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SCIENCE MEDICINES HEALTH

27 May 2024
EMA/CHMP/182386/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 27-30 May 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

27 May 2024, 09:00 – 19:30, virtual meeting/room 1C

28 May 2024, 08:30 – 19:30, virtual meeting/room 1C

29 May 2024, 08:30 – 19:30, virtual meeting/room 1C

30 May 2024, 08:30 – 15:00, virtual meeting/room 1C

Disclaimers

Some of the information contained in this agenda 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, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda 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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 27-30 May 2024. See May 2024 CHMP minutes (to be published post June 2024 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 27-30 May 2024

1.3. Adoption of the minutes

CHMP minutes for 22-25 April 2024.

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

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. 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.

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.

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.

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.

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.

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: Oral Explanation

Action: 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.

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Apadamtase alfa - 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

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

3.1.2. Paclitaxel - EMEA/H/C/005997

treatment of metastatic breast cancer

Scope: Opinion

Action: For adoption

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

19.05.2022.

3.1.3. Bevacizumab - EMEA/H/C/005574

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

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

3.1.4. Sugemalimab - EMEA/H/C/006088

treatment of adults with metastatic non-small-cell lung cancer (NSCLC)

Scope: Opinion

Action: For adoption

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

3.1.5. Dasatinib - EMEA/H/C/006251

Indicated for the treatment of chronic myelogenous leukaemia (CML)

Scope: Opinion

Action: For adoption

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

3.1.6. Fidanacogene elaparvovec - PRIME - ATMP - EMEA/H/C/004774

indicated for the treatment of severe and moderately severe haemophilia B

Scope: Opinion

Action: For adoption

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

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

Prophylaxis of influenza

Scope: Opinion scheduled for adoption at the May PROM Meeting

Action: For information

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

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

Scope: Opinion

Action: For adoption

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

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

prevention of disease caused by chikungunya (CHIKV) virus

Scope: Opinion

Action: For adoption

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

3.1.10. Pomalidomide - EMEA/H/C/006273

treatment of adult patients with multiple myeloma

Scope: Opinion

Action: For adoption

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

3.1.11. Pomalidomide - EMEA/H/C/006314

treatment of multiple myeloma

Scope: Opinion

Action: For adoption

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

3.1.12. Pomalidomide - EMEA/H/C/006294

treatment of adults with multiple myeloma

Scope: Opinion

Action: For adoption

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

25.01.2024.

3.1.13. Dasiglucagon - EMEA/H/C/006214

treatment of severe hypoglycemia in patients with diabetes

Scope: Opinion

Action: For adoption

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

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.

3.2.2. 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.

3.2.3. 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.

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

treatment of primary biliary cholangitis (PBC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.02.2024.

3.2.5. 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.

3.2.6. 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.

3.2.7. Ustekinumab - EMEA/H/C/006544

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

Scope: List of outstanding issues

Action: For adoption

3.2.8. 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.

3.2.9. 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.

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

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

Scope: List of questions

Action: For adoption

3.3.2. Trastuzumab - EMEA/H/C/006219

treatment of metastatic and early breast cancer

Scope: List of questions

Action: For adoption

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

Treatment of ATTR amyloidosis

Scope: List of questions

Action: For adoption

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

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

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

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

3.3.8. [Pegfilgrastim - PUMA - EMEA/H/C/006348](#)

treatment of neutropenia in paediatric patients

Scope: List of questions

Action: For adoption

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

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

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.

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.

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.

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.

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.

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.

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

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

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

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

treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction less than 30%

Scope: Withdrawal of marketing authorisation application

Action: For information

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

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.

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 21.0 of the RMP has also been submitted.”

Action: For adoption

List of Questions adopted on 14.12.2023.

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.

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.

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 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 include treatment of adult patients with moderately to severely active ulcerative colitis, for SKYRIZI, based on final results from studies M16-067 substudy 2: a phase 2b/3 multicenter, randomized, double-blind, placebo-controlled induction study to evaluate the efficacy and safety of risankizumab in subjects with moderately to severely active ulcerative colitis, and M16-066 substudy 1: a multicenter, randomized, double-blind, placebo controlled 52-week maintenance and an open-label extension study of the efficacy and safety of risankizumab in subjects with ulcerative colitis, as well as DDI study M19-974. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC for the Skyrizi 600 mg concentrate for solution for infusion, and sections 1, 2, 4.1, 4.2, 4.8, 5.1, 5.2, 5.3, 6.5 and 6.6 of the SmPC for the Skyrizi 360 mg solution for injection in cartridge are updated. The Annex II, Labelling and Package Leaflets are updated in accordance. Version 5.0 of the RMP has also been submitted.”

Action: For adoption

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

4.1.6. [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.

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

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.

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

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.

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

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) with type 2 inflammation on triple therapy or double therapy if inhaled corticosteroids (ICS) are contraindicated, based on final results from study EFC15804 (BOREAS); 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 are updated. The Package Leaflet is updated in accordance. Version 10.0 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

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

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; this is a Phase 3, randomized, 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 1.1 of the RMP has also been submitted.”

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

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 2 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, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Annex II 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 minor editorial changes.

2) B.I.b.1.b – Quality

In addition, further editorial changes are made in module 3 which are consequential to the extension of indication and the higher maximum daily dose.”,

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.

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

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.

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.

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-center 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

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

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

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

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 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 16 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024, 14.12.2023.

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.

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

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

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.”

Action: For adoption

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

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

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.

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.

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

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 tumor samples.

Scope: Opinion

Action: For adoption

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

8.1.2. lfileucel - 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

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

8.2. Priority Medicines (PRIME)

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. 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

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

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: "Grouped application comprising three type II variations (C.I.4) as follows:

- Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to add 3-IV induction dosing regimen and dose escalation of subcutaneous maintenance dose from CT-P13 SC 120 mg Q2W to 240 mg Q2W for patients with loss of response and update efficacy and safety information 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 Randomised, 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.
- Update of sections 4.2 and 5.2 of the SmPC in order to add subcutaneous induction posology and pharmacokinetic information based on Population PK and PK-PD Modelling and Simulation.
- Update of section 4.2 of the SmPC in order to switch from high-dose IV maintenance (> 5 mg/kg) to subcutaneous maintenance dose of 120 mg Q2W based on data from REMSWITCH study (Effectiveness of Switching From Intravenous to Subcutaneous Infliximab in Patients With Inflammatory Bowel Diseases: the REMSWITCH Study). The RMP version 16.1 has also been submitted. 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.

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

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

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: Thalia Marie Estrup Blicher, Referral Co-Rapporteur: Daniela Philadelphia

Scope: Revised timetable

Action: For adoption

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Mysimba (naltrexone/bupropion), taking into account any consequences from the failure to comply with the obligations laid down in the marketing authorisation.

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

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

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: Call for experts for AHEG

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.

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

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

No items

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

14.2.2. Paediatric Committee (PDCO)

Agenda of the May 2024 PDCO plenary meeting.

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Reports from the BWP meeting for CHMP adoption.

Action: For adoption

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.

