30.05.2024.
TAVNEOS - Avacopan - EMEA/H/C/005523/II/0013, Orphan Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder, "Submission of the analysis of 2 selected pharmacodynamic (PD) markers in the avacopan clinical studies CL003_168 and CL010_168: serum anti-proteinase 3 antibody (anti-PR3) titres and serum anti-myeloperoxidase antibody (anti-MPO) titres." Opinion adopted on 30.05.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Trumenba - Meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0052 Pfizer Europe MA EEIG, Rapporteur: Patrick Vrijlandt, "Update of sections 4.2 and 4.8 of the SmPC in order to add information regarding fever in infants 2 months of age based on final results from study C3511002; this is a Phase 2b trial to assess the safety, tolerability, and immunogenicity of MenABCWY in healthy infants 2 and 6 months of age. In addition, the MAH is taking this opportunity to implement a minor	Request for supplementary information adopted with a specific timetable.

editorial update to SmPC Section 4.4 to add a 'Traceability' subheading, in line with the QRD product information template version 10.3. Furthermore, as suggested by PEI in the linguistic review phase of variation procedure EMEA/H/C/004051/II/0037, the MAH is adding an 'Excipients' subheading to SmPC Section 4.4." Request for Supplementary Information adopted on 30.05.2024, 21.03.2024.	
Ultomiris - Ravulizumab - EMEA/H/C/004954/II/0041 Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, "Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update the frequency of adverse reactions and to update pharmacokinetic, efficacy and safety information on PNH based on final results from studies ALXN1210-PNH-304, ALXN1210-PNH-301 (listed as a category 3 study in the RMP), ALXN1210-PNH-201 and ALXN1210-PNH-103. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring section 4.5 of the IV formulation with that of the SC formulation and remove the black triangle in line with the outcome of the recent renewal procedure." Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 25.04.2024, 11.01.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Uptravi - Selexipag - EMEA/H/C/003774/II/0042/G Janssen-Cilag International N.V., Rapporteur: Martina Weise, "A grouped application comprised of 3 Type II Variations as follows: C.I.4: Update of sections 4.2 and 5.2 of the SmPC in order to update pharmacokinetic information based on results from the paediatric PK study AC-065A203; this is a phase 2 multicentre, open-label, single-arm study to evaluate the safety, tolerability and pharmacokinetics of selexipag in children from 2 years to less than 18 years of age with pulmonary arterial hypertension (PAH). C.I.4: Update of sections 4.2 and 5.1 of the SmPC in order to update efficacy and safety information based on results from study AC-	Request for supplementary information adopted with a specific timetable.

065A310 (SALTO); this is a phase 3 multicentre, double-blind, randomized, placebo-controlled, parallel group study with open-label extension period to assess the efficacy and safety of selexipag as add-on to standard of care in children from 2 years to less than 18 years of age with pulmonary arterial hypertension (PAH). C.I.4: Update of sections 4.2 and 5.1 of the SmPC in order to update efficacy information based on results from the pharmacodynamic (PD) similarity/comparison study to compare the PD and clinical responses for efficacy based on study AC-065A203, study AC-065A310 and study AC-065A302 in paediatric participants from 2 years to less than 18 years of age and adult participants with PAH. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information." Request for Supplementary Information adopted on 16.05.2024.	
VANFLYTA - Quizartinib - EMEA/H/C/005910/II/0002 Daiichi Sankyo Europe GmbH, Rapporteur: Peter Mol, "To update section 4.5 and 5.2 of the SmPC in order to add information on interaction with Breast cancer resistant protein (BCRP) substrates based on results from study GE-2161 – Inhibitory Effects of Quizartinib on the Transport Activity of BCRP (REC). In addition, the MAH is taking this opportunity to introduce editorial changes to the PI." Opinion adopted on 23.05.2024.	Positive Opinion adopted by consensus on 23.05.2024.
Veklury - Remdesivir - EMEA/H/C/005622/II/0054/G Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.2 of the SmPC to update pharmacokinetic information based on results from population PK study report QP-2023-1074. QP-2023-1074 is a population pharmacokinetic analysis of Sulfobutylether-β-cyclodextrin (SBECD) in adults with normal and impaired renal function following remdesivir administration. Update of section 5.2 of the SmPC to update	Positive Opinion adopted by consensus on 30.05.2024.

pharmacokinetic information based on results from population PK study report CTRA-2023-1084. CTRA-2023-1084 is a population pharmacokinetic analysis for remdesivir and metabolites (GS-704277 and GS-441524) after administration of remdesivir in adults." Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 14.03.2024.	
Veklury - Remdesivir - EMEA/H/C/005622/II/0056 Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update antiviral activity information based on the final results from the nonclinical study PC-540-2048 on the antiviral activity of remdesivir against SARS-CoV-2 Omicron XBF, XBB.1.16, FL.22, XBB.2.3.2, EG.5.1, EG.1.2, BA.2.86 and XBB.1.9.2 subvariants." Opinion adopted on 02.05.2024.	Positive Opinion adopted by consensus on 02.05.2024.
VELCADE - Bortezomib - EMEA/H/C/000539/II/0102 Janssen-Cilag International N.V., Rapporteur: Paolo Gasparini, "Update of sections 4.6 and 5.3 of the SmPC in order to update information on pregnancy and preclinical clinical information following EMA/CHMP/SWP/74077/2020 rev. 1* dated on 30 March 2023. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3." Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
Venclyxto - Venetoclax - EMEA/H/C/004106/II/0048 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update safety and efficacy information on paediatric population following the assessment of procedure P46/018 based on final results from study M13-833 - A Phase 1 Study of the Safety and Pharmacokinetics of Venetoclax in Paediatric and Young Adult Patients With Relapsed or Refractory Malignancies. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 16.05.2024.	Request for supplementary information adopted with a specific timetable.
Wegovy - Semaglutide -	Request for supplementary information adopted

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 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." Request for Supplementary Information adopted on 23.05.2024.	with a specific timetable.
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0002, Orphan Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, "Submission of the final report from study 1042-HME-1001 listed as post-authorisation measure (PAM) recommendation. This is an interventional Phase 1 Single Dose, Open-Label Crossover Comparative Bioavailability Study of Two Oral Formulations of Ganaxolone. The primary objective of this study was to evaluate and compare the pharmacokinetics of a new ganaxolone formulation (hot-melt extrusion [HME]) with ganaxolone oral suspension after a single oral dose administration under fed conditions." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 14.03.2024, 14.12.2023.	Positive Opinion adopted by consensus on 16.05.2024.
WS2520/G **Lyrica-EMEA/H/C/000546/WS2520/0124/G** **Pregabalin Pfizer-EMEA/H/C/003880/WS2520/0052/G** Upjohn EESV, Lead Rapporteur: Peter Mol, "Grouped application comprising of two type II as follows: C.I.4 - Update of sections 4.4 and 5.1 of the SmPC in order to add information on potential abuse in recreational drug users based on final results from study A0081365 "A Phase 4 Randomized Double-Blind Double-Dummy Placebo- and Active-Controlled Single-Dose Six-way Crossover Study Evaluating the Abuse Potential of Lyrica Taken Orally with Oxycodone HCl in Healthy Non-Drug Dependent	Positive Opinion adopted by consensus on 16.05.2024.

Recreational Opioid Users". A.6 - To change the ATC Code from N03AX16 to N02BF02." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 11.01.2024, 31.08.2023.	
WS2683 **Relvar Ellipta-** **EMEA/H/C/002673/WS2683/0068** **Revinty Ellipta-** **EMEA/H/C/002745/WS2683/0065** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Antonio Gomez-Outes, "Update of section 5.1 of the SmPC in order to update the results of study HZA107116 - A randomised, double-blind, parallel group, multicentre, stratified, study evaluating the efficacy and safety of once daily fluticasone furoate/vilanterol inhalation powder compared to once daily fluticasone furoate inhalation powder in the treatment of asthma in participants aged 5 to 17 years old (inclusive) currently uncontrolled on inhaled corticosteroids." Request for Supplementary Information adopted on 30.05.2024.	Request for supplementary information adopted with a specific timetable.

B.5.3. CHMP-PRAC assessed procedures

Akeega - Niraparib / Abiraterone acetate - EMEA/H/C/005932/II/0003 Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Jan Neuhauser, "Update of sections 4.8 and 5.1 of the SmPC in order to update the frequency of adverse drug reactions and to update information from MAGNITUDE study based on final results from study 64091742PCR3001 (MAGNITUDE) listed as a PAES in the Annex II. This is a phase 3 randomized, placebo-controlled, double-blind, multicentre study which assessed the efficacy and safety of niraparib 200 mg in combination with AA 1,000 mg once daily plus prednisone or prednisolone 10 mg daily (AAP)a, compared with placebo plus AAP in men with mCRPC and HRR gene alterations, approximately half of whom had BRCA gene alterations and comprised the	Request for supplementary information adopted with a specific timetable.

prespecified BRCA subgroup. The Annex II and Package Leaflet are updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took this opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI." Request for Supplementary Information adopted on 16.05.2024.	
Beovu - Brolucizumab - EMEA/H/C/004913/II/0029 Novartis Europharm Limited, Rapporteur: 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 12.0 has also been submitted." Request for Supplementary Information adopted on 30.05.2024.	Request for supplementary information adopted with a specific timetable.
COMIRNATY - COVID-19 mRNA vaccine - EMEA/H/C/005735/II/0201 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Liana Martirosyan, "Update of sections 4.5, 4.8 and 5.1 of the SmPC in order to update information regarding concomitant vaccine administration with influenza vaccine based on final results from study C4591030 listed as a category 3 study in the RMP. This is an interventional phase 3, randomized, observer-blind trial to evaluate the safety and immunogenicity of	Positive Opinion adopted by consensus on 30.05.2024.

