



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2024
EMA/CHMP/127161/2024 Corr.1¹
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 22-25 April 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

22 April 2024, 09:00 – 19:30, virtual meeting/room 1C

23 April 2024, 08:30 – 19:30, virtual meeting/room 1C

24 April 2024, 08:30 – 19:30, virtual meeting/room 1C

25 April 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).

¹ Correction in section 3.6



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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 22-25 April 2024. See April 2024 CHMP minutes (to be published post May 2024 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 22-25 April 2024

1.3. Adoption of the minutes

CHMP minutes for 19-21 March 2024.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 15 April 2024.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Fruquintinib - EMEA/H/C/005979

treatment of metastatic colorectal cancer

Scope: Oral explanation

Action: Oral explanation to be held on 24 April 2024 at 16:00

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 12.10.2023.

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 23 April 2024 at 11:00

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

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. SCENESSE - Afamelanotide - Orphan - EMEA/H/C/002548/II/0044

Clinuvel Europe Limited;

Rapporteur: Janet Koenig, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication for the prevention of phototoxicity in adolescent patients (12 to under 18 years of age) with erythropoietic protoporphyria (EPP), based on the analysis of the safety and efficacy data available. As a consequence, sections 4.1, 4.2 and 4.4 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.4 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial correction to the PI."

Scope: Oral explanation

Action: Oral explanation to be held on 23 April 2024 at 09:00

Participation of patient representatives

Request for Supplementary Information adopted on 14.12.2023, 25.05.2023.

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Efanesoctocog alfa - Orphan - EMEA/H/C/005968

Swedish Orphan Biovitrum AB (publ); Treatment and prophylaxis of bleeding in patients with haemophilia A

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 21.03.2024, 25.01.2024. List of Questions adopted on 14.09.2023.

3.1.2. Eribulin - EMEA/H/C/006191

treatment of breast cancer and liposarcoma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 14.09.2023.

3.1.3. [Aprocitentan - EMEA/H/C/006080](#)

treatment of resistant hypertension

Scope: Opinion

Action: For adoption

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

3.1.4. [Vibegron - EMEA/H/C/005957](#)

treatment of micturition frequency and/or urgency incontinence as may occur in adult patients with Over Active Bladder (OAB) syndrome.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 14.09.2023.

3.1.5. [Tocilizumab - EMEA/H/C/005984](#)

treatment of rheumatoid arthritis (RA), coronavirus disease 2019 (COVID-19), polyarticular juvenile idiopathic arthritis (pJIA), and systemic juvenile idiopathic arthritis (sJIA)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.05.2023. List of Questions adopted on 26.01.2023.

3.1.6. [Capivasertib - EMEA/H/C/006017](#)

is indicated in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative (defined as IHC 0 or 1+, or IHC 2+/ISH-) locally advanced or metastatic breast cancer following recurrence or progression on or after an endocrine based regimen

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 14.09.2023.

3.1.7. Ustekinumab - EMEA/H/C/006132

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 14.09.2023.

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

3.2.1. Polihexanide - Orphan - EMEA/H/C/005858

SIFI SPA; treatment of acanthamoeba keratitis

Scope: List of outstanding issues

Action: For adoption

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

3.2.2. Axitinib - EMEA/H/C/006206

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.07.2023.

3.2.3. Erdafitinib - EMEA/H/C/006050

treatment of adult patients with locally advanced unresectable or metastatic urothelial carcinoma (UC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

3.2.4. Enzalutamide - EMEA/H/C/006299

treatment of prostate cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

3.2.5. [Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated - PRIME – OPEN - EMEA/H/C/005797](#)

Accelerated assessment

prevention of disease caused by chikungunya (CHIKV) virus

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 20.02.2024.

3.2.6. [Donanemab - EMEA/H/C/006024](#)

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

3.2.7. [Catumaxomab - EMEA/H/C/005697](#)

indicated for the treatment of malignant ascites

Scope: List of outstanding issues

Action: adoption

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

3.2.8. [Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation - EMEA/H/C/006278](#)

Prevention of lower respiratory tract disease (LRTD) and acute respiratory disease (ARD) caused by respiratory syncytial virus (RSV)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

3.2.9. [Nilotinib - EMEA/H/C/006315](#)

treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (CML)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

3.2.10. [Odronextamab - Orphan - EMEA/H/C/006215](#)

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

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

treatment of paroxysmal nocturnal haemoglobinuria

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

3.2.12. [Pomalidomide - EMEA/H/C/006273](#)

treatment of adult patients with multiple myeloma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

3.2.13. [Pomalidomide - EMEA/H/C/006314](#)

treatment of multiple myeloma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

3.2.14. [Pomalidomide - EMEA/H/C/006294](#)

treatment of adults with multiple myeloma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.01.2024.

3.2.16. Macitentan / Tadalafil - EMEA/H/C/005001

treatment of pulmonary arterial hypertension (PAH) in adults patients

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

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

3.3.1. Repotrectinib - EMEA/H/C/006005

Treatment of ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) and for solid tumours

Scope: List of questions

Action: For adoption

3.3.2. Aflibercept - EMEA/H/C/005980

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

Scope: List of questions

Action: For adoption

3.3.3. Eltrombopag - EMEA/H/C/006417

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

Scope: List of questions

Action: For adoption

3.3.4. Aflibercept - EMEA/H/C/005899

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

Scope: List of questions

Action: For adoption

3.3.5. 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: List of questions

Action: For information

3.3.6. Govorestat - Orphan - EMEA/H/C/006270

Advanz Pharma Limited; treatment of adults and children aged 2 years and older with a confirmed diagnosis of classic galactosemia

Scope: List of questions

Action: For adoption

3.3.7. Odevixibat - EMEA/H/C/006462

treatment of cholestatic pruritus in Alagille syndrome (ALGS)

Scope: List of questions

Action: For adoption

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

Accelerated assessment

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

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

Scope: List of questions

Action: For adoption

3.3.9. Belzutifan - EMEA/H/C/005636

treatment of adult patients with advanced renal cell carcinoma (RCC) and treatment of adult patients with von Hippel-Lindau (VHL) disease

Scope: List of questions

Action: For adoption

3.3.10. Filgrastim - EMEA/H/C/006400

for the reduction in the duration of neutropenia and the incidence of febrile neutropenia

Scope: List of questions

Action: For adoption

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

3.4.1. rituximab - EMEA/H/C/006224

treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL) and Rheumatoid arthritis

Scope: Letter by the applicant dated 19.04.2024 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in March 2024.

Action: For adoption

List of Outstanding Issues adopted on 21.03.2024. List of Questions adopted on 14.09.2024.

3.4.2. Pomalidomide - EMEA/H/C/006302

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

Scope: Letter by the applicant dated 19.04.2024 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

No items

3.6. Initial applications in the decision-making phase

3.6.1. Qalsody - Tofersen - Orphan - EMEA/H/C/005493

Biogen Netherlands B.V.; treatment of adults with amyotrophic lateral sclerosis (ALS), associated with a mutation in the superoxide dismutase 1 (SOD1) gene.

Scope: Request from the European Commission for clarification in relation to the opinion adopted by the CHMP for Qalsody at its February meeting, adoption of revised opinion via written procedure

Action: for information

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

Opinion adopted on 22.02.2024. List of Outstanding Issues adopted on 09.11.2023, 14.09.2023. List of Questions adopted on 30.03.2023.

The Committee addressed the request from the European Commission for clarification in relation to the CHMP Opinion adopted at its February meeting.

The CHMP adopted the revised opinion for Qalsody via written procedure by majority.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. germanium (68Ge) chloride / gallium (68Ga) chloride - EMEA/H/C/005165

indicated for in vitro labelling of kits for radiopharmaceutical preparation

Scope: Withdrawal of marketing authorisation application

Action: For information

List of outstanding issues adopted on 12.10.2023. List of Questions adopted on 16.12.2021.

3.7.2. Ustekinumab - EMEA/H/C/006415

treatment of moderate to severe plaque psoriasis in adults, children and adolescents, active psoriatic arthritis in adults and Crohn's Disease, treatment of Crohn's Disease

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Outstanding issues adopted on 22.02.2024. List of Questions adopted on 14.09.2023.