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

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

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

15. Any other business

15.1. AOB topic

No items

Explanatory notes

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

Oral explanations (section 2)

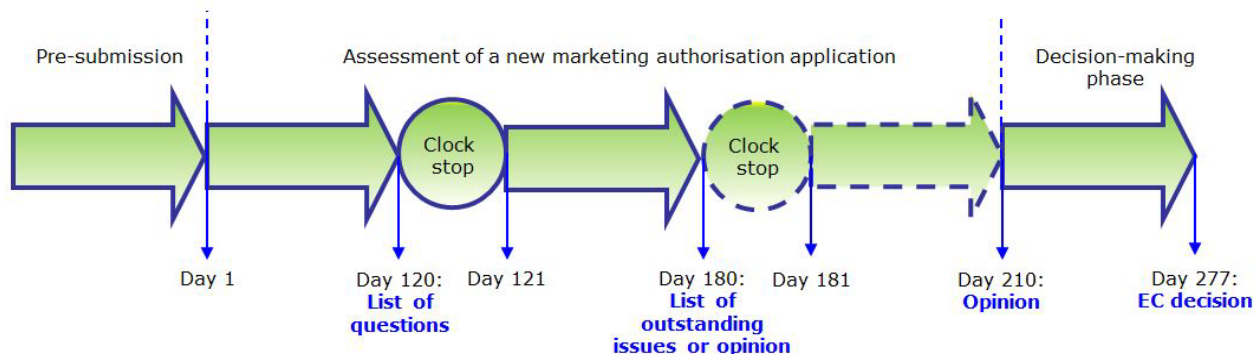
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications (section 3)

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

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

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



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

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

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

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

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

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

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

Ancillary medicinal substances in medical devices (section 6)

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

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

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

Re-examination procedures (section 5.3)

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

Withdrawal of application (section 3.7)

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

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

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

Pre-submission issues (section 8)

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

Post-authorisation issues (section 9)

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

Referral procedures (section 10)

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

Pharmacovigilance issues (section 11)

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

Inspections Issues (section 12)

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

Innovation task force (section 13)

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

Scientific advice working party (SAWP) (section 14.3.1)

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

Satellite groups / other committees (section 14.2)

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

Invented name issues (section 14.3)

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

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



27 May 2024
EMA/CHMP/182732/2024

Annex to 27-30 May 2024 CHMP Agenda

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for
May 2024: **For adoption**

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 - EMA/H/C/000796/S/0048

Laboratoires Delbert, Rapporteur: Jayne Crowe,
PRAC Rapporteur: Eamon O Murchu
Request for Supplementary Information adopted
on 25.04.2024.

Ebvallo - Tabelecleucel - EMA/H/C/004577/S/0008, Orphan, ATMP

Pierre Fabre Medicament, Rapporteur: Egbert
Flory, CHMP Coordinator: Jan Mueller-Berghaus,
PRAC Rapporteur: Amelia Cupelli

ELZONRIS - Tagraxofusp - EMA/H/C/005031/S/0025, Orphan

Stemline Therapeutics B.V., Rapporteur:
Alexandre Moreau, PRAC Rapporteur: Bianca
Mulder

Obizur - Susoctocog alfa - EMA/H/C/002792/S/0056

Baxalta Innovations GmbH, Rapporteur: Daniela
Philadelphia, PRAC Rapporteur: Gabriele Maurer

Tecovirimat SIGA - Tecovirimat - EMA/H/C/005248/S/0010

SIGA Technologies Netherlands B.V.,

Rapporteur: Jayne Crowe, PRAC Rapporteur:
Martin Huber

Voraxaze - Glucarpidase -
EMA/H/C/005467/S/0025, Orphan
SERB S.A.S., Rapporteur: Petr Vrbata, PRAC
Rapporteur: Martin Huber

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 -
EMA/H/C/005175/R/0009
Accord Healthcare S.L.U., Generic of TRISENOX,
Rapporteur: Alar Irs, PRAC Rapporteur: Tiphaine
Vaillant

Bortezomib Fresenius Kabi - Bortezomib -
EMA/H/C/005074/R/0010
Fresenius Kabi Deutschland GmbH, Generic of
VELCADE, Rapporteur: Hrefna Gudmundsdottir,
PRAC Rapporteur: Amelia Cupelli

Deferasirox Mylan - Deferasirox -
EMA/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.

Epidyolex - Cannabidiol -
EMA/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.

RINVOQ - Upadacitinib -
EMA/H/C/004760/R/0051
AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Kristina Dunder, Co-Rapporteur:
Outi Mäki-Ikola, PRAC Rapporteur: Petar Mas

B.2.3. Renewals of Conditional Marketing Authorisations

AYVAKYT - Avapritinib -

EMA/H/C/005208/R/0034, Orphan

Blueprint Medicines (Netherlands) B.V.,
Rapporteur: Carolina Prieto Fernandez, PRAC
Rapporteur: Bianca Mulder

Idefirix - Imlifidase -

EMA/H/C/004849/R/0020, Orphan

Hansa Biopharma AB, Rapporteur: Martina
Weise, Co-Rapporteur: Kristina Dunder, PRAC
Rapporteur: Bianca Mulder

MINJUVI - Tafasitamab -

EMA/H/C/005436/R/0015, Orphan

Incyte Biosciences Distribution B.V.,
Rapporteur: Aaron Sosa Mejia, Co-Rapporteur:
Alexandre Moreau, PRAC Rapporteur: Ulla
Wändel Liminga

ROCTAVIAN - Valoctocogene roxaparvovec - EMA/H/C/005830/R/0011, Orphan, ATMP

BioMarin International Limited, Rapporteur:
Violaine Closson Carella, Co-Rapporteur: Silke
Dorner, CHMP Coordinator: Jean-Michel Race,
PRAC Rapporteur: Bianca Mulder

Tepkinly - Epcoritamab -

EMA/H/C/005985/R/0004, Orphan

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Peter Mol, Co-Rapporteur: Ingrid
Wang, PRAC Rapporteur: Monica Martinez
Redondo

VITRAKVI - Larotrectinib -

EMA/H/C/004919/R/0035

Bayer AG, Rapporteur: Filip Josephson, PRAC
Rapporteur: Rugile Pilviniene

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

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 13-16 May 2024

PRAC:

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/0000459/202309

(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"

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 für klinische
Spezialpräparate mbH, Rapporteur: Janet Koenig

Leflunomide Zentiva (EMEA/H/C/001129)

(Leflunomide), Zentiva, k.s., Rapporteur: Peter
Mol

NAPS:

NAPs - EU

PRAC Rapporteur: Liana Martirosyan,

"10/09/2020 To: 10/09/2023"

EMA/H/C/PSUSA/00002113/202309

(buprenorphine / naloxone)

CAPS:

Suboxone (EMA/H/C/000697) (Buprenorphine / Naloxone), Indivior Europe Limited,

Rapporteur: Janet Koenig

Zubsolv (EMA/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"

EMA/H/C/PSUSA/00002480/202310

(posaconazole)

CAPS:

Noxafil (EMA/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"

EMA/H/C/PSUSA/00002999/202309

(toremifene)

CAPS:

Fareston (EMA/H/C/000091) (Toremifene),

Orion Corporation, Rapporteur: Alexandre

Moreau, PRAC Rapporteur: Tiphaine Vaillant,

"01/10/2020 To: 30/09/2023"

EMA/H/C/PSUSA/00010135/202309

(teriflunomide)

CAPS:

AUBAGIO (EMA/H/C/002514) (Teriflunomide),

Sanofi Winthrop Industrie, Rapporteur: Martina

Weise

Teriflunomide Accord (EMA/H/C/005960)