BNT162b2 and quadrivalent seasonal influenza vaccine when administered separately or concomitantly in adults 18 to 64 years of age. The Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted." Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 07.03.2024.	
Dovprela - Pretomanid - EMEA/H/C/005167/II/0019/G, Orphan Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Liana Martirosyan, "Grouped application comprising two variations as follows: Type II (C.I.4) – Update of sections 4.1 and 5.1 of the SmPC in order to rephrase the indication wording to align with the current WHO definitions. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. Type IB (C.I.11.z) - Submission of an updated RMP version 2.0 in order to align the safety concerns following the assessment of procedure EMEA/H/C/005167/11/0013." Request for Supplementary Information adopted on 07.03.2024.	Positive Opinion adopted by consensus on 16.05.2024
Eylea - Aflibercept - EMEA/H/C/002392/II/0090 Bayer AG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Nathalie Gault, "Update of sections 4.8 and 5.1 of the SmPC in order to update safety and clinical information based on results from studies PULSAR (20968) and PHOTON (21091). PULSAR (20968) is an ongoing pivotal Phase 3 study to investigate the efficacy and safety of HD aflibercept at treatment intervals of 12 weeks and longer for indication neovascular age-related macular degeneration (nAMD). PHOTON (21091), is an ongoing pivotal Phase 2/3 study to investigate the efficacy and safety of HD aflibercept at treatment intervals of 12 weeks and longer for indication Diabetic Macular Edema (DME). The Package Leaflet is updated accordingly. The RMP version 34.1 has also been submitted. In addition, the MAH took the opportunity to implement an editorial update in section 6.6 of	Positive Opinion adopted by consensus on 16.05.2024.

the SmPC to align the text with other similar products." Opinion adopted on 16.05.2024.	
Idefirix - Imlifidase - EMEA/H/C/004849/II/0019, Orphan Hansa Biopharma AB, Rapporteur: Martina Weise, PRAC Rapporteur: Bianca Mulder, "Update of section 5.1 of the SmPC in order to include the description of the final results from PAES study 17-HMedIdeS-14 listed as a specific obligation in the Annex II (SOB/002); this is a prospective, observational long-term follow-up study of patients treated with imlifidase (IdeS) prior to kidney transplantation. The primary objective of this trial was to evaluate graft survival in patients who have undergone kidney transplantation after imlifidase administration in earlier trials and relates to both safety and efficacy. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to update section E of Annex II and to implement editorial changes to sections 4.4, 4.6 and 9 of the SmPC. Furthermore, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 07.03.2024.	Positive Opinion adopted by consensus on 16.05.2024.
Ilumetri - Tildrakizumab - EMEA/H/C/004514/II/0054 Almirall S.A, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski, "Update of sections 4.8 and 5.1 of the SmPC in order to update the clinical and safety information based on long-term results from the extension periods of the pivotal clinical studies MK-3222-010 (A 64-Week, Phase 3, Randomized, Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous Tildrakizumab (SCH 900222/MK-3222), followed by an Optional Long-Term Safety Extension Study, in Subjects with Moderate-to-Severe Chronic Plaque Psoriasis (Protocol No. MK-3222-010)) and MK-3222-011 (A 52-Week, Phase 3, Randomized, Active Comparator and Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous Tildrakizumab (SCH 900222 / MK-3222), followed by an Optional Long-Term Safety	Positive Opinion adopted by consensus on 16.05.2024.

Extension Study, in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis). The Product information is also updated in accordance with the Annex of the excipients guideline. The RMP version 1.4 has also been submitted." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 07.03.2024.	
IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0100 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Update of section 5.1 of the SmPC in order to add vaccine effectiveness data, and the removal of the two open specific obligations (POX-MVA-039 (SOB02) and SEMVAc (SOB03)), based on the IMVANEX vaccine effectiveness data in real-world use during the 2022 monkeypox outbreak. Consequently, the MAH proposes a switch from exceptional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 30.05.2024, 21.03.2024.	Request for supplementary information adopted with a specific timetable.
Inrebic - Fedratinib - EMEA/H/C/005026/II/0019, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, PRAC Rapporteur: Sonja Hrabcik, "Update of sections 4.2 and 5.2 of the SmPC in order to update posology recommendations in patients with severe hepatic impairment and to update pharmacokinetic information based on final results from study FEDR-CP-001 listed as a category 3 study in the RMP; this is a phase 1, open-label, single-dose study to assess the pharmacokinetics, safety, and tolerability of fedratinib in subjects with moderate and severe hepatic impairment compared with healthy subjects. The RMP version 2.0 has also been submitted." Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 22.02.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Orkambi - Lumacaftor / Ivacaftor - EMEA/H/C/003954/II/0088	Positive Opinion adopted by consensus on

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Eamon O Murchu, "Submission of the final report from study VX19-809-124 (Study 124), listed as a category 3 study in the RMP. This is a Phase 3, open-label, rollover study to evaluate the long-term safety and tolerability of lumacaftor/ivacaftor in cystic fibrosis subjects homozygous for F508del who were 1 to <2 years of age at treatment initiation and who completed the Safety Follow Up (SFU) visit in Study 122 (Part B) or were lumacaftor/ivacaftor naïve. The RMP version 11.5 has also been submitted." Opinion adopted on 16.05.2024.	16.05.2024.
Piqray - Alpelisib - EMEA/H/C/004804/II/0022/G Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder, "Update of section 4.8 of the SmPC in order to add "uveitis" to the list of adverse drug reactions (ADRs) with a frequency "Not known" based on a cumulative review of the MAH safety database and literature. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to correct the spelling of the active substance 'alpelisib' in the SmPC. The RMP version 7.2 has also been submitted." Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 22.02.2024, 30.11.2023.	Positive Opinion adopted by consensus on 30.05.2024.
RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0052 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to change posology recommendations in adolescents with atopic dermatitis to include the 30mg dose option based on results from studies M16-045, M16-047 and M18-891 (pivotal phase 3 studies with adolescent sub studies). The Package Leaflet is updated accordingly. The RMP version 14.0 has also been submitted." Request for Supplementary Information adopted on 30.05.2024.	Request for supplementary information adopted with a specific timetable.
SCENESSE - Afamelanotide -	Request for supplementary information adopted

EMEA/H/C/002548/II/0052, Orphan Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of section 4.2 of the SmPC in order to update the posology recommendations by removing the current recommendation of a maximum of four implants per year, based on a literature review and analysis of safety data. The Package Leaflet is updated accordingly. The RMP version 9.8 has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial change to the Product Information." Request for Supplementary Information adopted on 30.05.2024.	with a specific timetable.
Tecvayli - Teclistamab - EMEA/H/C/005865/II/0012 Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Jana Lukacisinova, "Update of sections 4.2, 4.8, 5.1 of the SmPC in order to amend the recommendations for dose delays, as well as, to update safety and efficacy information based on final results from study 64007957MMY1001 listed as a specific obligation in the Annex II (SOB/005); this is a phase 1/2, first in human, open label, dose escalation study of teclistamab in subjects with relapsed or refractory multiple myeloma. The Package Leaflet is updated accordingly. The RMP version 4.2 has also been submitted. In addition, the MAH took the opportunity to update Annex II and Annex IV of the PI." Opinion adopted on 30.05.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Zeposia - Ozanimod - EMEA/H/C/004835/II/0023 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, "Update of sections 4.4 and 5.1 of the SmPC in order to update efficacy and safety information based on the final results from study RPC01-3001, listed as a category 3 study in the RMP. This is a multi-site, open label extension trial of RPC1063 in relapsing multiple sclerosis. The study's main objectives were to characterize the long-term safety and tolerability, and the long-term efficacy of ozanimod in patients with relapsing multiple sclerosis. The RMP was updated to version 7.1."	Positive Opinion adopted by consensus on 16.05.2024.

Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 11.01.2024.	
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0005, Orphan Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "Update of section 4.2 of the SmPC in order to update dosing instructions in severe hepatic impairment based on data from phase I study 1042-IHF-1001. The RMP version 1.3 has also been agreed." Opinion adopted on 30.05.2024. Request for Supplementary Information adopted on 21.03.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-EMEA/H/W/005362/WS2593/0012 Qdenga-EMEA/H/C/005155/WS2593/0013 Takeda GmbH, Lead Rapporteur: Sol Ruiz, Lead PRAC Rapporteur: Liana Martirosyan, "Update of section 4.5 of the SmPC in order to add co-administration information with HPV vaccine based on final results from study DEN-308 listed as a category 3 study in the RMP (MEA003/MEA004); this is a Phase 3, open-label, randomized trial to investigate the immunogenicity and safety of the co-administration of a subcutaneous dengue tetravalent vaccine (live, attenuated) (TDV) and an intramuscular recombinant 9-valent human papillomavirus (9vHPV) vaccine in subjects aged ≥9 to <15 years in an endemic country for dengue; the Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes and to update the text on PSUR submissions in Annex II for Dengue tetravalent vaccine." Request for Supplementary Information adopted on 16.05.2024, 07.03.2024.	Request for supplementary information adopted with a specific timetable.

B.5.4. PRAC assessed procedures

PRAC Led **Amlodipine-Valsartan Mylan - Amlodipine / Valsartan - EMEA/H/C/004037/II/0021** Mylan Pharmaceuticals Limited, Generic of	Request for supplementary information adopted with a specific timetable.

Exforge, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of an updated RMP version 4.0 in order to align the safety concerns with the latest version of RMP for Amlodipine/Valsartan available in the public domain and to bring the RMP in line with the latest RMP template." Request for Supplementary Information adopted on 16.05.2024.	
PRAC Led **ASPAVELI - Pegcetacoplan - EMEA/H/C/005553/II/0018, Orphan** Swedish Orphan Biovitrum AB (publ), PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of an updated RMP version 2.1 in order to revise the category 3 PASS Sobi.PEGCET-301 and Sobi.PEGCET-302." Request for Supplementary Information adopted on 16.05.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Avamys - Fluticasone furoate - EMEA/H/C/000770/II/0051/G** GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Grouped application comprising two type II variations as follows: C.I.11.b – Submission of an updated RMP version 12 in order to remove Headache, Nasal events (including: epistaxis, nasal ulceration, nasal septum perforation and other nasal events), Hypersensitivity, Cataract and glaucoma as Important Identified Risks; to remove Taste and smell disorders, Pyrexia, Systemic corticosteroids effect: adrenal suppression, Systemic corticosteroid effect: growth retardation, Psychiatric effects as Important Potential Risks and to remove Use in pregnancy and lactation, Off-label use (sinusitis and children < 6 years of age) as missing information. C.I.11.b – Submission of an updated RMP version 12 in order to remove targeted follow up questionnaires. In addition, the MAH took this opportunity to align the RMP template with GVP Module V Revision 2."	Positive Opinion adopted by consensus on 16.05.2024.