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. Mektovi - Binimetinib - EMEA/H/C/004579/X/0029

Pierre Fabre Medicament

Rapporteur: Janet Koenig

Scope: "Extension application to add a new strength of 45 mg (film-coated tablets)."

Action: For adoption

List of Questions adopted on 25.01.2024.

4.1.2. Ocrevus - Ocrelizumab - EMEA/H/C/004043/X/0039

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (920 mg) and new route of administration (subcutaneous use).

The RMP (version 9.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 25.01.2024.

4.1.3. [Ozempic - Semaglutide - EMEA/H/C/004174/X/0043](#)

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: quality

Action: For adoption

List of Questions adopted on 22.02.2024.

4.1.4. [Rozlytrek - Entrectinib - EMEA/H/C/004936/X/0017/G](#)

Roche Registration GmbH

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to:

- 1) Introduce a new pharmaceutical form (coated granules) associated with a new strength (50 mg).
- 2) Introduce a new route of administration (gastroenteral use) for the already authorised 100 mg and 200 mg hard capsules presentations.

The above two line extensions are grouped with 3 type II variations:

- C.I.6.a - To extend the currently approved indication in solid tumours with NTRK gene fusion to patients from birth to 12 years of age (both for the coated granules and already approved hard capsules presentations).
- C.I.6.a - To add a new paediatric indication from birth to 18 years of age for patients with solid tumours with a ROS1 gene fusion (both for the coated granules and already approved hard capsules presentations).

Based on final results from studies CO40778 (STARTRK-NG), GO40782 (STARTRK-2) and BO41932 (TAPISTRY). Study CO40778 is a Phase I/II open-label, dose-escalation and expansion study of entrectinib in pediatrics with locally advanced or metastatic solid or primary CNS tumors and/or who have no satisfactory treatment options; Study GO40782 is an open-label, multicenter, global Phase II basket study of entrectinib for the treatment of patients with solid tumors that harbor an NTRK1/2/3, ROS1, or ALK gene rearrangement (fusion), and Study BO41932 is a Phase II, global, multicenter, open-label, multi-cohort study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in rational, specified combinations in participants with unresectable, locally advanced or metastatic solid tumors determined to harbor specific oncogenic genomic alterations or who are tumor mutational burden (TMB)-high as identified by a validated next-generation sequencing (NGS) assay.

As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated accordingly. The Package Leaflet and Labelling are updated in accordance.

- C.I.4 - To add wording regarding the option of suspension in water of the content of the capsules to be used orally or via the e.g., gastric or nasogastric tube (in sections 4.2 and 5.2 of the SmPC). The RMP (version 5) is updated in accordance. The MAH took the opportunity to introduce minor editorial changes to the PI and to update Annex II of the

SmPC.”

Action: For adoption

List of Outstanding Issues adopted on 22.02.2024. List of Questions adopted on 14.09.2023.

4.1.5. [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 Questions adopted on 22.02.2024.

4.1.6. [Wegovy - Semaglutide - EMEA/H/C/005422/X/0016](#)

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: quality

Action: For adoption

List of Questions adopted on 22.02.2024.

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. [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 Questions adopted on 25.01.2024.

4.2.2. [Cresemba - Isavuconazole - Orphan - EMEA/H/C/002734/X/0042/G](#)

Basilea Pharmaceutica Deutschland GmbH

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski

Scope: “Extension application to add a new strength of 40 mg hard capsule to be used in

paediatric patients 6 years and older grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of paediatric patients aged 1 year and older for CRESEMBA 200 mg powder, based on final results from studies 9766-CL-0107 and 9766-CL-0046. Study 9766-CL-0046 is a Phase 1, open-label, multicenter study to evaluate the PK, safety and tolerability of intravenous and oral isavuconazonium sulfate in paediatric patients. This study was conducted in two sequential parts: Part 1 with three intravenous dosing cohorts, and Part 2 with two oral dosing cohorts. Study 9766-CL-0107 is a Phase 2, open-label, non-comparative, multicenter study to evaluate the safety and tolerability, efficacy, and PK of isavuconazole for the treatment of invasive aspergillosis or mucormycosis in paediatric patients aged 1 to < 18 years.

As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.1 of the RMP has also been submitted.”

Action: For adoption

List of Questions adopted on 25.01.2024.

4.2.3. [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, randomised, 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 Questions adopted on 25.01.2024.

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. [Cerdelga - Eliglustat - Orphan - EMEA/H/C/003724/X/0036/G](#)

Sanofi B.V.

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

Scope: "Extension application to introduce a new strength (21 mg capsule, hard) grouped with an extension of indication (C.I.6.a) to include treatment of paediatric patients with GD1 who are 6 years and older with a minimum body weight of 15 kg, who have been previously treated with enzyme replacement therapy (ERT), and who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs) or extensive metabolisers (EMs) for Cerdelga, based on interim results from study EFC13738 (Open label, two cohort (with and without imiglucerase), multicenter study to evaluate pharmacokinetics, safety, and efficacy of eliglustat in pediatric patients with Gaucher disease type 1 and type 3). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 8.0 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI."

Action: For adoption

4.3.2. [Jakavi - Ruxolitinib - EMEA/H/C/002464/X/0070/G](#)

Novartis Europharm Limited

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (5 mg/ml oral solution) and a new route of administration (gastric use), indicated for the treatment of Graft versus host disease (GvHD) in patients aged 28 days or older.

The above line extension is grouped with a type II variation:

- C.I.6.a - To include treatment of paediatric patients aged 28 days to less than 18 years old in acute and chronic Graft versus Host Disease for JAKAVI, based on final results from studies REACH4 (CINC424F12201) and REACH5 (Study CINC424G12201). REACH4 is a Phase I/II open-label, single-arm, multi-center study of ruxolitinib added to corticosteroids in pediatric patients with grade II-IV acute graft vs. host disease after allogeneic hematopoietic stem cell transplantation; while REACH5 is a Phase II open-label, single-arm, multi-center study of ruxolitinib added to corticosteroids in paediatric subjects with moderate and severe chronic graft vs. host disease after allogeneic stem cell transplantation (both for oral solution and already approved tablets presentations). As a consequence, sections 4.1,4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.

The RMP (version 16) is updated in accordance. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to implement editorial changes to Annex II."

Action: For adoption

4.3.3. [Kevzara - Sarilumab - EMEA/H/C/004254/X/0043/G](#)

Sanofi Winthrop Industrie

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

Scope: "Extension application to add a new strength of 175 mg/ml solution for injection in vial, grouped with an extension of indication to include treatment of active polyarticular-course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older for KEVZARA, based on results from study DRI13925; this is a multinational, multi-center, open-label, 2 phase, 3 portions study to describe the PK profile as well as safety and efficacy of

sarilumab. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

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. Alecensa - Alectinib - EMEA/H/C/004164/II/0047

Roche Registration GmbH

Rapporteur: Filip Josephson, PRAC Rapporteur: Jana Lukacisinova

Scope: “Extension of indication to include the use of Alecensa as monotherapy in adult patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) as adjuvant treatment following tumour resection, based on final results from study BO40336 (ALINA), a randomized, active controlled, multicenter, open-label, Phase III study designed to evaluate the efficacy and safety of alectinib compared with platinum-based chemotherapy in the adjuvant setting in patients with completely resected Stage IB (tumors 4 cm) to Stage IIIA ALK positive NSCLC. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.”, Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

5.1.2. [Amyvid - Florbetapir \(18F\) - EMEA/H/C/002422/II/0046](#)

Eli Lilly Nederland B.V.

Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include monitoring response to therapy for AMYVID, based on supporting literature. As a consequence, sections 4.1 and 4.4 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update section 4.8 of the SmPC to reflect the current clinical trial exposures to align it with the updated RMP."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

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

GlaxoSmithkline Biologicals S.A.