(Teriflunomide), Accord Healthcare S.L.U.,

Rapporteur: Kristina Nadrah

Teriflunomide Mylan (EMA/H/C/005962)

(Teriflunomide), Mylan Pharmaceuticals Limited,

Rapporteur: Alar Irs

NAPS:

NAPs - EU

PRAC Rapporteur: Martin Huber, "09/11/2022

To: 12/09/2023"

EMA/H/C/PSUSA/00011008/202310

(asciminib)

CAPS:

Scemblix (EMA/H/C/005605) (Asciminib),
Novartis Europharm Limited, Rapporteur: Janet
Koenig, PRAC Rapporteur: Eva Jirsová,
"29/04/2023 To: 28/10/2023"

B.4. EPARs / WPARs

**ALTUVOCT - Efanesoctocog alfa -
EMA/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 -
EMA/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 -
EMA/H/C/005979**

Takeda Pharmaceuticals International AG
Ireland Branch, treatment of metastatic
colorectal cancer, New active substance (Article
8(3) of Directive No 2001/83/EC)

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

**JERAYGO - Aprocitentan -
EMA/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.

Obgemsa - Vibegron - EMA/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 - EMA/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.

<p>Telmisartan Teva Pharma (SRD) – Telmisartan - EMEA/H/C/002511 Teva B.V., treatment of essential hypertension, New active substance (Article 8(3) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Tofidence - Tocilizumab - EMA/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)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Truqap - Capivasertib - EMEA/H/C/006017 AstraZeneca AB, treatment of locally advanced or metastatic breast cancer, New active substance (Article 8(3) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>WEZENLA - Ustekinumab - EMA/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, Crohn’s Disease and ulcerative colitis, treatment of Crohn’s Disease and Ulcerative colitis, Similar biological application (Article 10(4) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES</p>	
<p>Scopes related to Chemistry, Manufacturing, and Controls cannot be released at the present time as these contain commercially confidential information.</p>	
<p>B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects</p>	
<p>Adenuric - Febuxostat - EMA/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.</p>	<p>Positive Opinion adopted by consensus on 02.05.2024.</p>
<p>Adtralza - Tralokinumab - EMA/H/C/005255/II/0014/G LEO Pharma A/S, Rapporteur: Jayne Crowe Opinion adopted on 02.05.2024.</p>	<p>Positive Opinion adopted by consensus on 02.05.2024.</p>

Request for Supplementary Information adopted on 18.01.2024.

Advate - Octocog alfa -

EMA/H/C/000520/II/0122/G

Takeda Manufacturing Austria AG, Rapporteur:

Jan Mueller-Berghaus

Request for Supplementary Information adopted on 04.04.2024.

AREXVY - Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E -

EMA/H/C/006054/II/0009/G

GlaxoSmithkline Biologicals S.A., Rapporteur:

Patrick Vrijlandt

Opinion adopted on 02.05.2024.

Positive Opinion adopted by consensus on 02.05.2024.

Azacitidine betapharm - Azacitidine -

EMA/H/C/005075/II/0015

betapharm Arzneimittel GmbH, Generic of

Vidaza, Rapporteur: Petr Vrbata Request for

Supplementary Information adopted on

15.06.2023.

Besremi - Ropeginterferon alfa-2b -

EMA/H/C/004128/II/0033/G

AOP Orphan Pharmaceuticals GmbH,

Rapporteur: Janet Koenig

Candidas - Caspofungin -

EMA/H/C/000379/II/0083/G

Merck Sharp & Dohme B.V., Rapporteur:

Christophe Focke

Request for Supplementary Information adopted on 04.04.2024, 11.01.2024.

Clopidogrel Viatris - Clopidogrel -

EMA/H/C/001189/II/0049/G

Viатris 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 -

EMA/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 -

EMA/H/C/000665/II/0068/G

Request for supplementary information adopted with a specific timetable.

Novartis Europharm Limited, Rapporteur:
Antonio Gomez-Outes
Request for Supplementary Information adopted
on 16.05.2024.

**Elfabrio - Pegunigalsidase alfa -
EMA/H/C/005618/II/0002** Positive Opinion adopted by consensus on
02.05.2024.
Chiesi Farmaceutici S.p.A., Rapporteur:
Alexandre Moreau
Opinion adopted on 02.05.2024.
Request for Supplementary Information adopted
on 08.02.2024.

**Elfabrio - Pegunigalsidase alfa -
EMA/H/C/005618/II/0004/G**
Chiesi Farmaceutici S.p.A., Rapporteur:
Alexandre Moreau
Request for Supplementary Information adopted
on 04.04.2024.

**Enrylaze - Crisantaspase -
EMA/H/C/005917/II/0003/G** Positive Opinion adopted by consensus on
23.05.2024.
Jazz Pharmaceuticals Ireland Limited,
Rapporteur: Peter Mol
Opinion adopted on 23.05.2024.
Request for Supplementary Information adopted
on 14.03.2024.

**Erbix - Cetuximab -
EMA/H/C/000558/II/0098/G** Positive Opinion adopted by consensus on
23.05.2024.
Merck Europe B.V., Rapporteur: Filip Josephson
Opinion adopted on 23.05.2024.

**Evenity - Romosozumab -
EMA/H/C/004465/II/0023** Positive Opinion adopted by consensus on
16.05.2024.
UCB Pharma S.A., Rapporteur: Kristina Dunder
Opinion adopted on 16.05.2024.

**Evenity - Romosozumab -
EMA/H/C/004465/II/0024** Positive Opinion adopted by consensus on
16.05.2024.
UCB Pharma S.A., Rapporteur: Kristina Dunder
Opinion adopted on 16.05.2024.

**Flixabi - Infliximab -
EMA/H/C/004020/II/0086**
Samsung Bioepis NL B.V., Rapporteur: Jan
Mueller-Berghaus

**GONAL-f - Follitropin alfa -
EMA/H/C/000071/II/0168/G**
Merck Europe B.V., Rapporteur: Patrick Vrijlandt
Request for Supplementary Information adopted
on 18.04.2024.

Keytruda - Pembrolizumab - Positive Opinion adopted by consensus on

<p>EMA/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.</p>	02.05.2024.
<p>Leqvio - Inclisiran - EMA/H/C/005333/II/0027/G Novartis Europharm Limited, Rapporteur: Martina Weise</p>	
<p>LUTATHERA - Lutetium (177Lu) oxodotreotide - EMA/H/C/004123/II/0048, Orphan Advanced Accelerator Applications, Rapporteur: Janet Koenig Opinion adopted on 02.05.2024.</p>	Positive Opinion adopted by consensus on 02.05.2024.
<p>Mircera - Methoxy polyethylene glycol-epoetin beta - EMA/H/C/000739/II/0099/G Roche Registration GmbH, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 16.05.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p>Nucala - Mepolizumab - EMA/H/C/003860/II/0066/G GlaxoSmithKline Trading Services Limited, Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 02.05.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p>Opzelura - Ruxolitinib - EMA/H/C/005843/II/0002/G Incyte Biosciences Distribution B.V., Rapporteur: Peter Mol Request for Supplementary Information adopted on 30.11.2023, 31.08.2023.</p>	
<p>Orencia - Abatacept - EMA/H/C/000701/II/0166/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 16.05.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p>OXERVATE - Cenegermin - EMA/H/C/004209/II/0059, Orphan Dompe farmaceutici S.p.A., Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted</p>	Request for supplementary information adopted with a specific timetable.

on 02.05.2024.