Opinion adopted on 16.05.2024.	
PRAC Led **Beovu - Brolucizumab - EMEA/H/C/004913/II/0028** Novartis Europharm Limited, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 4.8 of the SmPC in order to add 'Scleritis' to the list of adverse drug reactions (ADRs) with frequency 'Not known', following the recommendation by PRAC in the outcome for the signal assessment of Scleritis. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 16.05.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Cholestagel - Colesevelam - EMEA/H/C/000512/II/0053** CHEPLAPHARM Arzneimittel GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 2.0 in order to remove important identified and potential risks, as well as missing information to bring it in line with GVP module V. Additionally, epidemiological data on indication and target population, clinical data and postmarking exposure data was updated." Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
PRAC Led **DaTSCAN - Ioflupane (123I) - EMEA/H/C/000266/II/0067** GE Healthcare B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "To update sections 4.4 and 4.5 of the SmPC and section 2 of the Package Leaflet to implement the recommendation of the PRAC following the PSUSA procedure (EMEA/H/C/PSUSA/00001767/202207). In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 11.04.2024.	Positive Opinion adopted by consensus on 16.05.2024.
PRAC Led **Efient - Prasugrel -**	Positive Opinion adopted by consensus on 16.05.2024.

EMEA/H/C/000984/II/0037 Substipharm, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of an updated RMP version 13 in order to remove of a region-specific additional risk-minimisation activity following previous PSUSA procedure (EMEA/H/C/PSUSA/00002499/202102), as well as to align content and format with new requirements according to GVP Module V Rev. 2. In addition, the MAH took the opportunity to update Annex II of the PI and to update the list of local representatives in the Package Leaflet." Opinion adopted on 16.05.2024.	
PRAC Led **Eurartesim - Piperaquine tetraphosphate / Artenimol - EMEA/H/C/001199/II/0040/G** Alfasigma S.p.A., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "C.I.13: Submission of the final report from the effectiveness evaluation survey for Eurartesim (protocol no. 3366) listed as a category 3 study in the RMP. This is a European multi-centre online survey to assess physician understanding of the revised edition of the educational material. Consequential changes to RMP version 16.1 have been implemented. C.I.11.b: Submission of an updated RMP version 16.1 in order to delete "Severe Malaria" from the Missing Information." Request for Supplementary Information adopted on 16.05.2024, 11.01.2024, 28.09.2023, 08.06.2023.	Request for supplementary information adopted with a specific timetable.
PRAC Led **HyQvia - Human normal immunoglobulin - EMEA/H/C/002491/II/0096** Baxalta Innovations GmbH, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of sections 4.8 and 5.1 of the SmPC in order to update long-term safety information based on final results from studies 161406 "Non-Interventional Post-Marketing Safety Study on the Long-Term Safety of HYQVIA (Global)" listed as category 3 a study in the RMP and 161302 "Non-Interventional Post-Authorization Safety Study on the Long-Term Safety of HyQvia in Subjects	Positive Opinion adopted by consensus on 16.05.2024.

Treated with HyQvia". Both studies were non-interventional, prospective, uncontrolled, multicentre, open-label, post-authorization studies. The RMP version 15.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3, to update the list of local representatives in the Package Leaflet and to introduce minor editorial changes to the PI." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 07.03.2024.	
PRAC Led **Intuniv - Guanfacine - EMEA/H/C/003759/II/0033/G** Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Antonio Gomez-Outes, "Submission of the final reports from the Drug Utilisation Study of Intuniv (guanfacine extended release) in European countries: a prescriber survey (EUPAS18739) and a retrospective database study (EUPAS18735), listed as category 3 studies in the RMP. The RMP version 4.1 has also been submitted." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 07.03.2024, 28.09.2023.	Positive Opinion adopted by consensus on 16.05.2024.
PRAC Led **Lysodren - Mitotane - EMEA/H/C/000521/II/0030** HRA Pharma Rare Diseases, PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Carolina Prieto Fernandez, "Update of sections 4.4 and 4.8 of the SmPC in order to amend existing warnings on hepatic impairment based on a cumulative review of cases with increase of transaminases >5 ULN and the outcome of these elevations after mitotane discontinuation, following the request by PRAC in the PSUSA/00002075/202304. The Package Leaflet is updated in accordance." Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
PRAC Led **MabThera - Rituximab - EMEA/H/C/000165/II/0201/G** Roche Registration GmbH, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Aaron Sosa	Positive Opinion adopted by consensus on 16.05.2024.

Mejia, "A grouped application comprising of: Type II (C.I.3.b): Update of sections 4.1, 4.2, 4.3, 4.8, 5.1, 6.2, 6.4 and 6.5 of the SmPC in order to introduce several structural and editorial changes to align with the current SmPC guideline and to remove the educational materials for HCPs and patients, following the request by the PRAC in the AR for the PSUSA procedure EMA/PRAC/257005/2023. The Annex II, Labelling and Package Leaflet are updated accordingly. The RMP version 25.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet. Type I (A.6): To change the ATC Code of rituximab from L01XC02 to L01FA01." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 08.02.2024.	
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 16.05.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Mysimba - Naltrexone hydrochloride / Bupropion hydrochloride - EMEA/H/C/003687/II/0063** Orexigen Therapeutics Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "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	Request for supplementary information adopted with a specific timetable.

procedure. The Package Leaflet is updated accordingly. The RMP version 12.9 has also been submitted." Request for Supplementary Information adopted on 16.05.2024, 09.02.2024, 31.08.2023.	
PRAC Led **Remicade - Infliximab - EMEA/H/C/000240/II/0247** Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 22.1 in order to remove reference to the immunogenicity sub study as part of protocol REMICADEPIB4002 in Part III. The MAH proposes to discontinue the Dutch portion of the immunogenicity sub study, which is part of protocol REMICADEPIB4002." Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
PRAC Led **TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0031** Gilead Sciences Ireland UC, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Peter Mol, "Submission of an updated RMP version 3.2 in order to remove the important identified risks 'Severe diarrhoea' and 'Hypersensitivity, and the important potential risk 'Embryo-foetal toxicity' from the list of safety concerns, and in addition to extend the due date for the final CSR for the category 3 study IMMU-132-15 from December 2023 to June 2027 in the Pharmacovigilance plan." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 07.03.2024.	Positive Opinion adopted by consensus on 16.05.2024.
PRAC Led **Zessly - Infliximab - EMEA/H/C/004647/II/0033** Sandoz GmbH, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 4.0 in order to remove the UKIBD (UK) registry from the additional pharmacovigilance activities." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 08.02.2024.	Positive Opinion adopted by consensus on 16.05.2024.
PRAC Led **WS2577**	Positive Opinion adopted by consensus on 16.05.2024.

Kinzalmono- **EMEA/H/C/000211/WS2577/0120** **Micardis-** **EMEA/H/C/000209/WS2577/0129** **Pritor-EMEA/H/C/000210/WS2577/0133** Boehringer Ingelheim International GmbH, Lead Rapporteur: Paolo Gasparini, Lead PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, "Submission of an updated RMP version 6.1 in order to implement an overall update regarding safety concerns based on literature and post marketing data; and to adapt the RMP to the current RMP format (Rev 2.0.1), in line with GVP Module V, Revision 2." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 11.01.2024.	
PRAC Led **WS2611** **Kinzalkomb-** **EMEA/H/C/000415/WS2611/0123** **MicardisPlus-** **EMEA/H/C/000413/WS2611/0130** **PritorPlus-** **EMEA/H/C/000414/WS2611/0133** Boehringer Ingelheim International GmbH, Lead PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, "Submission of an updated RMP version 9.1 for MicardisPlus, PritorPlus and Kinzalkomb in order to remove all important identified and potential risks from the list of safety concerns and to adapt the RMP to the current RMP format (Rev 2.0.1), in line with GVP Module V, Revision 2." Opinion adopted on 16.05.2024. Request for Supplementary Information adopted on 11.01.2024.	Positive Opinion adopted by consensus on 16.05.2024.
PRAC Led **WS2615** **Abseamed-** **EMEA/H/C/000727/WS2615/0108** **Binocrit-** **EMEA/H/C/000725/WS2615/0108** **Epoetin alfa Hexal-** **EMEA/H/C/000726/WS2615/0108** Sandoz GmbH, Lead PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from Non-Interventional Post Authorization Safety Study,	Request for supplementary information adopted with a specific timetable.

NI-PASS HX575-507 listed as a category 3 study in the RMP. The non-interventional study (NIS PASS) study HX575-507 was conducted to address a post-approval requirement (MEA 13.5) to evaluate the safety profile of HX575 administered s.c. in patients with CKD-induced anaemia under real-life conditions, in order to increase confidence on the safe use of s.c. HX575. The RMP version 19.0 has also been submitted." Request for Supplementary Information adopted on 16.05.2024, 08.02.2024.	
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: Martina Weise, "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 16.05.2024, 08.02.2024.	Request for supplementary information adopted with a specific timetable.

PRAC Led **WS2671** **Finlee-EMEA/H/C/005885/WS2671/0005** **Spexotras-** **EMEA/H/C/005886/WS2671/0004** **Tafinlar-** **EMEA/H/C/002604/WS2671/0067** Novartis Europharm Limited, Lead PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Eva Skovlund, "Update of section 4.8 of the SmPC in order to add 'Atrioventricular (AV) block' with an uncommon frequency for Finlee and Spexotras and common frequency for Tafinlar to the list of adverse drug reactions (ADRs), following the PRAC recommendation in the PSUR for Mekinist (PSUSA/00010262/202305). The Package Leaflet is updated accordingly." Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.