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

Scope: "Extension of indication to include treatment of adults 50-59 years of age who are at increased risk for RSV disease for AREXVY, based on results from study 219238 (RSV OA=ADJ-018); this is a phase 3, observer-blind, placebo-controlled, randomized, multi-country, multi-center, non-inferiority study with 2 cohorts to evaluate immunogenicity, reactogenicity and safety of a single dose of RSVPreF3 OA in adults 50-59 years of age. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI, to bring it in line with the latest QRD template version 10.3, and to update the list of local representatives in the Package Leaflet. As part of the application, the MAH 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

5.1.4. [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 25.01.2024, 12.10.2023, 20.07.2023.

5.1.5. [BUCCOLAM - Midazolam - EMEA/H/C/002267/II/0061](#)

Neuraxpharm Pharmaceuticals S.L.

Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan

Scope: “Extension of indication to include treatment of adults to Buccolam 10 mg, based on the results from study 2023-504903-10-00; this is an Interventional Study, Relative Bioavailability to investigate the pharmacokinetics of a single dose of midazolam oromucosal solution (Buccolam) compared to midazolam solution for intramuscular injection (Hypnovel) in healthy volunteers under fasting conditions. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 6.5 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 8.1 of the RMP has also been submitted.”

Action: For adoption

5.1.6. [Inaqovi - Decitabine / Cedazuridine - EMEA/H/C/005823/II/0002](#)

Otsuka Pharmaceutical Netherlands B.V.

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

Scope: “Grouped application consisting of:

C.I.6: Extension of indication to include treatment of adult patients with myelodysplastic syndromes (MDS) for INAQOVI.

C.I.6: Extension of indication to include treatment of adult patients with chronic myelomonocytic leukaemia (CMML) for INAQOVI.

Based on final results from studies ASTX727-01, ASTX727-02, ASTX727-04, E7727-01, and E7727-02. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3. As part of the application the MAH is requesting a 1-year extension of the market protection.”, Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

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

GlaxoSmithkline Biologicals SA

Rapporteur: Christophe Focke

Scope: "A grouped application consisting of two type II variations, as follows:
C.I.6.a: To modify the approved therapeutic indication to include treatment from the age of 6 weeks for the administration of the primary vaccination, section 4.1 of the SmPC is updated accordingly.
C.I.4: Update of section 4.2 of the SmPC for the use of mixed hexavalent/pentavalent primary vaccination schedule and vaccine interchangeability. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and the Package Leaflet."

Action: For adoption

5.1.8. [Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0150](#)

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include in combination with enfortumab vedotin, the first-line treatment of locally advanced or metastatic urothelial carcinoma in adults, based on the final results from KEYNOTE-A39/EV-302: "An open label, randomized, controlled phase 3 study of enfortumab vedotin in combination with pembrolizumab versus chemotherapy alone in previously untreated locally advanced (LA) or metastatic urothelial cancer (mUC)"; As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 45.1 of the RMP has also been submitted."

Action: For adoption

5.1.9. [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 25.01.2024.

5.1.10. [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.

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023, 20.07.2023.

5.1.11. [OPDIVO - Nivolumab - EMEA/H/C/003985/II/0137](#)

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include in combination with cisplatin-based chemotherapy the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma for OPDIVO, based on interim results from study CA209901 (CheckMate901); this is a Phase 3, open-label, randomized study of nivolumab combined with ipilimumab, or with standard of care chemotherapy, versus standard of care chemotherapy in participants with previously untreated unresectable or metastatic urothelial cancer. 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 35.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

5.1.12. [OPDIVO - Nivolumab - EMEA/H/C/003985/II/0140](#)

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include OPDIVO for the treatment of patients with resectable stage II-IIIB non-small cell lung cancer, based on results from study CA209977T; a phase 3, randomised, double-blind study of neoadjuvant chemotherapy plus nivolumab versus neoadjuvant chemotherapy plus placebo, followed by surgical resection and adjuvant treatment with nivolumab or placebo for participants with resectable stage II-IIIB non-small cell lung cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 36.0 of the RMP has also been submitted."

Action: For adoption

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

Astellas Pharma Europe B.V.

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

Scope: "Extension of indication to include in combination with pembrolizumab, the first-line treatment of adult patients with locally advanced or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy for PADCEV, based on the final results from study KEYNOTE-A39/EV-302: "An open label, randomized, controlled phase 3 study of enfortumab vedotin in combination with pembrolizumab versus chemotherapy alone in previously untreated locally advanced (LA) or metastatic urothelial cancer (mUC)"; As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

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

Incyte Biosciences Distribution B.V.

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

Scope: "Extension of indication to include treatment of adults with myeloid/lymphoid neoplasms (MLNs) with Fibroblast Growth Factor Receptor1 (FGFR1) rearrangement for PEMAZYRE, based on final results from study INCB 54828-203 (FIGHT-203); this is a phase 2, open-label, monotherapy, multicenter study to evaluate the efficacy and safety of INCB054828 in subjects with myeloid/lymphoid neoplasms with FGFR1 rearrangement. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.15. RYBREVANT - Amivantamab - EMEA/H/C/005454/II/0010

Janssen-Cilag International N.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include amivantamab in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating epidermal-growth factor receptor (EGFR) Exon 20 insertion mutations for RYBREVANT, based on the final results from study 61186372NSC3001 listed as a Specific Obligation in the Annex II of the Product Information; this is a global, open-label, randomized Phase 3 study of ACP compared to CP alone in participants with newly

diagnosed, locally advanced or metastatic NSCLC characterized by EGFR exon 20ins. The primary objective of the PAPILLON study is to compare efficacy, as demonstrated by PFS, in participants treated with ACP versus CP alone. As a consequence, sections 4.1, 4.2, 4.8, 4.9, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II and Annex IV of the PI. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation given the fulfilment of the SOB. As part of the application, the MAH also requests an extension of the market protection by one additional year.”, 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.

5.1.16. SCENESSE - Afamelanotide - Orphan - EMEA/H/C/002548/II/0044

Clinuvel Europe Limited

Rapporteur: Janet Koenig, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Martin Huber

Scope: “Extension of indication for the prevention of phototoxicity in adolescent patients (12 to under 18 years of age) with erythropoietic protoporphyria (EPP), based on the analysis of the safety and efficacy data available. As a consequence, sections 4.1, 4.2 and 4.4 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.4 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial correction to the PI.”

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023, 25.05.2023.

See 2.3

5.1.17. SIRTURO - Bedaquiline - Orphan - EMEA/H/C/002614/II/0056

Janssen-Cilag International N.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: “Extension of indications by removal of the restriction for use of SIRTURO (bedaquiline [BDQ]), based on final results from study STREAM Stage 2; this is a multicenter, open-label, parallel-group, randomized, active-controlled study in participants aged 15 years or older with RR/MDR-TB to evaluate an investigational BDQ-containing, all-oral, 40-week regimen of anti-TB drugs (Regimen C) compared to an injectable-containing 40-week control regimen (Regimen B). As a consequence of the data emerging from the submitted study, sections 2, 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. In addition, section E of Annex II has also been updated. The Labelling and Package Leaflet are 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. As part of the application, the MAH is requesting the switch from a conditional MA to standard MA.”

Action: For adoption

Request for Supplementary Information adopted on 22.02.2024.

5.1.18. 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 14.12.2023.

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

Roche Registration GmbH

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include first-line treatment of adult patients with non-small cell lung cancer (NSCLC) who are ineligible for platinum-based chemotherapy and who do not have EGFR mutant or ALK-positive disease, who have: locally advanced unresectable NSCLC not amenable for definitive chemoradiotherapy, or metastatic NSCLC, for TECENTRIQ, based on final results from study MO29872 (IPSOS); this is a phase 3, open-label, multicenter, randomized study to investigate the efficacy and safety of atezolizumab compared with chemotherapy in patients with treatment naive advanced or recurrent (stage IIIB not amenable for multimodality treatment) or metastatic (stage IV) non-small cell lung cancer who are deemed unsuitable for platinum-containing therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. Version 29.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023.