**Qarziba - Dinutuximab beta -
EMA/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) -
EMA/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 -
EMA/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 -
EMA/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 -
EMA/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 -
EMA/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 -
EMA/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 -
EMA/H/C/004780/II/0007**

Fresenius Kabi Deutschland GmbH, Rapporteur:
Christian Gartner
Request for Supplementary Information adopted

Request for supplementary information adopted
with a specific timetable.

on 16.05.2024.

**Tabrecta - Capmatinib -
EMA/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 -
EMA/H/C/000390/II/0071/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.

**TRODELVY - Sacituzumab govitecan -
EMA/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 -
EMA/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 -
EMA/H/D/004693/II/0005**

Vitrolife Sweden AB, Rapporteur: Maria Grazia
Evandri
Request for Supplementary Information adopted
on 14.03.2024.

**Vyvgart - Efgartigimod alfa -
EMA/H/C/005849/II/0016, Orphan**

Argenx, Rapporteur: Thalia Marie Estrup Blicher
Request for Supplementary Information adopted
on 04.04.2024.

**Vyvgart - Efgartigimod alfa -
EMA/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 -
EMA/H/C/004850/II/0009, Orphan**

Sanofi B.V., Rapporteur: Patrick Vrijlandt

Yellox - Bromfenac -**EMA/H/C/001198/II/0036/G**

Bausch + Lomb Ireland Limited, Rapporteur:
Thalia Marie Estrup Blicher
Request for Supplementary Information adopted
on 25.01.2024.

Yuflyma - Adalimumab -**EMA/H/C/005188/II/0035/G**

Celltrion Healthcare Hungary Kft., Rapporteur:
Outi Mäki-Ikola
Request for Supplementary Information adopted
on 25.04.2024.

Zebinix - Eslicarbazepine acetate -**EMA/H/C/000988/II/0089/G**

Bial - Portela & C^a, 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-EMA/H/C/000179/WS2550/0089****Zyclara-EMA/H/C/002387/WS2550/0031**

Viartis 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.

Letter from the applicant dated 17.05.2024
requesting a clock stop extension. **For
information.**

WS2634**Hexacima-****EMA/H/C/002702/WS2634/0154****Hexyon-****EMA/H/C/002796/WS2634/0158**

Sanofi Pasteur Europe, Duplicate of Hexacima,
Lead Rapporteur: Jan Mueller-Berghaus
Request for Supplementary Information adopted
on 04.04.2024.

WS2642/G**Riltrava Aerosphere-****EMA/H/C/005311/WS2642/0011/G****Trixeo Aerosphere-****EMA/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-EMA/H/C/002813/WS2684/0061

Vihuma-

EMA/H/C/004459/WS2684/0043

Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

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

**Bimzelx - Bimekizumab -
EMA/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, multicenter,
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.

Positive Opinion adopted by consensus on
16.05.2024.

**Duavive - Estrogens conjugated /
Bazedoxifene -**

EMA/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 -
EMA/H/C/005788/II/0018**

AstraZeneca AB, Rapporteur: Jan Mueller-
Berghaus , "Update of sections 4.2, 4.4, 4.8 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.”

**Gazyvaro - Obinutuzumab -
EMA/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 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.

Request for supplementary information adopted with a specific timetable.

**Helicobacter Test INFAI - 13C-Urea -
EMA/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.”

See 9.1

**Imfinzi - Durvalumab -
EMA/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.”

**JEMPERLI - Dostarlimab -
EMA/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 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, the MAH took the opportunity to introduce minor editorial changes to the Product Information.”

**Keytruda - Pembrolizumab -
EMA/H/C/003820/II/0152**

Positive Opinion adopted by consensus on 02.05.2024.

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.

**NUVAXOVID - Covid-19 Vaccine
(recombinant, adjuvanted) -
EMA/H/C/005808/II/0066**

Positive Opinion adopted by consensus on 16.05.2024.

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.

**Olumiant - Baricitinib -
EMA/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.”

Request for Supplementary Information adopted

on 04.04.2024, 08.02.2024.

**Oncaspar - Pegaspargase -
EMA/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 -
EMA/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 -
EMA/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 was for the evaluation of miglustat as a substrate and inhibitor of a panel of human drug

Request for supplementary information adopted with a specific timetable.

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 -
EMA/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 with a specific timetable.

**Orladeyo - Berotralstat -
EMA/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 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 21.03.2024.

**OZAWADE - Pitolisant -
EMA/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 center, 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 -
EMA/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, multicenter,
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
apnea (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.”

**Paxlovid - Nirmatrelvir / Ritonavir -
EMA/H/C/005973/II/0051/G**

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 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.

Remsuma - Infliximab -

EMEA/H/C/002576/II/0133/G

Celltrion Healthcare Hungary Kft., Rapporteur:

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 and dose escalation of subcutaneous maintenance dose from CT-P13 SC 120 mg Q2W to 240 mg Q2W for patients with loss of response and update efficacy and safety information 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

See 9.1

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.

- Update of section 4.2 and 5.2 of the SmPC in order to add subcutaneous induction posology and pharmacokinetic information based on Population PK and PK-PD Modelling and Simulation.

- Update of section 4.2 of the SmPC in order to switch from high-dose IV maintenance (> 5 mg/kg) to subcutaneous maintenance dose of 120 mg Q2W based on data from REMSWITCH study (Effectiveness of Switching From Intravenous to Subcutaneous Infliximab in Patients With Inflammatory Bowel Diseases: the REMSWITCH Study).

The RMP version 16.1 has also been submitted. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to introduce minor updates to the PI."

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

**Retsevmo - Selpercatinib -
EMA/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 -
EMA/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 postmarketing 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.”
Request for Supplementary Information adopted on 21.03.2024.

**Rivastigmine HEXAL - Rivastigmine -
EMA/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 postmarketing 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.”
Request for Supplementary Information adopted on 21.03.2024.

**Rivastigmine Sandoz - Rivastigmine -
EMA/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 postmarketing 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.”
Request for Supplementary Information adopted on 21.03.2024.

**Scemblix - Asciminib -
EMA/H/C/005605/II/0013/G, Orphan**

Novartis Europharm Limited, Rapporteur: Janet Koenig , “Grouped application comprising three type II variations as follows:
C.I.4 - Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with P-gp Substrates based on the final results from studies 2301078, CABL001A2301 and CABL001X2101, listed as a category 3 study in the RMP.
C.I.4 - Update of section 4.8 of the SmPC in order to update the Summary of the safety profile and safety information based on final results from study CABL001A2301 and CABL001X2101, listed as a category 3 study in the RMP.

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

Positive Opinion adopted by consensus on 16.05.2024.

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-center 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-center 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)

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 -

EMA/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 to add ‘Arachnoiditis’ to the list of adverse drug reactions (ADRs) with frequency not known, based on postmarketing review. The Package Leaflet is updated accordingly. The MAH took the opportunity to update the list of local representatives.”

Request for Supplementary Information adopted on 08.02.2024.

TAVNEOS - Avacopan -

EMA/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.”

Trumenba - Meningococcal group B vaccine (recombinant, adsorbed) -

EMA/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 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 21.03.2024.