B.5.5. CHMP-CAT assessed procedures

Abecma - Idecabtagene vicleucel - EMEA/H/C/004662/II/0047, Orphan, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang , "- To update section 6.6 of the SmPC - "Special precautions for disposal and other handling", and corresponding section of the Package Leaflet, to clarify dose preparation and administration instructions of the thawed finished product (IV administration set fitted with a non-leukodepleting in-line filter which can be used to reduce visible cellular aggregates that do not disperse after gentle manual mixing)." Request for Supplementary Information adopted on 24.05.2024.	Request for supplementary information adopted with a specific timetable.
Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0036/G, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini, "Grouped application comprising two variations as follows: C.I.4 – Update of sections 4.4 and 4.8 of the SmPC in order to add immune effector cell-associated neurotoxicity syndrome (ICANS) as an adverse drug reaction (ADR) based on the	Request for supplementary information adopted with a specific timetable.

cumulative review of MAH safety database and literature. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes. A.6 – To include the ATC Code L01XL08 in section 5.1 of the SmPC.” Request for Supplementary Information adopted on 24.05.2024, 16.02.2024.	
CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0027/G, Orphan, ATMP Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus Request for Supplementary Information adopted on 24.05.2024.	Request for supplementary information adopted with a specific timetable.
Libmeldy - Atidarsagene autotemcel - EMEA/H/C/005321/II/0025, Orphan, ATMP Orchard Therapeutics (Netherlands) B.V., Rapporteur: Emmely de Vries, CHMP Coordinator: Peter Mol, Opinion adopted on 30.05.2024, 24.05.2024.	Positive Opinion adopted by consensus on 30.05.2024.
Upstaza - Eladocagene exuparvovec - EMEA/H/C/005352/II/0021, Orphan, ATMP PTC Therapeutics International Limited, Rapporteur: Joseph DeCourcey, CHMP Coordinator: Finbarr Leacy, Opinion adopted on 30.05.2024, 24.05.2024.	Positive Opinion adopted by consensus on 30.05.2024.
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 Request for Supplementary Information adopted on 24.05.2024, 16.02.2024.	Request for supplementary information adopted with a specific timetable.

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

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

WS2533 **Jentadueto-** **EMEA/H/C/002279/WS2533/0071** **Trajenta-** **EMEA/H/C/002110/WS2533/0053** Boehringer Ingelheim International GmbH, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 02.05.2024. Request for Supplementary Information adopted on 01.02.2024.	Positive Opinion adopted by consensus on 02.05.2024.
WS2656/G **Copalia HCT-** **EMEA/H/C/001159/WS2656/0112/G** **Dafiro HCT-** **EMEA/H/C/001160/WS2656/0114/G** **Exforge HCT-** **EMEA/H/C/001068/WS2656/0111/G** Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 02.05.2024.	Request for supplementary information adopted with a specific timetable.
WS2657 **HyQvia-EMEA/H/C/002491/WS2657/0097** **Kiovig-EMEA/H/C/000628/WS2657/0127** Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 23.05.2024. Request for Supplementary Information adopted on 11.04.2024.	Positive Opinion adopted by consensus on 23.05.2024.
WS2669 **HyQvia-EMEA/H/C/002491/WS2669/0098** **Kiovig-EMEA/H/C/000628/WS2669/0128** Baxalta Innovations GmbH, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 02.05.2024.	Request for supplementary information adopted with a specific timetable.
WS2677 **Mircera-EMEA/H/C/000739/WS2677/0100** **NeoRecormon-** **EMEA/H/C/000116/WS2677/0124** Roche Registration GmbH, Lead Rapporteur: Martina Weise Opinion adopted on 02.05.2024.	Positive Opinion adopted by consensus on 02.05.2024.
WS2678 **Incresync-** **EMEA/H/C/002178/WS2678/0048**	Positive Opinion adopted by consensus on 16.05.2024.

Vipdomet- **EMEA/H/C/002654/WS2678/0047** **Vipidia-EMEA/H/C/002182/WS2678/0037** Takeda Pharma A/S, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 16.05.2024.	
WS2685 **Mekinist-** **EMEA/H/C/002643/WS2685/0065** **Tafinlar-** **EMEA/H/C/002604/WS2685/0070** Novartis Europharm Limited, Lead Rapporteur: Filip Josephson, "To update the product information section 4.2 with the pharmaceutical form capsule and tablets, respectively and section 5.2 with pharmacokinetic exposure at weight adjusted dosage for adolescents." Opinion adopted on 30.05.2024.	Positive Opinion adopted by consensus on 30.05.2024.
WS2687 **Eucreas-** **EMEA/H/C/000807/WS2687/0109** **Icandra-** **EMEA/H/C/001050/WS2687/0114** **Zomarist-** **EMEA/H/C/001049/WS2687/0111** Novartis Europharm Limited, Lead Rapporteur: Kristina Dunder Opinion adopted on 16.05.2024.	Positive Opinion adopted by consensus on 16.05.2024.
WS2704 **Filgrastim Hexal-** **EMEA/H/C/000918/WS2704/0077** **Zarzio-EMEA/H/C/000917/WS2704/0078** Sandoz GmbH, Lead Rapporteur: Peter Mol, "To update section 4.8 of the SmPC to add "extramedullary haematopoiesis" as adverse a reaction with frequency "rare", following assessment of the same change in the reference product, Neupogen. The Package Leaflet (section 4) has been updated accordingly. Furthermore, the Marketing Authorisation Holder has taken the opportunity to update the local representative details for Cyprus." Opinion adopted on 23.05.2024.	Positive Opinion adopted by consensus on 23.05.2024.

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

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

Hemangiol - propranolol -	Request by the applicant for an extension to the

EMEA/H/C/002621/II/0025 Pierre Fabre Medicament, Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 05.10.2023.	clock stop to respond to the RSI adopted in October 2023. The CHMP agreed to the request by the applicant.
WS2550 **Aldara-EMEA/H/C/000179/WS2550/0089** **Zyclara-EMEA/H/C/002387/WS2550/0031** Viatris Healthcare Limited, Lead Rapporteur: Ewa Balkowiec Iskra Request for Supplementary Information adopted on 02.05.2024.	Request by the applicant for an extension to the clock stop to respond to the RSI adopted in May 2024. The CHMP agreed to the request by the applicant.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

Ustekinumab - EMEA/H/C/006585 treatment of active plaque psoriasis, paediatric plaque psoriasis, psoriatic arthritis (PsA) and Crohn's disease.
ATROPINE SULFATE PH. EUR. - EMEA/H/C/006385, PUMA treatment of myopia in children aged 3 years and older
Denosumab - EMEA/H/C/006199prevention of skeletal related events with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone
Denosumab - EMEA/H/C/006376 prevention of skeletal related events with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone
Deutivacaftor / Tezacaftor / Vanzacaftor - EMEA/H/C/006382, Orphan Vertex Pharmaceuticals (Ireland) Limited, indicated for the treatment of cystic fibrosis
Ustekinumab - EMEA/H/C/006448, treatment of Crohn's disease and Ulcerative colitis, Plaque psoriasis, Paediatric plaque psoriasis and Psoriatic arthritis (PsA),
Inavolisib - EMEA/H/C/006353, treatment of adult patients with PIK3CA-mutated,

hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer

Denosumab - EMEA/H/C/006152 for the treatment of osteoporosis and bone loss.

In vitro diagnostic medical device - EMEA/H/D/006536
to detect ITD and TKD mutations in the FLT3 gene in patients with acute myelogenous leukaemia (AML).

Macitentan - EMEA/H/C/006524 treatment of pulmonary arterial hypertension (PAH)

Macitentan - EMEA/H/C/006523, treatment of pulmonary arterial hypertension (PAH)

Octreotide - EMEA/H/C/006322, for treatment of acromegaly in adult patients in whom surgery is inappropriate or ineffective

Ranibizumab - EMEA/H/C/006528
treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to diabetic macular oedema (DME), proliferative diabetic retinopathy (PDR), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) and visual impairment due to choroidal neovascularisation (CNV)

Sepiapterin - EMEA/H/C/006331, Orphan
PTC Therapeutics International Limited, Treatment of hyperphenylalaninemia (HPA) in adult and paediatric patients with phenylketonuria (PKU)
patients with phenylketonuria (PKU).

Teprotumumab - EMEA/H/C/006396, treatment of moderate to severe Thyroid Eye Disease (TED).

In vitro diagnostic medical device - EMEA/H/D/006543
, Qualitative immunohistochemical assay using mouse monoclonal anti-claudin 18, clone 43 14A, intended for laboratory use in the assessment of claudin 18 (CLDN18) protein in formalin-fixed, paraffin-embedded (FFPE) gastric adenocarcinoma including gastroesophageal junction (GEJ) tissue

specimens by light microscopy.

In vitro diagnostic medical device - EMEA/H/D/006545
laboratory use in the assessment of folate receptor alpha (FOLR1) protein in formalin-fixed paraffin embedded (FFPE) epithelial ovarian, fallopian tube or primary peritoneal cancer tissue specimens by light microscopy

Denosumab - EMEA/H/C/006377, for the treatment of osteoporosis and bone loss

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

Evrysdi - Risdiplam - EMEA/H/C/005145/X/0024/G
Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Extension application to introduce a new pharmaceutical form associated with a new strength (5 mg film-coated tablets) grouped with a Type II variation (C.I.4) to update sections 4.2 and 5.2 of the SmPC in order to update the recommended method of administration based on the food effect results from study BP42066; this is a phase 1, open-label, multiperiod crossover study to investigate the safety, food effect, bioavailability, and bioequivalence of oral doses of two different formulations of risdiplam in healthy subjects. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the Product Information and to align the Package Leaflets of both formulations."

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, multicentre, 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. Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
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 (200mg) 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 from 3 studies conducted under protocol CNTO1959UCO3001 (Induction Study 1 Phase 2b, Induction Study 2 Phase 3 and Maintenance Study). All 3 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 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."

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

Aflibercept - EMEA/H/C/006150
treatment of age-related macular degeneration (AMD), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO), due to diabetic macular oedema (DME) and due to myopic choroidal neovascularisation (myopic CNV) or central RVO),
List of Questions adopted on 25.01.2024.

Apremilast - EMEA/H/C/006193
treatment of psoriatic arthritis, psoriasis, Behçet's disease
List of Questions adopted on 22.02.2024.

Cerdelga - Eliglustat - EMEA/H/C/003724/X/0036/G, Orphan
Sanofi B.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon, "Extension application to introduce a new strength (21 mg capsule, hard) grouped with an extension of indication (C.I.6.a) to include treatment of paediatric patients with GD1 who are 6 years and older with a minimum body weight of 15 kg, who have been previously treated with enzyme replacement therapy (ERT), and who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs) or extensive metabolisers (EMs) for Cerdelga, based on interim results from study EFC13738 (Open label, two cohort (with and without imiglucerase), multicentre study to evaluate pharmacokinetics, safety, and efficacy of eliglustat in paediatric patients with Gaucher disease type 1 and type 3). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 8.0 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI."
List of Questions adopted on 25.04.2024.

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
List of Questions adopted on 12.10.2023.