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

Beigene Ireland Limited

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

Scope: "Extension of indication to include in combination with platinum-based chemotherapy the first-line treatment of adult patients with unresectable, locally advanced

or metastatic oesophageal squamous cell carcinoma (OSCC) for TEVIMBRA, based on results from study BGB-A317-306; this is a multi-regional, randomized, placebo-controlled, double-blind phase 3 study evaluating the efficacy and safety of tislelizumab in combination with chemotherapy compared to placebo in combination with chemotherapy as first-line treatment in patients with unresectable or locally advanced recurrent or metastatic OSCC. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 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. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

Action: For adoption

5.1.21. Triumeq - Dolutegravir / Abacavir / Lamivudine - EMEA/H/C/002754/II/0116

ViiV Healthcare B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber

Scope: “Extension of indication to include treatment of paediatric patients from 6 kg to less than 25 kg for Triumeq Dispersible Tablets, based on PK, safety and efficacy data observed in the final results of study 205860 (IMPAACT 2019), further supported by extrapolation to data generated in adults and additional data in paediatric patients with the single entities. IMPAACT 2019 is a Phase 1/2 open-label, multicenter, multiple dose study of dolutegravir/lamivudine/abacavir fixed dose combination tablets in treatment-experienced and treatment-naïve HIV-1-infected children less than 12 years of age. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 22.0 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.”

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024, 25.01.2024.

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

Novo Nordisk A/S

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

Scope: “Extension of indication to include risk reduction of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and BMI ≥ 27 kg/m² for WEGOVY, based on results from study EX9536-4388 (SELECT); this is a randomised, double-blind, placebo-controlled, trial comparing semaglutide 2.4 mg with placebo both administered s.c. once weekly in subjects with established cardiovascular disease and overweight or obesity. As a consequence, section 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. As part of the application the MAH is requesting a 1-year extension of the market protection.”, Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

5.1.23. [Zavicefta - Ceftazidime / Avibactam - EMEA/H/C/004027/II/0035](#)

Pfizer Ireland Pharmaceuticals

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

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

Action: For adoption

5.1.24. [WS2463](#) [Imfinzi - Durvalumab - EMEA/H/C/004771/WS2463/0063](#) [Lynparza - Olaparib - EMEA/H/C/003726/WS2463/0066](#)

AstraZeneca AB

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

Scope: "Extension of indication for Lynparza in combination with Imfinzi for the maintenance treatment of adult patients with newly diagnosed advanced or recurrent endometrial cancer following treatment with Imfinzi and platinum-based chemotherapy, based on results from pivotal Phase III study, D9311C00001 (DUO-E). This was a phase III, randomised, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of durvalumab in combination with platinum-based chemotherapy (paclitaxel + carboplatin) followed by maintenance durvalumab with or without olaparib for patients with newly diagnosed advanced or recurrent endometrial cancer. 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 30 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 25.01.2024.

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

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

Vertex Pharmaceuticals (Ireland) Limited

Lead Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

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

Update on the procedure; intervention by a third party

Action: For information

Request for Supplementary Information adopted on 22.02.2024.

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

Novartis Europharm Limited

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

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

Letter by the applicant dated 19.04.2024 requesting an extension to the clock stop to respond to the RSI adopted in March 2024.

Action: For information

Request for Supplementary Information adopted on 21.03.2024, 14.12.2023.

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

No items

6.4. Companion diagnostics – follow-up consultation

6.4.1. In vitro diagnostic medical device - EMEA/H/D/006470

to detect amplification of the HER2/neu gene via quantitative fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer and adenocarcinomas of the stomach (including gastroesophageal junction) tissue specimens.

Scope: Opinion

Action: For adoption

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. Levacetylleucine - Orphan - H0006327

Intrabio Ireland Limited; Niemann-Pick disease type C (NPC)

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

Action: For adoption

8.1.2. Inavolisib - H0006353

Inavolisib in combination with palbociclib and fulvestrant, is indicated for the 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 (LA/mBC), following recurrence on or within 12 months of completing adjuvant endocrine treatment

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

Action: For adoption

8.1.3. Pridopidine - H0006261

Treatment of Huntington's disease (HD)

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

Action: For adoption

8.1.4. Zanidatamab - Orphan - H0006380

Jazz Pharmaceuticals Ireland Limited; Zanidatamab is indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic HER2-positive biliary tract cancer (BTC)

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. LUMYKRAS - Sotorasib - EMEA/H/C/005522/II/0010/G

Amgen Europe B.V.

Rapporteur: Alexandre Moreau

Scope: "Update of sections 4.2, 4.4, 4.8, 5.2 and 5.3 of the SmPC in order to change in the recommended dose and to update safety and efficacy information based on results from study 20190009 (CodeBreak 200) listed as a specific obligation in the Annex II, in order to fulfil SOB/001; and results from study 20170543 (CodeBreak 100) Phase 2 Part B. Study 20190009 is a Phase 3 Multicenter, Randomized, Open Label, Active-controlled, Study of AMG 510 Versus Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC Subjects With Mutated KRAS p.G12C; while study 20170543 is a Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumors With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023 and 25.05.2023.

9.1.2. Ofev - nintedanib - EMEA/H/C/003821/X/0052/G

Boehringer Ingelheim International GmbH

Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra

Scope: AHEG meeting nomination of experts

Action: For adoption

9.1.3. Ozempic - Semaglutide - EMEA/H/C/004174/II/0044/G

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: quality

Action: For adoption

9.1.4. 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 of 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 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."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024, 09.11.2023.

9.1.5. [Ronapreve - Casirivimab / Imdevimab - EMEA/H/C/005814/II/0015](#)

Roche Registration GmbH

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Update of section 4.6 of the SmPC in order to update information on pregnancy based on a comprehensive analysis of the results from the drug pregnancy registry cohort (PDC study GV44373), listed as a category 3 PASS in the RMP, as well as data from clinical studies and post-marketing surveillance. The RMP version 3.0 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."

Action: For adoption

Request for Supplementary Information adopted on 07.03.2024.

9.1.6. [Wegovy - Semaglutide - EMEA/H/C/005422/II/0020/G](#)

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: quality

Action: For adoption

Request for Supplementary Information adopted on 07.03.2024.

10. Referral procedures

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

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

Advanz Pharma Limited

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

Scope: List of outstanding issues / opinion; intervention by a third party

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 25.01.2024.

10.1.2. 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: List of outstanding issues / opinion

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 14.12.2023.

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

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

MAH various (NAPs only)

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

Scope: List of outstanding issues

Action: For adoption

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

The German National Competent Authority triggered a referral under Article 31 of Directive 2001/83 based on interest of the Union, requesting an opinion to CHMP on the benefit-risk of azithromycin-containing products and whether marketing authorisations of azithromycin-containing products for systemic use should be maintained, varied, suspended, or revoked.

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

April 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 April 2024

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

Agenda of the April 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

Reports from the BWP meeting for CHMP adoption:

Action: For adoption

14.3.2. Election of Vice-Chair – Biologics Working Party (BWP)

Following the call for nominations launched in March, CHMP to elect the Vice-Chair from the candidates who submitted nominations.

Nomination(s) received

Action: For election

14.3.3. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 16-17 April 2024.

Action: For adoption

14.3.4. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 15-18 April 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.

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

14.8.1. H-MAAs 3-year forecast report (March 2024 - December 2026)

3-year forecast report of initial marketing authorisations, Type II Variations and Line Extension applications planned for the next three years (March 2024 - December 2026).