**Ultomiris - Ravulizumab -
EMEA/H/C/004954/II/0041**

Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez , "Update of section 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 align the warning in Annex II and the PI where male patients should not father a child or donate sperm up to eight months after treatment and to introduce editorial changes."

Request for Supplementary Information adopted on 25.04.2024, 11.01.2024.

**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 multicenter, 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-065A310 (SALTO); this is a phase 3 multicenter, double-blind, randomized, placebo-controlled, parallel group study with open-label extension period to assess the efficacy and safety of

Request for supplementary information adopted with a specific timetable.

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 -
EMA/H/C/005910/II/0002**

Positive Opinion adopted by consensus on 23.05.2024.

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

**Veklury - Remdesivir -
EMA/H/C/005622/II/0054/G**

Gilead Sciences Ireland UC, Rapporteur: Janet Koenig , “Grouped application to update section 5.2 of the SmPC to update pharmacokinetic information based on results from two Population PK Study reports, QP-2023-1074 and CTRA-2023-1084. QP-2023-1074 is a population pharmacokinetic analysis of Sulfobutylether- β -cyclodextrin (SBECD) in adults with normal and impaired renal function following remdesivir administration. CTRA-2023-1084 is a population pharmacokinetic analysis for remdesivir and metabolites (GS-704277 and GS-441524) after administration of remdesivir in adults.”

Request for Supplementary Information adopted on 14.03.2024.

Veklury - Remdesivir -

Positive Opinion adopted by consensus on

EMA/H/C/005622/II/0056

02.05.2024.

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.

VELCADE - Bortezomib -**EMA/H/C/000539/II/0102**

Positive Opinion adopted by consensus on 16.05.2024.

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."

Venclyxto - Venetoclax -**EMA/H/C/004106/II/0048**

Request for supplementary information adopted with a specific timetable.

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 Pediatric and Young Adult Patients With Relapsed or Refractory Malignancies. The Package Leaflet is updated accordingly."

Request for Supplementary Information adopted on 16.05.2024.

Wegovy - Semaglutide -**EMA/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.”

**ZTALMY - Ganaxolone -
EMA/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-
EMA/H/C/000546/WS2520/0124/G
Pregabalin Pfizer-
EMA/H/C/003880/WS2520/0052/G**
Upjohn EESV, Lead Rapporteur: Peter Mol ,
“Grouped application comprising 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
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.

Positive Opinion adopted by consensus on
16.05.2024.

**WS2683
Relvar Ellipta-
EMA/H/C/002673/WS2683/0068
Revinty Ellipta-
EMA/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."

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, multicenter 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 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 with a specific timetable.

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 brolicizumab 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 brolicizumab 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.”

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 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.” 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

Positive Opinion adopted by consensus on 16.05.2024

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.

**Eylea - Aflibercept -
EMEA/H/C/002392/II/0090**

Positive Opinion adopted by consensus on 16.05.2024.

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 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**

Positive Opinion adopted by consensus on 16.05.2024.

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.

**Ilumetri - Tildrakizumab -
EMA/H/C/004514/II/0054**

Positive Opinion adopted by consensus on 16.05.2024.

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 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) -
EMA/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 21.03.2024.

Inrebic - Fedratinib -

EMA/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.”

Request for Supplementary Information adopted on 22.02.2024.

Orkambi - Lumacaftor / Ivacaftor -

EMA/H/C/003954/II/0088

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.

Positive Opinion adopted by consensus on 16.05.2024.

Piqray - Alpelisib -

EMA/H/C/004804/II/0022/G

Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur:

Bianca Mulder , “Grouped application comprising two type II variations (C.I.4) as follows:

- Update of sections 4.2, 4.4, 4.8 of the SmPC in order to update information on prophylactic use of metformin for hyperglycaemia based on the results from study CBYL719CES01T (METALLICA). METALLICA is a Phase II study aimed to evaluate the effect of prophylactic use of metformin for hyperglycaemia in HR-positive, HER2-negative, PIK3CA-mutated advanced breast cancer patients treated with alpelisib plus endocrine therapy.

- Update of section 4.8 of the SmPC in order to add “uveitis” to the list of adverse drug reactions (ADRs) with frequency “Not known” based on a cumulative review of the MAH safety database and literature.

The Package Leaflet and Annex II are updated accordingly. The RMP version 7.0 has also been submitted.”

Request for Supplementary Information adopted on 22.02.2024, 30.11.2023.

**RINVOQ - Upadacitinib -
EMA/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 substudies). The Package Leaflet is updated accordingly. The RMP version 14.0 has also been submitted.”

**SCENESSE - Afamelanotide -
EMA/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.”

**Tecvayli - Teclistamab -
EMA/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."

**Zeposia - Ozanimod -
EMA/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."
Opinion adopted on 16.05.2024.
Request for Supplementary Information adopted
on 11.01.2024.

Positive Opinion adopted by consensus on
16.05.2024.

**ZTALMY - Ganaxolone -
EMA/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 submitted."
Request for Supplementary Information adopted
on 21.03.2024.

**Dengue Tetravalent Vaccine (Live,
Attenuated) Takeda-**

Request for supplementary information adopted
with a specific timetable.

EMA/H/W/005362/WS2593/0012

Qdenga-

EMA/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.

B.5.4. PRAC assessed procedures

PRAC Led

Amlodipine-Valsartan Mylan - Amlodipine / Valsartan - EMA/H/C/004037/II/0021

Mylan Pharmaceuticals Limited, Generic of 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.

Request for supplementary information adopted with a specific timetable.

PRAC Led

ASPAVELI - Pegcetacoplan - EMA/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 with a specific timetable.

Request for Supplementary Information adopted on 16.05.2024.

PRAC Led

**Avamys - Fluticasone furoate -
EMA/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."

Opinion adopted on 16.05.2024.

Positive Opinion adopted by consensus on
16.05.2024.

PRAC Led

**Beovu - Brolucizumab -
EMA/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 -
EMA/H/C/000512/II/0053**

Positive Opinion adopted by consensus on
16.05.2024.

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 postmarketing exposure data was updated."
Opinion adopted on 16.05.2024.

PRAC Led	Positive Opinion adopted by consensus on 16.05.2024.
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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 (EMA/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.

PRAC Led	Positive Opinion adopted by consensus on 16.05.2024.
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Efient - Prasugrel - EMEA/H/C/000984/II/0037
Substipharma, 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 (EMA/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	Request for supplementary information adopted with a specific timetable.
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Eurartesim - Piperaquine tetraphosphate / Artemimol - 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.

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 Treated with HyQvia". Both studies were non-interventional, prospective, uncontrolled, multicenter, 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.

Positive Opinion adopted by consensus on 16.05.2024.

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 4.0 has also been submitted.”

Request for Supplementary Information adopted on 07.03.2024, 28.09.2023.

PRAC Led

Lysodren - Mitotane -

EMA/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 -

EMA/H/C/000165/II/0201/G

Roche Registration GmbH, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Aaron Sosa 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.

Positive Opinion adopted by consensus on 16.05.2024.

PRAC Led

Request for supplementary information adopted

**Moventig - Naloxegol -
EMA/H/C/002810/II/0043**

Gruenthal 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.

with a specific timetable.

PRAC Led
**Mysimba - Naltrexone hydrochloride /
Bupropion hydrochloride -
EMA/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 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.

Request for supplementary information adopted with a specific timetable.