Bimatoprost - EMEA/H/C/005916
indicated for the reduction of intraocular pressure (IOP) in adults with open angle glaucoma (OAG) or ocular hypertension (OHT) who are unsuitable for topical IOP-lowering medications
List of Questions adopted on 20.07.2023.

Mirvetuximab soravtansine - EMEA/H/C/005036, Orphan
Immunogen Biopharma (Ireland) Limited, treatment of ovarian, fallopian tube, or primary peritoneal cancer
List of Questions adopted on 22.02.2024.

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).
List of Questions adopted on 14.12.2023.

Marstacimab - EMEA/H/C/006240, Orphan
Pfizer Europe Ma EEIG, Tradename is indicated for routine prophylaxis of bleeding episodes in patients with haemophilia A or haemophilia B
List of Questions adopted on 22.02.2024.

Ustekinumab - EMEA/H/C/006221
, treatment of active plaque psoriasis, Crohn’s disease, active ulcerative colitis and active psoriatic arthritis,
List of Questions adopted on 09.11.2023.

Temozolomide - EMEA/H/C/006169, Orphan
Orphelia Pharma, treatment of neuroblastoma
List of Questions adopted on 14.12.2023.

Meningococcal group A, B, C, W and Y vaccine - EMEA/H/C/006165
indicated for active immunisation to prevent invasive disease caused by Neisseria meningitidis groups A, B, C, W, and Y

List of Questions adopted on 12.10.2023.

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

GSK Vaccines S.r.l, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan, "Extension application to introduce a new pharmaceutical form (solution for injection). The RMP (version 11.0) is updated in accordance."
List of Questions adopted on 12.10.2023.

Odevixibat - EMEA/H/C/006462

treatment of cholestatic pruritus in Alagille syndrome (ALGS)
List of Questions adopted on 25.04.2024.

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

Boehringer Ingelheim International GmbH, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Barbara Kovacic Bytyqi, "Extension application to add a new strength of 25 mg hard capsules, grouped with an extension of indication (C.I.6.a) to include treatment of fibrosing Interstitial Lung Diseases (ILDs) in children and adolescents from 6 to 17 years of age for Ofev, following the assessment of procedure X/0052/G, based on final results from study 1199-0337 (A Double Blind, Randomised, Placebo-controlled Trial to Evaluate the Dose-exposure and Safety of Nintedanib Per os on Top of Standard of Care for 24 Weeks, Followed by Open Label Treatment With Nintedanib of Variable Duration, in Children and Adolescents (6 to 17 Year-old) With Clinically Significant Fibrosing Interstitial Lung Disease), which is supplemented by the currently ongoing prospective Phase III extension trial 1199-0378 (An Open-label Trial of the Long-term Safety and Tolerability of Nintedanib Per os, on Top of Standard of Care, Over at Least 2 Years, in Children and Adolescents With Clinically Significant Fibrosing Interstitial Lung Disease). The main objective of the study 1199-0337 was to evaluate dose-exposure and safety of nintedanib in children and adolescents with fibrosing Interstitial Lung Disease (ILD). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 12.0 of the RMP

has also been submitted."
List of Questions adopted on 22.02.2024.

Opsumit - Macitentan - EMEA/H/C/002697/X/0051/G
Janssen-Cilag International N.V., Rapporteur: Antonio Gomez-Outes, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon, "Extension application to introduce a new pharmaceutical form associated with new strengths (1 and 2.5 mg dispersible tablet) grouped with an extension of indication (C.I.6.a) to include, as monotherapy or in combination, the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged 1 month to less than 18 years of age of WHO Functional Class (FC) I to III for OPSUMIT, based on interim results from AC-055-312 study (TOMORROW). This is a multicentre, open-label, randomized study with single-arm extension period to assess the pharmacokinetics, safety, and efficacy of macitentan versus standard of care in children with pulmonary arterial hypertension. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC for film-coated tablets are updated. The Package Leaflet and Labelling are updated in accordance. Version 14.1 of the RMP has also been submitted."
List of Questions adopted on 22.02.2024.

Aflibercept - EMEA/H/C/006056
treatment of age-related macular degeneration (AMD) and visual impairment
List of Questions adopted on 21.03.2024.

PHEBURANE - Sodium phenylbutyrate - EMEA/H/C/002500/X/0037
Eurocept International B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu, "Extension application to introduce a new pharmaceutical form associated with new strength (500 mg film-coated tablets). The RMP (version 1.1) is updated in accordance."
List of Questions adopted on 25.01.2024.

Pomalidomide - EMEA/H/C/006302
in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM)
List of Questions adopted on 25.01.2024.

Vorasidenib - EMEA/H/C/006284, Orphan

Les Laboratoires Servier, treatment of predominantly non-enhancing astrocytoma or oligodendroglioma with a IDH1 R132 mutation or IDH2 R172 mutation
List of Questions adopted on 23.04.2024.

Eplontersen - EMEA/H/C/006295, Orphan
AstraZeneca AB, indicated for the treatment of adult patients with polyneuropathy associated with hereditary transthyretin-mediated amyloidosis (ATTRv).
List of Questions adopted on 22.02.2024.

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

Chenodeoxycholic acid Leadiant - Chenodeoxycholic acid - EMEA/H/C/004061/S/0024, Orphan
Leadiant GmbH, Rapporteur: Anastasia Mountaki, PRAC Rapporteur: Adam Przybylkowski

DECTOVA - Zanamivir - EMEA/H/C/004102/S/0018
GlaxoSmithKline Trading Services Limited, Rapporteur: Ingrid Wang, PRAC Rapporteur: Ulla Wändel Liminga

Elaprase - Idursulfase - EMEA/H/C/000700/S/0116
Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan

Firdapse - Amifampridine - EMEA/H/C/001032/S/0077
SERB SA, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga

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

Amsparity - Adalimumab - EMEA/H/C/004879/R/0008
Pfizer Europe MA EEIG, Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Simona Badoi, PRAC Rapporteur: Mari Thorn

Beovu - Brolucizumab - EMEA/H/C/004913/R/0030
Novartis Europharm Limited, Rapporteur: Alexandre Moreau, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Gabriele

Maurer

Deferasirox Accord - Deferasirox - EMEA/H/C/005156/R/0011
Accord Healthcare S.L.U., Generic of EXJADE, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Tiphaine Vaillant

GAVRETO - Pralsetinib - EMEA/H/C/005413/R/0019
Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Ulla Wändel Liminga

Isturisa - Osilodrostat - EMEA/H/C/004821/R/0022, Orphan
Recordati Rare Diseases, Rapporteur: Kristina Dunder, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Maria del Pilar Rayon

Jaypirca - Pirtobrutinib - EMEA/H/C/005863/R/0004
Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Edward Laane, PRAC Rapporteur: Bianca Mulder

Mayzent - Siponimod - EMEA/H/C/004712/R/0029
Novartis Europharm Limited, Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Maria del Pilar Rayon

Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/R/0029
Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Adam Przybylkowski

Senshio - Ospemifene - EMEA/H/C/002780/R/0048
Shionogi B.V., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Kirsti Villikka

Sunosi - Solriamfetol - EMEA/H/C/004893/R/0023
Atnahs Pharma Netherlands B.V., Rapporteur: Janet Koenig, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Julia Pallos

Tavlesse - Fostamatinib - EMEA/H/C/005012/R/0018
Instituto Grifols, S.A., Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Daniela Philadelphy,

PRAC Rapporteur: Bianca Mulder

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

ADCETRIS - Brentuximab vedotin - EMEA/H/C/002455/II/0111, Orphan Takeda Pharma A/S, Rapporteur: Peter Mol, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "Extension of indication for ADCETRIS to include treatment for adult patients with previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone (BrECADD), based on final results from phase 3 study HD21 (NCT02661503). This study is titled Treatment Optimization Trial in the First-Line Treatment of Advanced-Stage Hodgkin Lymphoma; Comparison of 4-6 Cycles of Escalated BEACOPP With 4-6 Cycles of BrECADD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 20.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the SmPC."	
Aflunov - Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - EMEA/H/C/002094/II/0086 Seqirus S.r.l, Rapporteur: Maria Grazia Evandri, PRAC Rapporteur: Amelia Cupelli, "Extension of indication to include treatment of individuals 6 months of age and older for AFLUNOV, based on final results from study V87_30. This is a Phase 2, Randomized, Observer-Blind, Multicentre Study to Evaluate the Immunogenicity and Safety of Several Doses of Antigen and MF59 Adjuvant Content in a Monovalent H5N1 Pandemic Influenza Vaccine in Healthy Paediatric Subjects 6 Months to < 9 Years of Age. As a consequence, sections 4.1, 4.2, 4.8 and	

5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 5.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC. ”

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

Ultragenyx Germany GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Mari Thorn, “Extension of indication for EVKEEZA to include the treatment of paediatric patients with homozygous familial hypercholesterolaemia aged 6 months to less than 5 years, based on the results of population PK and population PK/PD model-based extrapolation reports (R1500-PM-23202-SR-01V2 and R1500-PM-23089-SR-01V2). As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement minor changes to sections 4.2, 4.4, and 4.7 of the SmPC, along with editorial changes to the SmPC.”

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

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

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

Sanofi Winthrop Industrie, Rapporteur: Peter Mol, PRAC Rapporteur: Monica Martinez Redondo, "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."

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

AstraZeneca AB, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder, "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."