Action: For information

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)

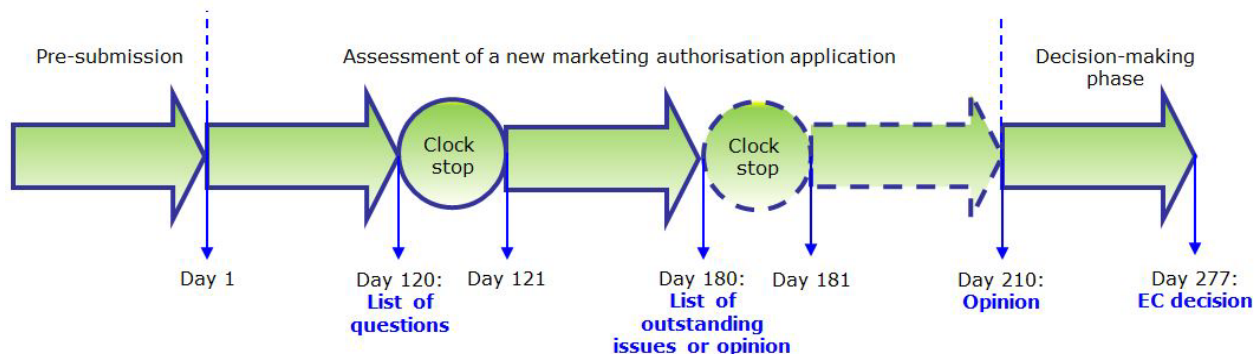
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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



19 April 2024
EMA/CHMP/127768/2024

Annex to 22-25 April 2024 CHMP Agenda

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for
April 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

LIVMARLI - Maralixibat - EMA/H/C/005857/S/0012, Orphan

Mirum Pharmaceuticals International B.V.,
Rapporteur: Martina Weise, PRAC Rapporteur:
Adam Przybylkowski

SCENESSE - Afamelanotide - EMA/H/C/002548/S/0050, Orphan

Clinuvel Europe Limited, Rapporteur: Janet
Koenig, 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

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

Inbrija - Levodopa -

EMA/H/C/004786/R/0022

Acorda Therapeutics Ireland Limited,
Rapporteur: Peter Mol, Co-Rapporteur: Jayne
Crowe, PRAC Rapporteur: Barbara Kovacic
Bytyqi

XOSPATA - Gilteritinib -

EMA/H/C/004752/R/0017, Orphan

Astellas Pharma Europe B.V., Rapporteur: Ingrid
Wang, Co-Rapporteur: Elita Poplavska, PRAC
Rapporteur: Martin Huber

Zydelig - Idelalisib -

EMA/H/C/003843/R/0059

Gilead Sciences Ireland UC, Rapporteur: Filip
Josephson, Co-Rapporteur: Peter Mol, PRAC
Rapporteur: Martin Huber
Request for Supplementary Information adopted
on 22.02.2024.

B.2.3. Renewals of Conditional Marketing Authorisations

Kinpeygo - Budesonide -

EMA/H/C/005653/R/0010, Orphan

STADA Arzneimittel AG, Rapporteur: Christian
Gartner, PRAC Rapporteur: Marie Louise
Schougaard Christiansen

TALVEY - Talquetamab -

EMA/H/C/005864/R/0005, Orphan

Janssen-Cilag International N.V., Rapporteur:
Alexandre Moreau, Co-Rapporteur: Paolo
Gasparini, PRAC Rapporteur: Barbara Kovacic
Bytyqi

Tecvayli - Teclistamab -

EMA/H/C/005865/R/0010

Janssen-Cilag International N.V., Rapporteur:
Johanna Lähteenvuo, Co-Rapporteur: Paolo
Gasparini, PRAC Rapporteur: Jana Lukacisinova

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 08-11 April 2024
PRAC:

Signal of serious cutaneous adverse reactions

Adagrasib – KRAZATI (CAP)
Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola
PRAC recommendation on a variation
Action: For adoption

Signal of coeliac disease

Atezolizumab; aveluma; cemiplima; dostarlimab; durvalumab; ipilimumab; nivolumab; nivolumab, relatlimab; pembrolizumab; tislelizumab; tremelimumab - TECENTRIQ; BAVENCIO; LIBTAYO; JEMPERLI; IMFINZI; YERVOY; OPDIVO; OPDUALAG; KEYTRUDA; TEVIMBRA; IMJUDO
Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: Bianca Mulder
PRAC recommendation on a variation
Action: For adoption

Signal of pancreatic failure

Atezolizumab; aveluma; cemiplima; dostarlimab; durvalumab; ipilimumab; nivolumab; nivolumab, relatlimab; pembrolizumab; tislelizumab; tremelimumab - TECENTRIQ; BAVENCIO; LIBTAYO; JEMPERLI; IMFINZI; YERVOY; OPDIVO; OPDUALAG; KEYTRUDA; TEVIMBRA; IMJUDO (CAP)
Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: Martin Huber
PRAC recommendation on a variation
Action: For adoption

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

EMA/H/C/PSUSA/00001187/202308

(duloxetine)

CAPS:

Cymbalta (EMA/H/C/000572) (Duloxetine), Eli Lilly Nederland B.V., Rapporteur: Antonio Gómez Outes

Duloxetine Lilly (EMA/H/C/004000)

(Duloxetine), Eli Lilly Nederland B.V.,

Rapporteur: Antonio Gómez Outes

Yentreve (EMA/H/C/000545) (Duloxetine), Eli

Lilly Nederland B.V., Rapporteur: Antonio Gómez

Outes

NAPS:

NAPs - EU, PRAC Rapporteur: Maria del Pilar

Rayon, "03/08/2020 To: 03/08/2023"

EMA/H/C/PSUSA/0001988/202309

(mercaptopurine)

CAPS:

Xaluprine (EMA/H/C/002022)

(Mercaptopurine), Nova Laboratories Ireland

Limited, Rapporteur: Filip Josephson

NAPS:

NAPs - EU, PRAC Rapporteur: Ulla Wändel

Liminga, "02/09/2021 To: 01/09/2023"

EMA/H/C/PSUSA/00003149/202308

(zoledronic acid (indicated for cancer and fractures))

CAPS:

Zoledronic acid Hospira (SRD)

(EMA/H/C/002365) (Zoledronic acid), Pfizer

Europe MA EEIG, Rapporteur: Kristina Dunder

Zoledronic acid medac (EMA/H/C/002359)

(Zoledronic acid), medac Gesellschaft für

klinische Spezialpräparate mbH, Rapporteur:

Alar Irs

Zometa (EMA/H/C/000336) (Zoledronic acid),

Phoenix Labs Unlimited Company, Rapporteur:

Thalia Marie Estrup Blicher

NAPS:

NAPS - EUR, PRAC Rapporteur: Karin Erneholt,

"01/09/2020 To: 31/08/2023"

EMA/H/C/PSUSA/00009142/202308

(emtricitabine / rilpivirine / tenofovir disoproxil)

CAPS:

Eviplera (EMA/H/C/002312) (Emtricitabine /

Rilpivirine / Tenofovir disoproxil), Gilead

Sciences Ireland UC, Rapporteur: Patrick

Vrijlandt, PRAC Rapporteur: Liana Martirosyan,

"11/08/2020 To: 10/08/2023"

EMA/H/C/PSUSA/00010082/202308

(cobicistat / elvitegravir / emtricitabine /

tenofovir disoproxil)

CAPS:

Stribild (EMA/H/C/002574) (Elvitegravir /

Cobicistat / Emtricitabine / Tenofovir disoproxil),

Gilead Sciences Ireland UC, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ana Sofia Diniz Martins, "27/08/2020 To: 26/08/2023"

EMEA/H/C/PSUSA/00010095/202308

(enzalutamide)

CAPS:

Xtandi (EMEA/H/C/002639) (Enzalutamide),
Astellas Pharma Europe B.V., Rapporteur:
Carolina Prieto Fernandez, PRAC Rapporteur:
Maria del Pilar Rayon, "31/08/2020 To:
30/08/2023"

EMEA/H/C/PSUSA/00010456/202309

(mepolizumab)

CAPS:

Nucala (EMEA/H/C/003860) (Mepolizumab),
GlaxoSmithKline Trading Services Limited,
Rapporteur: Finbarr Leacy, PRAC Rapporteur:
Gabriele Maurer, "24/03/2023 To: 23/09/2023"

EMEA/H/C/PSUSA/00010718/202308

(eravacycline)

CAPS:

Xerava (EMEA/H/C/004237) (Eravacycline),
Paion Deutschland GmbH, Rapporteur: Filip
Josephson, PRAC Rapporteur: Adam
Przybylkowski, "26/08/2022 To: 26/08/2023"

EMEA/H/C/PSUSA/00010857/202309

(ebola vaccine (rDNA, replication-incompetent))

CAPS:

MVABEA (EMEA/H/C/005343) (Ebola vaccine
(rDNA, replication-incompetent)), Janssen-Cilag
International N.V., Rapporteur: Patrick Vrijlandt
ZABDENO (EMEA/H/C/005337) (Ebola vaccine
(rDNA, replication-incompetent)), Janssen-Cilag
International N.V., Rapporteur: Patrick Vrijlandt,
PRAC Rapporteur: Jean-Michel Dogné,
"27/09/2022 To: 26/09/2023"

EMEA/H/C/PSUSA/00010927/202309

(ofatumumab)

CAPS:

Kesimpta (EMEA/H/C/005410) (Ofatumumab),
Novartis Ireland Limited, Rapporteur: Thalia
Marie Estrup Blicher, PRAC Rapporteur: Amelia
Cupelli, "26/03/2023 To: 25/09/2023"

EMEA/H/C/PSUSA/00010952/202308

(vosoritide)

CAPS:

Voxzogo (EMEA/H/C/005475) (Vosoritide),

BioMarin International Limited, Rapporteur:
Martina Weise, PRAC Rapporteur: Zane Neikena,
"26/02/2023 To: 25/08/2023"

EMA/H/C/PSUSA/00010954/202309

(idecabtagene vicleucel)

CAPS:

Abecma (EMA/H/C/004662) (Idecabtagene vicleucel), Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjekken, PRAC Rapporteur: Ulla Wändel Liminga, "24/03/2023 To: 24/09/2023"

EMA/H/C/PSUSA/00010967/202309

(avacopan)

CAPS:

TAVNEOS (EMA/H/C/005523) (Avacopan), Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder, PRAC Rapporteur: Liana Martirosyan, "26/03/2023 To: 26/09/2023"

EMA/H/C/PSUSA/00011032/202309

(maralixibat)

CAPS:

LIVMARLI (EMA/H/C/005857) (Maralixibat), Mirum Pharmaceuticals International B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Adam Przybylkowski, "28/03/2023 To: 28/09/2023"

B.4. EPARs / WPARs

AGILUS - Dantrolene sodium, hemiheptahydrate - EMA/H/C/006009, Orphan

Norgine B.V., treatment of malignant hyperthermia (including suspected cases), Hybrid application (Article 10(3) of Directive No 2001/83/EC)

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

Awikli - Insulin icodex - EMA/H/C/005978
Novo Nordisk A/S, treatment of diabetes mellitus in adults, 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.

Dimethyl fumarate Accord - Dimethyl fumarate - EMA/H/C/006471

Accord Healthcare, treatment of multiple sclerosis, Generic of TECFIDERA, Generic application (Article 10(1) of Directive No 2001/83/EC)

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

<p>Dimethyl fumarate Mylan - Dimethyl fumarate - EMEA/H/C/006397</p> <p>Mylan Ireland Limited, for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS), Generic of TECFIDERA, Generic application (Article 10(1) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Dimethyl fumarate Neuraxpharm - Dimethyl fumarate - EMEA/H/C/006500</p> <p>Neuraxpharm Pharmaceuticals S.L., treatment of multiple sclerosis, Generic of TECFIDERA, Generic application (Article 10(1) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Emblaveo - Aztreonam / Avibactam - EMEA/H/C/006113</p> <p>Pfizer Europe Ma EEIG, treatment of complicated Intra-Abdominal Infection (cIAI), complicated Urinary Tract Infection (cUTI), including pyelonephritis, Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), and aerobic Gram-negative infections with limited treatment options, 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>Fabhalta - Iptacopan - EMEA/H/C/005764, Orphan</p> <p>Novartis Europharm Limited, treatment of paroxysmal nocturnal haemoglobinuria, 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>Jubbonti - Denosumab - EMEA/H/C/005964</p> <p>Sandoz GmbH, treatment of osteoporosis, 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>Lytenava - Bevacizumab - EMEA/H/C/005723</p> <p>Outlook Therapeutics Limited, Treatment of neovascular (wet) age-related macular degeneration (nAMD)., Known 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>Neoatrimon - Dopamine hydrochloride - EMEA/H/C/006044, PUMA</p> <p>BrePco Biopharma Limited, Treatment of hypotension in neonates, infants and children, Hybrid application (Article 10(3) of Directive No 2001/83/EC)</p>	<p>For information only. Comments can be sent to the PL in case necessary.</p>
<p>Omlyclo - Omalizumab - EMEA/H/C/005958</p>	<p>For information only. Comments can be sent to</p>

Celltrion Healthcare Hungary Kft., treatment of asthma, chronic rhinosinusitis with nasal polyps and chronic spontaneous urticaria, treatment of asthma and chronic rhinosinusitis with nasal polyps, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	the PL in case necessary.
PD-L1 IHC 22C3 pharmDx (SK006) - In vitro diagnostic medical device - EMEA/H/D/006454 Agilent Technologies, Inc., To detect PD-L1 proteinCompanion Diagnostics (Article 48 (3), (4), (7), (8) of Regulation (EU) 2017/746)	For information only. Comments can be sent to the PL in case necessary.
UPSTELDA (WD) - Ustekinumab - EMEA/H/C/006415 Amgen Technology (Ireland) Unlimited Company, treatment of moderate to severe plaque psoriasis in adults, children and adolescents, active psoriatic arthritis in adults and Crohn's Disease, treatment of Crohn's Disease, Duplicate, Duplicate of WEZENLA, Similar biological application (Article 10(4) of Directive No 2001/83/EC) WPAR	For information only. Comments can be sent to the PL in case necessary.
Wyost - Denosumab - EMEA/H/C/006378 Sandoz GmbH, prevention of skeletal related events with advanced malignancies Duplicate of Jubbonti, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Adtralza - Tralokinumab - EMEA/H/C/005255/II/0015 LEO Pharma A/S, Rapporteur: Jayne Crowe Opinion adopted on 11.04.2024. Request for Supplementary Information adopted on 01.02.2024.	Positive Opinion adopted by consensus on 11.04.2024.
Adtralza - Tralokinumab - EMEA/H/C/005255/II/0018 LEO Pharma A/S, Rapporteur: Jayne Crowe Opinion adopted on 11.04.2024.	Positive Opinion adopted by consensus on 11.04.2024.
Advate - Octocog alfa - EMEA/H/C/000520/II/0122/G	Request for supplementary information adopted with a specific timetable.

Takeda Manufacturing Austria AG, Rapporteur:
Jan Mueller-Berghaus
Request for Supplementary Information adopted
on 04.04.2024.

Aimovig - Erenumab -
EMA/H/C/004447/II/0030
Novartis Europharm Limited, Rapporteur: Kristina
Dunder

AQUIPTA - Atogepant -
EMA/H/C/005871/II/0001/G
AbbVie Deutschland GmbH & Co. KG, Rapporteur:
Janet Koenig
Request for Supplementary
Information adopted on 04.04.2024.

Request for supplementary information adopted
with a specific timetable.

Atosiban SUN – Atosiban -
EMA/VR/0000167976
Sun Pharmaceutical Industries (Europe) B.V.,
Rapporteur: John Joseph Borg

Buvidal - Buprenorphine -
EMA/H/C/004651/II/0025
Camurus AB, Rapporteur: Finbarr Leacy

Cancidas - 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.

Request for supplementary information adopted
with a specific timetable.

Cetrotide - Cetrorelix -
EMA/H/C/000233/II/0090
Merck Europe B.V., Rapporteur: Martina Weise
Request for Supplementary Information adopted
on 01.02.2024, 29.06.2023.

Dovprela - Pretomanid -
EMA/H/C/005167/II/0020, Orphan
Mylan IRE Healthcare Limited, Rapporteur: Filip
Josephson
Opinion adopted on 11.04.2024.
Request for Supplementary Information adopted
on 07.03.2024.

Positive Opinion adopted by consensus on
11.04.2024.

Ebixa - Memantine / Memantine
hydrochloride - EMA/H/C/000463/II/0101
H. Lundbeck A/S, Duplicate, Duplicate of Axura,
Rapporteur: Antonio Gómez Outes
Request for Supplementary Information adopted
on 11.01.2024.