PRAC Led
**Remicade - Infliximab -
EMA/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 substudy as part of protocol REMICADEPIB4002 in Part III. The MAH proposes to discontinue the Dutch portion of the immunogenicity substudy, 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 -
EMA/H/C/005182/II/0031**

Gilead Sciences Ireland UC, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Peter Mol ,

Positive Opinion adopted by consensus on 16.05.2024.

"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.

PRAC Led Zessly - Infliximab - EMA/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.
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PRAC Led WS2577 Kinzalmono- EMA/H/C/000211/WS2577/0120 Micardis- EMA/H/C/000209/WS2577/0129 Pritor-EMA/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.	Positive Opinion adopted by consensus on 16.05.2024.
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PRAC Led WS2611 Kinzalkomb- EMA/H/C/000415/WS2611/0123 MicardisPlus- EMA/H/C/000413/WS2611/0130 PritorPlus-	Positive Opinion adopted by consensus on 16.05.2024.
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EMA/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.

PRAC Led

WS2615**Abseamed-****EMA/H/C/000727/WS2615/0108****Binocrit-****EMA/H/C/000725/WS2615/0108****Epoetin alfa Hexal-****EMA/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, 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 anemia 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.

Request for supplementary information adopted with a specific timetable.

PRAC Led

WS2620**Dovato-EMA/H/C/004909/WS2620/0047****Juluca-EMA/H/C/004427/WS2620/0056****Tivicay-EMA/H/C/002753/WS2620/0092****Triumeq-****EMA/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

Request for supplementary information adopted with a specific timetable.

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 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.

PRAC Led

WS2671

Finlee-EMA/H/C/005885/WS2671/0005

Spexotras-

EMA/H/C/005886/WS2671/0004

Tafinlar-

EMA/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 -
EMA/H/C/004662/II/0047, Orphan,
ATMP**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjekken, 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)."

Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel -

EMA/H/C/004731/II/0036/G, ATMP

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

C.I.4 – Update of sections 4.4 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 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 16.02.2024.

CARVYKTI - Ciltacabtagene autoleucel - EMA/H/C/005095/II/0027/G, Orphan, ATMP

Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Libmeldy - Atidarsagene autotemcel - EMA/H/C/005321/II/0025, Orphan, ATMP

Orchard Therapeutics (Netherlands) B.V., Rapporteur: Emmely de Vries, CHMP Coordinator: Peter Mol

Upstaza - Eladocagene exuparvovec - EMA/H/C/005352/II/0021, Orphan, ATMP

PTC Therapeutics International Limited, Rapporteur: Joseph DeCoursey, CHMP

Coordinator: Finbarr Leacy

WS2500

Tecartus-

EMA/H/C/005102/WS2500/0040

Yescarta-

EMA/H/C/004480/WS2500/0068

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

Request for Supplementary Information adopted
on 16.02.2024.

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

Jentaduetto-

EMA/H/C/002279/WS2533/0071

Trajenta-

EMA/H/C/002110/WS2533/0053

Boehringer Ingelheim International GmbH, Lead
Rapporteur: Patrick Vrijlandt , "Quality variation
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-

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

Dafiro HCT-

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

Exforge HCT-

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

Novartis Europharm Limited, Lead Rapporteur:
Thalia Marie Estrup Blicher , Quality variation
Request for Supplementary Information adopted
on 02.05.2024.

Request for supplementary information adopted
with a specific timetable.

WS2657

HyQvia-EMA/H/C/002491/WS2657/0097

Kiovig-EMA/H/C/000628/WS2657/0127

Takeda Manufacturing Austria AG, Lead
Rapporteur: Jan Mueller-Berghaus , Quality
variation Request for Supplementary
Information adopted on 11.04.2024.

WS2665

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

NeoRecormon-
EMA/H/C/000116/WS2665/0125
Roche Registration GmbH, Lead Rapporteur:
Antonio Gomez-Outes

WS2669
HyQvia-EMA/H/C/002491/WS2669/0098
Kiovig-EMA/H/C/000628/WS2669/0128
Baxalta Innovations GmbH, Lead Rapporteur:
Jan Mueller-Berghaus , Quality variation
Request for Supplementary Information adopted
on 02.05.2024.

Request for supplementary information adopted
with a specific timetable.

WS2677
Mircera-EMA/H/C/000739/WS2677/0100
NeoRecormon-
EMA/H/C/000116/WS2677/0124
Roche Registration GmbH, Lead Rapporteur:
Martina Weise , Quality Variation
Opinion adopted on 02.05.2024.

Positive Opinion adopted by consensus on
02.05.2024.

WS2678
Incresync-
EMA/H/C/002178/WS2678/0048
Vipdomet-
EMA/H/C/002654/WS2678/0047
Vipidia-EMA/H/C/002182/WS2678/0037
Takeda Pharma A/S, Lead Rapporteur: Patrick
Vrijlandt , Quality variation

Positive Opinion adopted by consensus on
16.05.2024.

WS2685
Mekinist-
EMA/H/C/002643/WS2685/0065
Tafinlar-
EMA/H/C/002604/WS2685/0070
Novartis Europharm Limited, Lead Rapporteur:
Filip Josephson , Quality Variation

WS2687
Eucreas-
EMA/H/C/000807/WS2687/0109
Icandra-
EMA/H/C/001050/WS2687/0114
Zomarist-
EMA/H/C/001049/WS2687/0111
Novartis Europharm Limited, Lead Rapporteur:
Kristina Dunder

Positive Opinion adopted by consensus on
16.05.2024.

WS2704
Filgrastim Hexal-
EMA/H/C/000918/WS2704/0077
Zarzio-EMA/H/C/000917/WS2704/0078
Sandoz GmbH, Lead Rapporteur: Peter Mol , "To

Positive Opinion adopted by consensus on
23.05.2024.

update section 4.8 of the SmPC to add "extramedullary hematopoiesis" 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."

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

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

Hemangioli - propranolol - EMA/H/C/002621/II/0025

Pierre Fabre Medicament, Rapporteur: Jean-Michel Race
Request for Supplementary Information adopted on 05.10.2023.

Request by the applicant for an extension to the clock stop to respond to the RSI adopted in October 2023.

WS2550 Aldara-EMA/H/C/000179/WS2550/0089 Zyclara-EMA/H/C/002387/WS2550/0031

Viatrix 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.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

Ustekinumab - EMA/H/C/006585

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

ATROPINE SULFATE PH. EUR. - EMA/H/C/006385, PUMA

treatment of myopia in children aged 3 years and older

Inavolisib - EMA/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 leukemia (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

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

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

Evrysdi - Risdiplam -

EMA/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 -**EMA/H/C/005122/X/0006/G**

Eli Lilly Nederland B.V., Rapporteur: Finbarr Leacy, PRAC Rapporteur: Sonja Hrabcik , "Extension application to add a new strength of 200 mg grouped with an extension of indication (C.I.6) to include treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment, for OmvoH, based mainly on final results from study I6T-MC-AMAM; this is a phase 3, multicenter, randomized, double-blind, placebo- and active-controlled, treat-through study to evaluate the efficacy and safety of mirikizumab in patients with moderately to severely active Crohn's disease. As a consequence, sections 1, 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.1, 6.5, 6.6 and 8 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. Version 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and to update the list of local representatives in the Package Leaflet. As part of the application, the MAH is requesting a 1-year extension of the market protection. Request for 1 year of market protection for a new indication (Article 14(11) of Regulation

**Tremfya - Guselkumab -
EMA/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
CNT01959UCO3001 (Induction Study 1 Phase
2b, Induction Study 2 Phase 3 and Maintenance
Study). All 3 studies were randomized, double-
blind, placebo-controlled, parallel-group,
multicenter 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 - EMA/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.