WS2672
OPDIVO-
EMEA/H/C/003985/WS2672/0141
Yervoy-EMEA/H/C/002213/WS2672/0111
Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Peter Mol, Lead PRAC Rapporteur: Martin Huber, "A Worksharing application for OPDIVO and YERVOY, as follows:

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

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

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Afstyla - Lonoctocog alfa -
EMEA/H/C/004075/II/0055
CSL Behring GmbH, Rapporteur: Jan Mueller-

Berghaus

BEKEMV - Eculizumab - EMEA/H/C/005652/II/0005
Amgen Technology (Ireland) Unlimited Company, Rapporteur: Outi Mäki-Ikola

Benlysta - Belimumab - EMEA/H/C/002015/II/0130
GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder

Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0022/G
Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher

Bortezomib SUN - Bortezomib - EMEA/H/C/004076/II/0023
Sun Pharmaceutical Industries Europe B.V., Generic of VELCADE, Rapporteur: Margareta Bego

Brineura - Cerliponase alfa - EMEA/H/C/004065/II/0045/G, Orphan
BioMarin International Limited, Rapporteur: Martina Weise

BroPair Spiromax - Salmeterol / Fluticasone propionate - EMEA/H/C/005591/II/0011
Teva B.V., Duplicate of Seffalair Spiromax, Rapporteur: John Joseph Borg

Cablivi - Caplacizumab - EMEA/H/C/004426/II/0049/G, Orphan
Ablynx NV, Rapporteur: Filip Josephson

COMIRNATY - COVID-19 mRNA vaccine - EMEA/H/C/005735/II/0216
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

Cresemba - Isavuconazole - EMEA/H/C/002734/II/0046, Orphan
Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Patrick Vrijlandt

Entyvio - Vedolizumab - EMEA/H/C/002782/II/0083/G
Takeda Pharma A/S, Rapporteur: Paolo Gasparini

Esperoct - Turoctocog alfa pegol - EMEA/H/C/004883/II/0024/G
Novo Nordisk A/S, Rapporteur: Daniela

Philadelphy

Fluad Tetra - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0053
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

Flucelvax Tetra - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/II/0045
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

Fluenz - Influenza vaccine (live attenuated, nasal) - EMEA/H/C/006514/II/0001
AstraZeneca AB, Rapporteur: Christophe Focke

Gardasil 9 - Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0074
Merck Sharp & Dohme B.V., Rapporteur: Kristina Dunder

Imfinzi - Durvalumab - EMEA/H/C/004771/II/0067/G
AstraZeneca AB, Rapporteur: Aaron Sosa Mejia

Juluca - Dolutegravir / Rilpivirine - EMEA/H/C/004427/II/0059/G
ViiV Healthcare B.V., Rapporteur: Janet Koenig

Kengrexal - Cangrelor - EMEA/H/C/003773/II/0033
Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt

Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0155
Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini

LIVOGIVA - Teriparatide - EMEA/H/C/005087/II/0012
Theramex Ireland Limited, Rapporteur: Christian Gartner

M-M-RvaxPro - Measles, mumps and rubella vaccine (live) - EMEA/H/C/000604/II/0124/G
Merck Sharp & Dohme B.V., Rapporteur: Jan Mueller-Berghaus

Nustendi - Bempedoic acid / Ezetimibe - EMEA/H/C/004959/II/0046
Daiichi Sankyo Europe GmbH, Rapporteur:

Patrick Vrijlandt

NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0071/G
Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt

NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0075
Novavax CZ a.s., Rapporteur: Patrick Vrijlandt

Pegasys - Peginterferon alfa-2a - EMEA/H/C/000395/II/0120
Pharmaand GmbH, Rapporteur: Filip Josephson

Praluent - Alirocumab - EMEA/H/C/003882/II/0091/G
Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt

Puregon - Follitropin beta - EMEA/H/C/000086/II/0130
Organon N.V., Rapporteur: Finbarr Leacy

Ranivisio - Ranibizumab - EMEA/H/C/005019/II/0015/G
Midas Pharma GmbH, Rapporteur: Jan Mueller-Berghaus

Rezzayo - Rezafungin - EMEA/H/C/005900/II/0002, Orphan
Mundipharma GmbH, Rapporteur: Bruno Sepodes

Rystiggo - Rozanolixizumab - EMEA/H/C/005824/II/0003, Orphan
UCB Pharma, Rapporteur: Thalia Marie Estrup Blicher

Ryzneuta - Efbemalenograstim alfa - EMEA/H/C/005828/II/0001
Evive Biotechnology Ireland Limited, Rapporteur: Vilma Petrikaite

Seffalair Spiromax - Salmeterol / Fluticasone propionate - EMEA/H/C/004881/II/0011
Teva B.V., Rapporteur: John Joseph Borg

Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0004, Orphan
Reata Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher

Soliris - Eculizumab -

EMEA/H/C/000791/II/0132, Orphan
Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez

Spectrila - Asparaginase - EMEA/H/C/002661/II/0040
medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Christian Gartner

Tyenne - Tocilizumab - EMEA/H/C/005781/II/0003
Fresenius Kabi Deutschland GmbH, Rapporteur: Kristina Dunder

Uzpruvo - Ustekinumab - EMEA/H/C/006101/II/0002
STADA Arzneimittel AG, Rapporteur: Christian Gartner

Vabysmo - Faricimab - EMEA/H/C/005642/II/0011/G
Roche Registration GmbH, Rapporteur: Jayne Crowe

Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0144
MCM Vaccine B.V., Rapporteur: Christophe Focke

VEGZELMA - Bevacizumab - EMEA/H/C/005534/II/0010/G
Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola

Voxzogo - Vosoritide - EMEA/H/C/005475/II/0015, Orphan
BioMarin International Limited, Rapporteur: Martina Weise

WS2529
Keppra-EMEA/H/C/000277/WS2529/0200
UCB Pharma S.A., Lead Rapporteur: Karin Janssen van Doorn, Lead PRAC Rapporteur: Jo Robays

WS2652/G
Edistride-
Forxiga-
AstraZeneca AB, Lead Rapporteur: Kristina Dunder

WS2692/G
Hexacima-

EMEA/H/C/002702/WS2692/0157/G
Hexyon-
EMEA/H/C/002796/WS2692/0161/G
Sanofi Pasteur Europe, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus

B.6.9. 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 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."

Bylvay - Odevixibat -
EMEA/H/C/004691/II/0018, Orphan
Ipsen Pharma, Rapporteur: Patrick Vrijlandt, "Update of section 4.2 of the SmPC in order to add instructions for odevixibat administration in liquids. The Package Leaflet is updated accordingly."

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."

CAMZYOS - Mavacamten - EMEA/H/C/005457/II/0009

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

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

Sanofi Pasteur, Rapporteur: Christophe Focke, "Submission of the final report from study CYD69 listed as a category 3 study in the RMP. This is an Observational study: Effectiveness of the tetravalent dengue vaccine, CYD-TDV (DENGVAXIA) in the Philippines."

Dengvaxia - Dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0030

Sanofi Pasteur, Rapporteur: Christophe Focke, "Submission of the final report from study CYD50 (Safety and Immunogenicity of a Tetravalent Dengue Vaccine in HIV Positive Adults Aged 18 to 50 Years in Brazil) listed as a category 3 study in the RMP. This was a randomized, observer-blind, placebo-controlled, multi-centre, Phase II study planned in 150 HIV-positive adults, treated with antiretrovirals, and previously exposed to dengue."

Drovelis - Drospirenone / Estetrol - EMEA/H/C/005336/II/0025

Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder, "Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding renal impairment based on final results from study MIT-Do001-C103. This is a Phase 1, open-label,

sequential group, single-dose study to evaluate the pharmacokinetics and safety of estetrol monohydrate (E4) in female subjects with varying degrees of renal function. The Package Leaflet is updated accordingly."

Drovelis - Drospirenone / Estetrol - EMEA/H/C/005336/II/0026

Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on results from study MIT-Es001-C303. This is a Phase III, Open-label, Single-Arm Study to Evaluate the Safety, Compliance and Pharmacokinetics associated with the use of a Combined Oral Contraceptive Containing 15 mg Estetrol monohydrate and 3 mg Drospirenone in Post-menarchal Female Adolescents for 6 cycles. The Package Leaflet is updated accordingly."

Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva - Efavirenz / Emtricitabine / Tenofovir disoproxil - EMEA/H/C/004250/II/0037

Zentiva k.s., Generic of Atripla (SRD), Rapporteur: Tomas Radimersky, "Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on Bone effects and to add bone mineral density decreased to the list of adverse drug reactions (ADRs) with frequency common based on the cumulative review of literature. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes to the PI."

Evrysdi - Risdiplam - EMEA/H/C/005145/II/0025

Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Update of sections 4.4, 4.5 and 5.3 of the SmPC in order to remove the warning on retinal toxicity, based on thorough ophthalmological monitoring in clinical studies to date."

Fexinidazole Winthrop - Fexinidazole - EMEA/H/W/002320/II/0017

Sanofi Winthrop Industrie, Rapporteur: Fátima Ventura, "Update of sections 4.2, 4.3, 4.4 and 5.2 of the SmPC in order to add PK information in participants with mild and moderate hepatic impairment based on final results from study POP17145 - A multicentric, open-label, non-randomized, pharmacokinetic and tolerability study of fexinidazole given as an oral single 1200 mg dose in participants with mild and moderate hepatic impairment, and in matched participants with normal hepatic function. The Package Leaflet is updated accordingly."	
Fexinidazole Winthrop - Fexinidazole - EMEA/H/W/002320/II/0018 Sanofi Winthrop Industrie, Rapporteur: Fátima Ventura, "Update of sections 4.5 and 5.2 of the SmPC in order to update information regarding the interaction with CYP3A4/3A5 drugs based mainly on final results from study INT17144; this is an open-label, non-randomized, two-treatment, one-sequence crossover pharmacokinetic interaction study of 5-day repeated oral doses of fexinidazole on a single oral dose of midazolam used as probe substrate for CYP3A4 in healthy male and female participants."	
Lorviqua - Lorlatinib - EMEA/H/C/004646/II/0034 Pfizer Europe MA EEIG, Rapporteur: Aaron Sosa Mejia, "Submission of the final report from study B7461001. This was a Phase 1/2, open-label, multicentre, multiple-dose, dose escalation, safety, PK, pharmacodynamics, and anti-cancer efficacy exploration study of lorlatinib as a single agent in participants with advanced ALK-positive or advanced ROS1-positive NSCLC."	
Lydisilka - Drospirenone / Estetrol - EMEA/H/C/005382/II/0025 Estetra SRL, Duplicate of Drovelis, Rapporteur: Kristina Dunder, "Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding renal impairment based on final results from study MIT-Do001-C103. This is a Phase 1, open-label, sequential group, single-dose study to evaluate the pharmacokinetics and safety of estetrol monohydrate (E4) in female subjects with varying degrees of renal function. The Package Leaflet is updated	

accordingly.”

Lydisilka - Drospirenone / Estetrol - EMEA/H/C/005382/II/0026

Estetra SRL, Duplicate of Drovelis, Rapporteur: Kristina Dunder, “Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on results from study MIT-Es001-C303. This is a Phase III, Open-label, Single-Arm Study to Evaluate the Safety, Compliance and Pharmacokinetics associated with the use of a Combined Oral Contraceptive Containing 15 mg Estetrol monohydrate and 3 mg Drospirenone in Post-menarchal Female Adolescents for 6 cycles. The Package Leaflet is updated accordingly.”

MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine - EMEA/H/C/005084/II/0034/G

Sanofi Pasteur, Rapporteur: Daniela Philadelphy, “Grouped application comprising two type II variations as follows:
C.I.4 - Update of section 5.1 of the SmPC in order to add 5 years persistence of immune response based on final results from study MEQ00066. MEQ00066 was a Phase III, two--stage, randomized, open-label, multi-centre trial to evaluate the immunogenicity and safety of a single dose of MenACYW conjugate vaccine at least 3 years after a prior dose of either MenACYW conjugate vaccine or Menomune.
C.I.4 – Update of section 5.1 of the SmPC in order to add immune persistence and booster response data in children based on interim results from study MEQ00073. MEQ00073 is a Phase IIIb, open-label, multi-centre study to evaluate the immunogenicity and safety of a booster dose of MenQuadfi administered to children and describe 5- and/or 10-year immune persistence of MenQuadfi after primary vaccination.
Annex II is also being updated. In addition, the MAH took the opportunity to introduce editorial changes to the PI.”

MULTAQ - Dronedarone - EMEA/H/C/001043/II/0053

Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt, “Update of section 4.6 of the SmPC in order to update recommendations on

contraception, pregnancy and lactation, and to propose pregnancy testing prior to treatment. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”	
Nexavar - Sorafenib - EMEA/H/C/000690/II/0059, Orphan Bayer AG, Rapporteur: Filip Josephson, “Update of section 5.3 of the SmPC in order to update preclinical safety data on carcinogenicity studies based on final results from studies T4079666 - Carcinogenicity Study in CD-1 Mice (2 Years Administration by Diet) and T8076320 - Carcinogenicity Study in Wistar Rats (2 Years Administration in the Diet with Dose Adjustment). In addition, the MAH took the opportunity to introduce editorial changes to the PI and to update the list of local representatives in the Package Leaflet.”	
Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0135 Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang, “Update of section 5.1 of the SmPC in order to update immunogenicity response information based on results from Study C0921062 and following EMEA/H/C/002226/P46/057 procedure. Study C0921062 is a Phase 3b, open-label, with a single-arm design study, to evaluate the safety and immunogenicity of a single dose of Nimenrix in infants at 3 months of age, followed by a booster dose at 12 months of age. In addition, the MAH took the opportunity to implement editorial changes in the SmPC”	
Opfolda - Miglustat - EMEA/H/C/005695/II/0013 Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, “Update of section 4.8 SmPC in order to update the frequency of adverse drug reactions and to add ''paraesthesia'' to the list of adverse drug reactions (ADRs) with frequency ''common'' based on an updated pooled analysis (Pool 2) of integrated safety data of Phase 2/3 studies (Study ATB200-02, Study ATB200-03 and Study ATB200-07). The Package Leaflet is updated	

accordingly."

Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0056

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Update of section 4.6 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."

Piqray - Alpelisib - EMEA/H/C/004804/II/0025

Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update the frequency of Adverse Drug Reactions and safety information based on final results from study CBYL719C2301 (SOLAR-1). This is a randomized, double-blind, placebo-controlled, international, multicentre, Phase III study to determine the efficacy and safety of treatment with alpelisib plus fulvestrant versus placebo plus fulvestrant in men and postmenopausal women with hormone receptor-positive, HER2-negative advanced breast cancer which progressed on or after AI (Aromatase Inhibitor) treatment. The Package Leaflet is updated accordingly."

Pombiliti - Cipaglucosidase alfa - EMEA/H/C/005703/II/0012

Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, "Update of section 4.8 of the SmPC in order to update the frequency of adverse drug reactions and to add swelling face to the list of adverse drug reactions (ADRs) with frequency Uncommon based on the updated integrated analysis of safety data for Pool 2 (All Studies ATB200-02/03/07). The Package Leaflet is updated accordingly."

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."	
Pylclari - Piflufolastat (18F) - EMEA/H/C/005520/II/0004 Curium Pet France, Rapporteur: Antonio Gomez-Outes, "Update of section 11 of the SmPC in order to update information on dosimetry data based on results obtained with a new generation software. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."	
Saxenda - Liraglutide - EMEA/H/C/003780/II/0041 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "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."	
Siklos - Hydroxycarbamide - EMEA/H/C/000689/II/0061 Theravia, Rapporteur: Karin Janssen van Doorn, "Update of section 4.5 of the SmPC in order to update information regarding the interference with certain Continuous Glucose Monitoring (CGM) sensors, based on a literature review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Soliris - Eculizumab - EMEA/H/C/000791/II/0131, Orphan Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, "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."

Trulicity - Dulaglutide - EMEA/H/C/002825/II/0070

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

Wegovy - Semaglutide - EMEA/H/C/005422/II/0022

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Update of section 4.8 of the SmPC in order to add "Dysaesthesia" to the list of adverse drug reactions (ADRs) with frequency "common" based on post marketing data and literature. The Package Leaflet is updated accordingly."

Xarelto - Rivaroxaban - EMEA/H/C/000944/II/0110/G

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

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."

WS2647
Mekinist-
EMEA/H/C/002643/WS2647/0066
Tafinlar-
EMEA/H/C/002604/WS2647/0071
Novartis Europharm Limited, Lead Rapporteur: Peter Mol, "Update of section 5.1 of the SmPC for Tafinlar and Mekinist in order to update efficacy information based on final results from study CDRB436F2301 (COMBI-AD); this is a phase 3 randomized double blind study of dabrafenib in combination with trametinib versus two placebos in the adjuvant treatment of high-risk BRAF V600 mutation-positive melanoma after surgical resection. The RMP version 11.1 for Tafinlar and version 19.2 for Mekinist have also been submitted. In addition, MAH took the opportunity to introduce minor editorial changes to the Product Information."

WS2691
Hycamtin-
EMEA/H/C/000123/WS2691/0102
Sandoz Pharmaceuticals d.d., Lead Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update recommendations on duration of contraception in males and females, in line with the SWP/NcWP recommendations (EMA/CHMP/SWP/74077/2020 rev. 1*) on the duration of contraception following the end of treatment with a genotoxic drug and based on the proposed wording suggested in the CMDh report for EMA/CMDh/409368/2021. The Package Leaflet is updated accordingly."

WS2693
Finlee-EMEA/H/C/005885/WS2693/0007
Spexotras-
EMEA/H/C/005886/WS2693/0006
Novartis Europharm Limited, Lead Rapporteur: Filip Josephson, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to add photosensitivity to the list of adverse drug reactions (ADRs) with frequency Common respectively and to update efficacy and safety information on paediatric population based on

final results from study CDRB436G2201; this is a phase II open-label global study to evaluate the effect of dabrafenib in combination with trametinib in children and adolescent patients with BRAF V600 mutation positive Low Grade Glioma (LGG) or relapsed or refractory High Grade Glioma (HGG). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes."

WS2700
M-M-RvaxPro-EMEA/H/C/000604/WS2700/0123
ProQuad-EMEA/H/C/000622/WS2700/0166
Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on literature search. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce minor editorial changes to the PI."

WS2701
Ofev-EMEA/H/C/003821/WS2701/0061
Vargatef-EMEA/H/C/002569/WS2701/0053
Boehringer Ingelheim International GmbH, Lead Rapporteur: Finbarr Leacy, "Update of sections 4.4 and 4.8 of the SmPC in order to add 'posterior reversible encephalopathy syndrome (PRES)' to the list of adverse drug reactions (ADRs) with frequency 'Not know' based on post marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the SmPC."

WS2707
Celldemic-EMEA/H/C/006052/WS2707/0001
Zoonotic Influenza Vaccine Seqirus-EMEA/H/C/006375/WS2707/0003
Seqirus Netherlands B.V., Lead Rapporteur: Daniela Philadelphy, "Submission of the final report from extension study V89_18E1 (NCT05422326). This is a Phase 2, Randomized, Study to Evaluate Safety and Immunogenicity of One or Two Heterologous Booster Vaccinations With an MF59-adjuvanted, Cell Culture-derived

H5N6 Influenza Vaccine in Adults Primed With MF59-adjuvanted, Cell Culture-derived H5N1 Influenza Vaccine or Unprimed. ”

B.6.10. CHMP-PRAC assessed procedures

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.”

ILARIS - Canakinumab - EMEA/H/C/001109/II/0085

Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer

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

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

changes to the PI."

Nyxoid - Naloxone - EMEA/H/C/004325/II/0019

Mundipharma Corporation (Ireland) Limited, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Liana Martirosyan, "Submission of the interim report from the PAES MR903-9501 listed as an obligation in the Annex II, supported by Real World Evidence from literature and European Take-Home Naloxone programs (THN) demonstrating the effectiveness of Nyxoid in a real-world setting. Study MR903-9501 is a non-interventional multi-national, prospective, mixed methods study of the effectiveness of naloxone (including intranasal Nyxoid) administration by lay people in reversing opioid overdose. The Annex II and the RMP version 3.0 are updated accordingly. In addition, the MAH took the opportunity to introduce minor administrative changes to the Package Leaflet."