Elaprase - Idursulfase -
EMA/H/C/000700/II/0109

Positive Opinion adopted by consensus on

<p>Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Patrick Vrijlandt Opinion adopted on 04.04.2024. Request for Supplementary Information adopted on 14.12.2023, 31.08.2023, 25.05.2023.</p>	04.04.2024.
<p>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.</p>	Request for supplementary information adopted with a specific timetable.
<p>Enhertu - Trastuzumab - EMA/H/C/005124/II/0043/G Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia Opinion adopted on 18.04.2024. Request for Supplementary Information adopted on 15.02.2024.</p>	Positive Opinion adopted by consensus on 18.04.2024.
<p>Ervebo - Recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live) - EMA/H/C/004554/II/0035 Merck Sharp & Dohme B.V., Rapporteur: Christophe Focke</p>	
<p>Eylea - Aflibercept - EMA/H/C/002392/II/0088 Bayer AG, Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 04.04.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p>Gilenya - Fingolimod - EMA/H/C/002202/II/0088 Novartis Europharm Limited, Rapporteur: Alexandre Moreau</p>	
<p>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.</p>	Request for supplementary information adopted with a specific timetable.
<p>Herzuma - Trastuzumab - EMA/H/C/002575/II/0061/G Celltrion Healthcare Hungary Kft., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 11.04.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p>Hizentra - Human normal immunoglobulin - EMA/H/C/002127/II/0151/G CSL Behring GmbH, Rapporteur: Jan Mueller- Berghaus</p>	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 18.04.2024.

Ibandronic Acid Teva - Ibandronic acid - EMEA/H/C/001195/II/0021

Teva B.V., Generic of Bondronat, Bonviva, Rapporteur: Hrefna Gudmundsdottir
Request for Supplementary Information adopted on 11.04.2024, 29.02.2024, 16.11.2023.

Request for supplementary information adopted with a specific timetable.

Insuman - Insulin human - EMEA/H/C/000201/II/0146

Sanofi-Aventis Deutschland GmbH, Rapporteur: Karin Janssen van Doorn
Opinion adopted on 11.04.2024.
Request for Supplementary Information adopted on 15.02.2024.

Positive Opinion adopted by consensus on 11.04.2024.

Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/II/0031/G

Bayer AG, Rapporteur: Thalia Marie Estrup Blicher
Opinion adopted on 11.04.2024.

Positive Opinion adopted by consensus on 11.04.2024.

Latuda - Lurasidone - EMEA/H/C/002713/II/0041

Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Rapporteur: Filip Josephson
Opinion adopted on 04.04.2024.
Request for Supplementary Information adopted on 08.02.2024.

Positive Opinion adopted by consensus on 04.04.2024.

NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0063/G

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

Ogivri - Trastuzumab - EMEA/H/C/004916/II/0060

Biosimilar Collaborations Ireland Limited, Rapporteur: Karin Janssen van Doorn
Opinion adopted on 04.04.2024.

Positive Opinion adopted by consensus on 04.04.2024.

Origio A.R.T. Media - Gentamicin sulfate / Sargramostim / Heparin sodium / Insulin human - EMEA/H/D/006090/II/0002

Coopersurgical Inc., Rapporteur: Jayne Crowe

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

Theramex Ireland Limited, Rapporteur: Patrick Vrijlandt
Request for Supplementary Information adopted on 11.04.2024, 07.12.2023.

Request for supplementary information adopted with a specific timetable.

<p>Ozempic - Semaglutide - EMA/H/C/004174/II/0044/G Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt</p>	See 9.1
<p>Posaconazole Accord - Posaconazole - EMA/H/C/005005/II/0012/G Accord Healthcare S.L.U., Generic of Noxafil, Rapporteur: Hrefna Gudmundsdottir Opinion adopted on 18.04.2024. Request for Supplementary Information adopted on 11.01.2024.</p>	Positive Opinion adopted by consensus on 18.04.2024.
<p>PREVYMIS - Letermovir - EMA/H/C/004536/II/0036, Orphan Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson Request for Supplementary Information adopted on 25.01.2024.</p>	
<p>Privigen - Human normal immunoglobulin - EMA/H/C/000831/II/0202/G CSL Behring GmbH, Rapporteur: Jan Mueller- Berghaus Request for Supplementary Information adopted on 18.04.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p>Reblozyl - Luspatercept - EMA/H/C/004444/II/0027, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Daniela Philadelphly Opinion adopted on 11.04.2024. Request for Supplementary Information adopted on 15.02.2024.</p>	Positive Opinion adopted by consensus on 11.04.2024.
<p>Ruxience - Rituximab - EMA/H/C/004696/II/0015 Pfizer Europe MA EEIG, Rapporteur: Peter Mol Request for Supplementary Information adopted on 04.04.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p>Saxenda - Liraglutide - EMA/H/C/003780/II/0038 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 11.04.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p>Skyrizi - Risankizumab - EMA/H/C/004759/II/0046/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy Opinion adopted on 18.04.2024. Request for Supplementary Information adopted on 08.02.2024.</p>	Positive Opinion adopted by consensus on 18.04.2024.

<p>Skytrofa - Lonapegsomatropin - EMEA/H/C/005367/II/0025/G, Orphan Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 04.04.2024, 08.02.2024.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>Spectrila - Asparaginase - EMEA/H/C/002661/II/0036 medac Gesellschaft für klinische Spezialpräparate mbH, Rapporteur: Christian Gartner Opinion adopted on 04.04.2024. Request for Supplementary Information adopted on 22.02.2024.</p>	<p>Positive Opinion adopted by consensus on 04.04.2024.</p>
<p>Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0123/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus</p>	
<p>Sugammadex Mylan - Sugammadex - EMEA/H/C/005403/II/0010/G Mylan Ireland Limited, Generic of Bridion, Rapporteur: Hrefna Gudmundsdottir Opinion adopted on 18.04.2024. Request for Supplementary Information adopted on 22.02.2024.</p>	<p>Positive Opinion adopted by consensus on 18.04.2024.</p>
<p>TEPADINA - Thiotepa - EMEA/H/C/001046/II/0050/G ADIENNE S.r.l. S.U., Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 04.04.2024.</p>	<p>Request for supplementary information adopted with a specific timetable.</p>
<p>TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0032 Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus</p>	
<p>Trumenba - Meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0050/G Pfizer Europe MA EEIG, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 22.02.2024, 14.12.2023.</p>	
<p>Vazkepa - Icosapent ethyl - EMEA/H/C/005398/II/0023/G Amarin Pharmaceuticals Ireland Limited, Rapporteur: Martina Weise</p>	
<p>Vyvgart - Efgartigimod alfa -</p>	<p>Request for supplementary information adopted</p>

<p>EMA/H/C/005849/II/0016, Orphan Argenx, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 04.04.2024.</p>	with a specific timetable.
<p>Wegovy - Semaglutide - EMA/H/C/005422/II/0020/G Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt</p>	See 9.1
<p>Yuflyma - Adalimumab - EMA/H/C/005188/II/0035/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola</p>	
<p>WS2608/G Apretude- EMA/H/C/005756/WS2608/0001/G Vocabria- EMA/H/C/004976/WS2608/0020/G ViiV Healthcare B.V., Duplicate, Duplicate of Vocabria, Lead Rapporteur: Bruno Sepodes Request for Supplementary Information adopted on 08.02.2024.</p>	
<p>WS2630 Hefiya-EMA/H/C/004865/WS2630/0052 Hyrimoz-EMA/H/C/004320/WS2630/0051 Sandoz GmbH, Lead Rapporteur: Christian Gartner Opinion adopted on 11.04.2024. Request for Supplementary Information adopted on 07.03.2024.</p>	Positive Opinion adopted by consensus on 11.04.2024.
<p>WS2634 Hexacima- EMA/H/C/002702/WS2634/0154 Hexyon-EMA/H/C/002796/WS2634/0158 Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller- Berghaus Request for Supplementary Information adopted on 04.04.2024.</p>	Request for supplementary information adopted with a specific timetable.
<p>WS2651 Nilemdo-EMA/H/C/004958/WS2651/0036 Nustendi-EMA/H/C/004959/WS2651/0041 Daiichi Sankyo Europe GmbH, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 11.04.2024.</p>	Positive Opinion adopted by consensus on 11.04.2024.
<p>WS2655/G GONAL-f- EMA/H/C/000071/WS2655/0167/G Pergoveris-</p>	Positive Opinion adopted by consensus on 11.04.2024.