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 -

EMA/H/C/004155

treatment of alopecia areata in children and adolescents

List of Questions adopted on 12.10.2023.

Bimatoprost - EMA/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 - EMA/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.

Eplontersen - EMA/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.

Vilobelimab - EMA/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.

Ustekinumab - EMA/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 - EMA/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 -
EMA/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 multicenter, open-label, randomized study with single-arm extension period to assess the pharmacokinetics, safety, and efficacy of macitentan versus standard of care in children with pulmonary arterial hypertension. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC for film-coated tablets are updated. The Package Leaflet and Labelling are updated in accordance. Version 14.1 of the RMP has also been submitted.”

List of Questions adopted on 22.02.2024.

Aflibercept - EMA/H/C/006056

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

List of Questions adopted on 21.03.2024.

**PHEBURANE - Sodium phenylbutyrate -
EMA/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.

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

Chenodeoxycholic acid Leadiant -

Chenodeoxycholic acid -

EMA/H/C/004061/S/0024, Orphan

Leadiant GmbH, Rapporteur: Anastasia

Mountaki, PRAC Rapporteur: Adam

Przybylkowski

DECTOVA - Zanamivir -

EMA/H/C/004102/S/0018

GlaxoSmithKline Trading Services Limited,

Rapporteur: Ingrid Wang, PRAC Rapporteur:

Ulla Wändel Liminga

Elaprase - Idursulfase -

EMA/H/C/000700/S/0116

Takeda Pharmaceuticals International AG

Ireland Branch, Rapporteur: Patrick Vrijlandt,

PRAC Rapporteur: Liana Martirosyan

Firdapse - Amifampridine -

EMA/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 -

EMA/H/C/004879/R/0008

Pfizer Europe MA EEIG, Rapporteur: Outi Mäki-

Ikola, Co-Rapporteur: Simona Badoi, PRAC

Rapporteur: Mari Thorn

Beovu - Brolucizumab -

EMA/H/C/004913/R/0030

Novartis Europharm Limited, Rapporteur:

Alexandre Moreau, Co-Rapporteur: Antonio

Gomez-Outes, PRAC Rapporteur: Gabriele

Maurer

Deferasirox Accord - Deferasirox -

EMA/H/C/005156/R/0011

Accord Healthcare S.L.U., Generic of EXJADE,

Rapporteur: Daniela Philadelphia, PRAC

Rapporteur: Tiphaine Vaillant

Isturisa - Osilodrostat -

EMA/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 -
EMA/H/C/005863/R/0004**

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Edward Laane, PRAC Rapporteur: Bianca Mulder

**Mayzent - Siponimod -
EMA/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 - EMA/H/C/004808/R/0029**

Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Adam Przybylkowski

**Senshio - Ospemifene -
EMA/H/C/002780/R/0048**

Shionogi B.V., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Kirsti Villikka

**Sunosi - Solriamfetol -
EMA/H/C/004893/R/0023**

Atnahs Pharma Netherlands B.V., Rapporteur: Janet Koenig, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Julia Pallos

**Tavlesse - Fostamatinib -
EMA/H/C/005012/R/0018**

Instituto Grifols, S.A., Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Daniela Philadelphly, 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 -
EMA/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, Multicenter 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 Pediatric 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 -
EMA/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 multicenter, open-label, Phase 2/3 randomized study to evaluate the efficacy and safety of pembrolizumab in combination with pemetrexed/platinum chemotherapy in participants with unresectable advanced or metastatic malignant pleural mesothelioma (MPM). As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 47.1 of the RMP has also been submitted.”

**SARCLISA - Isatuximab -
EMA/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, multicenter, international, randomized, open-label, 2-arm parallelgroup 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.”

**TAGRISSE - Osimertinib -
EMA/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 TAGRISSE as monotherapy, based on results from study D5160C00048 (LAURA); this is a Phase III, randomised, double-blind, placebo-controlled, multicenter 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-
EMA/H/C/003985/WS2672/0141
Yervoy-EMA/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 - Lonococog alfa - EMA/H/C/004075/II/0055

CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Benlysta - Belimumab - EMA/H/C/002015/II/0130

GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder

Beyfortus - Nirsevimab - EMA/H/C/005304/II/0022/G

Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher

Bortezomib SUN - Bortezomib - EMA/H/C/004076/II/0023

Sun Pharmaceutical Industries Europe B.V.,
Generic of VELCADE, Rapporteur: Margareta Bego

Brineura - Cerliponase alfa - EMA/H/C/004065/II/0045/G, Orphan

BioMarin International Limited, Rapporteur: Martina Weise

**BroPair Spiromax - Salmeterol /
Fluticasone propionate -
EMA/H/C/005591/II/0011**

Teva B.V., Duplicate of Seffalair Spiromax,
Rapporteur: John Joseph Borg

**Cablivi - Caplacizumab -
EMA/H/C/004426/II/0049/G, Orphan**

Ablynx NV, Rapporteur: Filip Josephson

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

BioNTech Manufacturing GmbH, Rapporteur:
Filip Josephson

**Efavirenz/Emtricitabine/Tenofovir
disoproxil Mylan -Efavirenz / Emtricitabine
/ Tenofovir disoproxil -
EMA/VR/0000177462 -
EMA/H/C/004240)**

Mylan Pharmaceuticals Limited, Rapporteur:
Vilma Petrikaite

**Emtricitabin - Emtricitabine / Tenofovir
disoproxil - EMA/VR/0000177324
(EMA/H/C/004050)**

Mylan Pharmaceuticals Limited, Rapporteur:
Vilma Petrikaite

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

Seqirus Netherlands B.V., Rapporteur: Sol Ruiz

**Gardasil 9 - Human papillomavirus vaccine
[types 6, 11, 16, 18, 31, 33, 45, 52, 58]
(recombinant, adsorbed) -
EMA/H/C/003852/II/0074**