Ocrevus - Ocrelizumab - EMEA/H/C/004043/II/0041

Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.6 and 5.3 of the SmPC in order to amend the recommendations for breast-feeding during ocrelizumab therapy, based on newly available clinical data. The Package Leaflet is updated accordingly. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0057/G

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Martin Huber, "Grouped application consisting of:
C.I.4: Update of sections 4.2, 4.4, 4.8 and 5.2 of the SmPC in order to provide a new dosing recommendation in patients with severe renal impairment based on final results from study C4671028; this is a Phase 1, Open-Label, Non-Randomized Study to Investigate the Safety and PK Following Multiple Oral Doses of PF-07321332 (Nirmatrelvir)/Ritonavir in Adult Participants With COVID-19 and Severe Renal Impairment Either on Hemodialysis or Not on Hemodialysis. The Package Leaflet and Labelling

are updated accordingly. The updated RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. B.II.e.5.a.2: To introduce a new pack size ”
Retsevmo - Selpercatinib - EMEA/H/C/005375/II/0032 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder, “Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to add urinary tract infections, stomatitis, calcium decreased, albumin decreased, sodium decreased and potassium decreased to the list of adverse drug reactions (ADRs) with frequency Very common and to update efficacy, safety and pk information based on results from study LIBRETTO-531 (JZJB) listed as a specific obligation in the Annex II; This study is a Phase 3 confirmatory study comparing selpercatinib to physicians choice of cabozantinib or vandetanib in patients with progressive advanced, kinase inhibitor naive RET-mutant medullary thyroid cancer (MTC). The Package Leaflet and Annex II are updated accordingly. The RMP version 9.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”
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.”
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0136 Moderna Biotech Spain S.L., Rapporteur: Jan

Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen

VELSIPITY - Etrasimod - EMEA/H/C/006007/II/0002/G

Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Mari Thorn, "A grouped application comprised of two Type II variations, as follows:

C.I.4: Update of sections 4.2, 4.3 and 5.2 of the SmPC in order to amend recommendation regarding administration to patients with severe hepatic impairment and remove contraindication for severe hepatic impairment, based on in vitro studies to further characterise the drug-drug interaction (DDI) potential of metabolites M3 and M6. The Annex II and Package Leaflet are updated accordingly. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

C.I.13: Submission of the final report from study 24GR036 (hERG Channel Automated Patch-Clamp Test); this is an assessment of the effects of PF-08034694, PF-08034742, PF-08039030, and PF-08039032 on the Kv11.1 (hERG) potassium current."

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

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

WS2695
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-EMEA/H/W/005362/WS2695/0015
Qdenga-EMEA/H/C/005155/WS2695/0016
Takeda GmbH, Lead Rapporteur: Sol Ruiz, Lead PRAC Rapporteur: Liana Martirosyan, "Update of section 4.4 and 4.8 of the SmPC in order to add anaphylactic reaction to the list of adverse drug reactions (ADRs) with frequency not known, based on post-authorization experience. The Package Leaflet is updated accordingly. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes to the PI."

WS2702
Ongentys-EMEA/H/C/002790/WS2702/0066
Ontilyv-EMEA/H/C/005782/WS2702/0021
Bial - Portela & Cª, S.A., Lead Rapporteur: Martina Weise, Lead PRAC Rapporteur: Maria del Pilar Rayon, "Update of section 4.8 of the SmPC in order to add 'fall' and 'fatigue' to the list of adverse drug reactions (ADRs) with frequency uncommon based on the cumulative review of literature. The Package Leaflet is updated accordingly. The Ongentys RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes to the PI."

B.6.11. PRAC assessed procedures

PRAC Led
NeoRecormon - Epoetin beta - EMEA/H/C/000116/II/0126
Roche Registration GmbH, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of an updated RMP version 4.0 in order to align with GVP Module V (Rev. 2)."

PRAC Led
Oxbryta - Voxelotor -

EMEA/H/C/004869/II/0011, Orphan Pfizer Europe Ma EEIG, PRAC Rapporteur: Jo Robays, PRAC-CHMP liaison: Christophe Focke, "Submission of an updated RMP version 1.2 in order to include the current data for the main existing treatment options and to extend the submission deadline for Study GBT440-0122 (C5341029) and for Study GBT440-034 (C5341022)."	
PRAC Led **Piqray - Alpelisib -** **EMEA/H/C/004804/II/0024** Novartis Europharm Limited, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Peter Mol, "Submission of an updated RMP version 8.0 in order to remove the PASS CBYL719C2404 (Cat. 3) RMP commitment (MEA 002)."	
PRAC Led **VITRAKVI - Larotrectinib -** **EMEA/H/C/004919/II/0036** Bayer AG, PRAC Rapporteur: Rugile Pilviniene, PRAC-CHMP liaison: Vilma Petrikaite, "Submission of an updated RMP version 2.1 in order to adjust the sample size for the non-interventional PASS ON-TRK as well as to update epidemiological, clinical trial and post-marketing data."	
PRAC Led **WS2686** **Cinacalcet Accordpharma-** **EMEA/H/C/005236/WS2686/0011** Accord Healthcare S.L.U., Generic of Mimpara, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "To update the RMP to make updated in following safety concerns (important identified risks) after approval of the same changes in the reference product, Mimpara (in procedure EMEA/H/C/000570/IB/0069): -Update of "Hypocalcemia" to "Hypocalcemia in the paediatric population" -Removal of "QT prolongation and ventricular arrhythmias secondary to hypocalcaemia" -Removal of "Convulsions/seizures" Furthermore, the Marketing Authorisation Holder is taking the opportunity to consolidate into a single RMP the RMPs approved for Cinacalcet 30mg/60mg/90mg Film-coated	

tablets through CP (EMEA/H/C/005236) and DCP (FI/H/869/01-03/DC) procedures."	
PRAC Led **WS2705** **Lixiana-EMEA/H/C/002629/WS2705/0050** **Roteas-EMEA/H/C/004339/WS2705/0036** Daiichi Sankyo Europe GmbH, Lead PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Alexandre Moreau, "Submission of a Summary of Changes for the DSE-EDO-05-14-EU clinical study report, as an erratum detailing the updates. DSE-EDO-05-14-EU is a non-interventional Post-Authorisation Safety Study (PASS) on Edoxaban treatment in routine clinical practice for patients with acute venous thromboembolism in Europe (ETNA-VTE-Europe) which was listed as a category 3 study in the RMP (MEA 007)."	

B.6.12. CHMP-CAT assessed procedures

Abecma - Idecabtagene vicleucel - EMEA/H/C/004662/II/0048, Orphan, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang	
Casgevy - Exagamglogene autotemcel - EMEA/H/C/005763/II/0003/G, Orphan, ATMP Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus	
Hemgenix - Etranacogene dezaparvovec - EMEA/H/C/004827/II/0014/G, Orphan, ATMP CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy	
Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/II/0066/G, ATMP Amgen Europe B.V., Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lähteenvuo, "A grouped application consisting of two Type II variations, as follows: C.I.13: Submission of the final report from Study 5 (added in EMEA-001251-PIP01-11-M04) titled "Exposure-Response analysis of	

Talimogene Laherparepvec for adult subjects with melanoma from Study 20120324 and comparison to paediatric subjects' data from Study 20110261 in support of a paediatric investigational plan"

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

Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/II/0067/G, ATMP

Amgen Europe B.V., Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lähteenvuo, "A grouped application as follows:

Type II (C.I.4): Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update paediatric information based on the paediatric study 20110261, which was previously submitted in procedure II/0063. This is a phase 1, multicentre, open-label study of talimogene laherparepvec in paediatric subjects with advanced non-CNS tumours that were amenable to direct injection in the clinical setting. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the Product Information.

Type IA (A.6): To change the ATC Code of Antineoplastic cell and gene therapy from L01XX51 to L01XL02."

Upstaza - Eladocagene exuparvovec - EMEA/H/C/005352/II/0022/G, Orphan, ATMP

PTC Therapeutics International Limited, Rapporteur: Joseph DeCourcey, CHMP Coordinator: Finbarr Leacy

Yescarta - Axicabtagene ciloleucel - EMEA/H/C/004480/II/0077, Orphan,

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

WS2689
Tecartus-
EMEA/H/C/005102/WS2689/0045
Yescarta-
EMEA/H/C/004480/WS2689/0076
Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus

B.6.13. CHMP-PRAC-CAT assessed procedures

Alofisel - Darvadstrocel -
EMEA/H/C/004258/II/0051/G, Orphan, ATMP
Takeda Pharma A/S, Rapporteur: Maria Luttgen, CHMP Coordinator: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer, "A grouped application comprised of 4 Type II Variations, as follows:

(C.I.4): Update of sections 4.8 and 5.1 of the SmPC in order to update the safety information, based on pooled safety data from the two phase 3 controlled studies (ADMIRE-CD & ADMIRE-CD II) and to update efficacy information based on final results from study ADMIRE-CD II, listed as an obligation in the Annex II. ADMIRE-CD II (Cx601-0303) is a Phase III randomised double blind, placebo-controlled study to assess efficacy and safety of Cx601, adult allogeneic expanded adipose-derived stem cells (eASC) for the treatment of complex perianal fistula(s) in patients with Crohn's disease. The Annex II is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI, including to section 4.2 of the SmPC and to the Package Leaflet.

3 x (C.I.13): Submission of interim results from studies Darvadstrocel-3003 and Alofisel-5003 (INSPIRE) and final results from study Darvadstrocel-3002 to support the benefit-risk assessment of darvadstrocel based on all new available clinical data.

The RMP version 8.0 has also been submitted."

Yescarta - Axicabtagene ciloleucel -

EMEA/H/C/004480/II/0075/G, Orphan, ATMP

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Erneholm, "Grouped application comprising two type II variations as follows:
C.I.13 - Submission of the final report from study KTE-C19-101 (ZUMA-1) listed as a category 3 study in the RMP. This is a Phase 1/2 Multicentre Study Evaluating the Safety and Efficacy of Kte-C19 In Subjects With Refractory Aggressive Non-Hodgkin Lymphoma.
C.I.13 - Submission of the final report from study KTE-C19-106 (ZUMA-6) listed as a category 3 study in the RMP. This is a Phase 1-2 Multi-Centre Study Evaluating the Safety and Efficacy Of Kte-C19 In Combination With Atezolizumab In Subjects With Refractory Diffuse Large B-Cell Lymphoma (Dlbcl).
The RMP version 9.2 has also been submitted."

B.6.14. PRAC assessed ATMP procedures

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

WS2681
Ambirix-
EMEA/H/C/000426/WS2681/0133
Fendrix-
EMEA/H/C/000550/WS2681/0086
Infanrix hexa-
EMEA/H/C/000296/WS2681/0345
Twinrix Adult-
EMEA/H/C/000112/WS2681/0168
Twinrix Paediatric-
EMEA/H/C/000129/WS2681/0169

GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS2694/G
GONAL-f-
EMEA/H/C/000071/WS2694/0170/G
Pergoveris-
EMEA/H/C/000714/WS2694/0092/G

Merck Europe B.V., Lead Rapporteur: Thalia Marie Estrup Blicher

WS2699
Adrovance-
EMEA/H/C/000759/WS2699/0054
FOSAVANCE-

EMEA/H/C/000619/WS2699/0057
VANTAVO-
EMEA/H/C/001180/WS2699/0044
Organon N.V., Lead Rapporteur: Christian Gartner

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. Timetables – 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