Merck Sharp & Dohme B.V., Rapporteur:
Kristina Dunder

**Imfinzi - Durvalumab -
EMA/H/C/004771/II/0067/G**

AstraZeneca AB, Rapporteur: Aaron Sosa Mejia

**Kengrexal - Cangrelor -
EMA/H/C/003773/II/0033**

Chiesi Farmaceutici S.p.A., Rapporteur: Patrick
Vrijlandt

**Keytruda - Pembrolizumab -
EMA/H/C/003820/II/0155**

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

Gasparini

**LIVOGIVA - Teriparatide -
EMA/H/C/005087/II/0012**

Theramex Ireland Limited, Rapporteur:
Christian Gartner

**Nustendi - Bempedoic acid / Ezetimibe -
EMA/H/C/004959/II/0046**

Daiichi Sankyo Europe GmbH, Rapporteur:
Patrick Vrijlandt

**NUVAXOVID - Covid-19 Vaccine
(recombinant, adjuvanted) -
EMA/H/C/005808/II/0071/G**

Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt

**Praluent - Alirocumab -
EMA/H/C/003882/II/0091/G**

Sanofi Winthrop Industrie, Rapporteur: Patrick
Vrijlandt

**Puregon - Follitropin beta -
EMA/H/C/000086/II/0130**

Organon N.V., Rapporteur: Finbarr Leacy

**Ranivisio - Ranibizumab -
EMA/H/C/005019/II/0015/G**

Midas Pharma GmbH, Rapporteur: Jan Mueller-
Berghaus

**Rezzayo - Rezafungin -
EMA/H/C/005900/II/0002, Orphan**

Mundipharma GmbH, Rapporteur: Bruno
Sepodes

**Ryzneuta - Efbemalenograstim alfa -
EMA/H/C/005828/II/0001**

Evive Biotechnology Ireland Limited,
Rapporteur: Vilma Petrikaite

**Rystiggo - Rozanolixizumab -
EMA/H/C/005824/II/0003, Orphan**

UCB Pharma, Rapporteur: Thalia Marie Estrup
Blicher

**Seffalair Spiromax - Salmeterol /
Fluticasone propionate -
EMA/H/C/004881/II/0011**

Teva B.V., Rapporteur: John Joseph Borg

**Skyclarys - Omaveloxolone -
EMA/H/C/006084/II/0004, Orphan**

Reata Ireland Limited, Rapporteur: Thalia Marie
Estrup Blicher

Soliris - Eculizumab -

EMA/H/C/000791/II/0132, Orphan

Alexion Europe SAS, Rapporteur: Carolina Prieto
Fernandez

Spectrila - Asparaginase -

EMA/H/C/002661/II/0040

medac Gesellschaft für klinische
Spezialpräparate mbH, Rapporteur: Christian
Gartner

Spikevax - COVID-19 mRNA vaccine -

EMA/H/C/005791/II/0136

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

Tyenne - Tocilizumab -

EMA/H/C/005781/II/0003

Fresenius Kabi Deutschland GmbH, Rapporteur:
Kristina Dunder

Uzpruvo - Ustekinumab -

EMA/H/C/006101/II/0002

STADA Arzneimittel AG, Rapporteur: Christian
Gartner

Vabysmo - Faricimab -

EMA/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) -**

EMA/H/C/003982/II/0144

MCM Vaccine B.V., Rapporteur: Christophe
Focke

VEGZELMA - Bevacizumab -

EMA/H/C/005534/II/0010/G

Celltrion Healthcare Hungary Kft., Rapporteur:
Outi Mäki-Ikola

Voxzogo - Vosoritide -

EMA/H/C/005475/II/0015, Orphan

BioMarin International Limited, Rapporteur:
Martina Weise

WS2529

Keppra-EMA/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

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

Alecensa - Alectinib -

EMA/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 fetus 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 -

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

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

Cablivi - Caplacizumab -

EMA/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-center, 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 -
EMA/H/C/005457/II/0009**

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

**Dengvaxia - Dengue tetravalent vaccine
(live, attenuated) -
EMA/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 (DENVAXIA) in the Philippines.”

**Dengvaxia - Dengue tetravalent vaccine
(live, attenuated) -
EMA/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-center, Phase II study planned in 150 HIV-positive adults, treated with antiretrovirals, and previously exposed to dengue.”

**Drovelis - Drospirenone / Estetrol -
EMA/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 -
EMA/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 -
EMA/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 -
EMA/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 -

EMA/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 -
EMA/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 -**EMA/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, multicenter, 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 -**EMA/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 -
EMA/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 -
EMA/H/C/005084/II/0034/G**

Sanofi Pasteur, Rapporteur: Daniela Philadelphia , “Grouped application comprising of 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-center 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-center 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 - Dronedaron -
EMA/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 -

EMA/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 -

EMA/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 EMA/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 -

EMA/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 -
EMA/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 -
EMA/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, multicenter, 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 -
EMA/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) -
EMA/H/C/005451/II/0026**

Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphly , “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) -
EMA/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 -
EMA/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 -
EMA/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 -
EMA/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, multicenter study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of eculizumab in pediatric patients with refractory generalized myasthenia gravis (gMG). In addition, the MAH took the opportunity to introduce minor changes to the PI.”

**Trulicity - Dulaglutide -
EMA/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, postmarketing 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 -
EMA/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 -
EMA/H/C/000944/II/0110/G**

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

**Xultophy - Insulin degludec / Liraglutide -
EMA/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-

EMA/H/C/002643/WS2647/0066

Tafinlar-

EMA/H/C/002604/WS2647/0071

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

WS2691

Hycamtin-

EMA/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-EMA/H/C/005885/WS2693/0007

Spexotras-

EMA/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-

EMA/H/C/000604/WS2700/0123

ProQuad-

EMA/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-EMA/H/C/003821/WS2701/0061

Vargatef-

EMA/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 postmarketing 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-

EMA/H/C/006052/WS2707/0001

Zoonotic Influenza Vaccine Seqirus-

EMA/H/C/006375/WS2707/0003

Seqirus Netherlands B.V., Lead Rapporteur: Daniela Philadelphia , “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

Erbix - Cetuximab -

EMA/H/C/000558/II/0099

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

ILARIS - Canakinumab -

EMA/H/C/001109/II/0085

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

MVABEA - Ebola vaccine (rDNA, replication-incompetent) -

EMA/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 -
EMA/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 -
EMA/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 -
EMA/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 -
EMA/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 -
EMA/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.”

VELSIPITY - Etrasimod -

EMA/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) -
EMA/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-

EMA/H/W/005362/WS2695/0015

Qdenga-

EMA/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-****EMA/H/C/002790/WS2702/0066****Ontilyv-EMA/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 -**EMA/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 -**EMA/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 -

EMA/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 -

EMA/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-

EMA/H/C/005236/WS2686/0011

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

- Update of "Hypocalcemia" to "Hypocalcemia in the pediatric population"
- Removal of "QT prolongation and ventricular arrhythmias secondary to hypocalcaemia"
- Removal of "Convulsions/seizures"

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

PRAC Led

WS2705

Lixiana-EMA/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 Kjekken, CHMP Coordinator: Ingrid Wang

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

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

**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 pediatric subjects' data from
Study 20110261 in support of a pediatric
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 -
EMA/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 pediatric subjects with advanced non-CNS tumors 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.”

**Yescarta - Axicabtagene ciloleucel -
EMA/H/C/004480/II/0077, Orphan,
ATMP**

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

WS2689

Tecartus-

EMA/H/C/005102/WS2689/0045

Yescarta-

EMA/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 -
EMA/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 -
EMA/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 Multicenter Study Evaluating The Safety And Efficacy Of Kte-C19 In Subjects With Refractory Aggressive Non-Hodgkin Lymphoma.

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

The RMP version 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

WS2694/G

GONAL-f-

EMA/H/C/000071/WS2694/0170/G

Pergoveris-

EMA/H/C/000714/WS2694/0092/G

Merck Europe B.V., Lead Rapporteur: Thalia

Marie Estrup Blicher, Quality variation

WS2699

Adrovan-

EMA/H/C/000759/WS2699/0054

FOSAVANCE-

EMA/H/C/000619/WS2699/0057

VANTAVO-

EMA/H/C/001180/WS2699/0044

Organon N.V., Lead Rapporteur: Christian

Gartner Quality variation

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

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

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

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

G. ANNEX G

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

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

G.2. PRIME

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

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