EMA/H/C/000714/WS2655/0091/G

Merck Europe B.V., Lead Rapporteur: Patrick Vrijlandt
Opinion adopted on 11.04.2024.

WS2659/G**Riarify-****EMA/H/C/004836/WS2659/0032/G****Trimbow-****EMA/H/C/004257/WS2659/0039/G****Trydonis-****EMA/H/C/004702/WS2659/0036/G**

Chiesi Farmaceutici S.p.A., Informed Consent of Trimbow, Lead Rapporteur: Janet Koenig

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

AREXVY - Respiratory syncytial virus, glycoprotein F, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E -**EMA/H/C/006054/II/0002/G**

GlaxoSmithkline Biologicals S.A., Rapporteur: Patrick Vrijlandt, "Update of section 4.5 of the SmPC in order to update information on the co-administration with inactivated seasonal quadrivalent influenza vaccines: with a high dose unadjuvanted influenza vaccine (FLU HD) and a standard dose adjuvanted influenza vaccine (FLU aQIV) based on final results from studies RSV OA=ADJ-008 and RSV OA=ADJ-017. These are Phase III studies intended to evaluate the immune response, safety and reactogenicity of Arexvy when co-administered with a high dose unadjuvanted influenza vaccine (FLU HD) and a standard dose adjuvanted influenza vaccine (FLU aQIV), respectively."
Opinion adopted on 11.04.2024.
Request for Supplementary Information adopted on 07.03.2024, 09.11.2023.

Positive Opinion adopted by consensus on 11.04.2024.

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

GlaxoSmithkline Biologicals S.A., Rapporteur: Patrick Vrijlandt, "Update of sections 4.8 and 5.1 of the SmPC in order to include data on persistence of protection over at least 2 RSV seasons following administration of a single dose of Arexvy based on final results from study

RSV OA=ADJ-006 (A Phase 3, randomized, placebo-controlled, observer-blind, multi-country study to demonstrate the efficacy of a single dose and annual revaccination doses of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above) and RSV OA=ADJ-004 (A phase 3, randomized, open-label, multi-country study to evaluate the immunogenicity, safety, reactogenicity and persistence of a single dose of the RSVPreF3 OA investigational vaccine and different revaccination schedules in adults aged 60 years and above)."

Request for Supplementary Information adopted on 25.01.2024.

Biktarvy - Bictegravir / Emtricitabine / Tenofovir alafenamide -

EMA/H/C/004449/II/0059

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

CAMZYOS - Mavacamten -

EMA/H/C/005457/II/0006

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Patrick Vrijlandt, "Update of section 4.9 of the SmPC in order to include information on the management of mavacamten overdose with administration of activated charcoal, based on final results from study CV027043. This is a single-center, open-label, randomized, parallel-group study to evaluate the effects of co-administration of activated charcoal with sorbitol on the single-dose PK of mavacamten in healthy subjects. In addition, the MAH took the opportunity to introduce minor updates to the PI and to update the list of local representatives in

the Package Leaflet.”

Request for Supplementary Information adopted on 25.01.2024.

Cetrotide - Cetrorelix -

EMA/H/C/000233/II/0091

Merck Europe B.V., Rapporteur: Martina Weise, “Type II C.I.4 To update section 6.6 of the SmPC to amend the administered dose of cetrorelix from ‘dose of at least 0.23 mg’ to ‘dose of 0.21 mg’ based on the representative dose study conducted to evaluate the administered dose after reconstitution.”

Cresemba - Isavuconazole -

EMA/H/C/002734/II/0045, Orphan

Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Patrick Vrijlandt, “Update of section 4.5 of the SmPC in order to revise the interactions table to improve guidance for health care professionals in relation to the co-administration of cyclophosphamide with isavuconazole based on literature and postmarketing data. In addition, the MAH took the opportunity to correct a mistake in section 4.5 of the SmPC.”

Opinion adopted on 11.04.2024.

Positive Opinion adopted by consensus on 11.04.2024.

Cuprior - Trientine -

EMA/H/C/004005/II/0028

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

Request for supplementary information adopted with a specific timetable.

Drovelis - Drospirenone / Estetrol -

EMA/H/C/005336/II/0021

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 hepatic impairment based on final results from study MIT-Do001-C102; this is a Phase 1, open-label, parallel group, single-dose study to evaluate the pharmacokinetics and safety of estetrol (E4) in

Positive Opinion adopted by consensus on 11.04.2024.

subjects with varying degrees of hepatic function.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 14.12.2023.

**Edarbi - Azilsartan medoxomil -
EMA/H/C/002293/II/0033/G**

Takeda Pharma A/S, Rapporteur: Patrick Vrijlandt, “Grouped application comprising two type II variations as follows:

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

The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI.”

Request for Supplementary Information adopted on 25.01.2024.

**Erleada - Apalutamide -
EMA/H/C/004452/II/0036**

Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez, “- to update the method of administration for Erleada 60 mg film-coated tablets provided in the SmPC section 4.2 (and related section of the PL) to allow patients to take tablets with non-fizzy beverage or soft food, or by a nasogastric feeding tube; hence, aligning the vehicles for administration between the two Erleada strengths (i.e. 60 mg and 240 mg).

The MAH took the opportunity to introduce the following editorial changes:

- Irish country code has been added in the contact information of the local representative;
 - New link for reporting of adverse events in section 4.8 of the SmPC and section 4 of the PL has been provided.”
-

**Glyxambi - Empagliflozin / Linagliptin -
EMA/H/C/003833/II/0057**

Boehringer Ingelheim International GmbH,

Positive Opinion adopted by consensus on 11.04.2024.

Rapporteur: Patrick Vrijlandt, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update the information on paediatric population based on final results from study DINAMO 1218-0091 - 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. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."
Opinion adopted on 11.04.2024.

Kisqali - Ribociclib -

EMA/H/C/004213/II/0049

Novartis Europharm Limited, Rapporteur: Filip Josephson, "Update of sections 4.2 and 4.4 of the SmPC in order to update the ECG monitoring recommendations in patients with advanced or metastatic breast cancer (aBC) treated with ribociclib based on the continuing and comprehensive assessments of QT/QTcF effects in patients with cancer from studies A2301 (MONALEESA-2), E2301 (MONALEESA-7) and F2301 (MONALEESA-3). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes."

Lydisilka - Drospirenone / Estetrol -

EMA/H/C/005382/II/0021

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 hepatic impairment based on final results from study MIT-Do001-C102; this is a Phase 1, open-label, parallel group, single-dose study to evaluate the pharmacokinetics and safety of estetrol (E4) in subjects with varying degrees of hepatic function."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 14.12.2023.

Positive Opinion adopted by consensus on 11.04.2024.

Lysodren - Mitotane -

EMA/H/C/000521/II/0029/G

HRA Pharma Rare Diseases, Rapporteur: Carolina Prieto Fernandez, "A grouped

Request for supplementary information adopted with a specific timetable.

application consisting of two Type II variations: Update of sections 4.4, 4.5, 4.6, 4.8 and 4.9 of the SmPC in order to update the special warnings information and to update the pregnancy information, as well as, to add "Corticosteroid binding globulin increased" and "Thyroxin binding globulin increased" to the list of adverse drug reactions (ADRs) with frequency 'Not Known'; based on clinical practice guidance and post-marketing data.

The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3, and to implement editorial changes to the SmPC."

Request for Supplementary Information adopted on 18.04.2024.

MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine - EMEA/H/C/005084/II/0030

Sanofi Pasteur, Rapporteur: Daniela Philadelphia, "Update of sections 4.5 and 5.1 of the SmPC in order to update immunogenicity and safety information based on final results from study MEQ00071; this is a parallel, multi-center, multinational, randomized, active-controlled phase 3b immunogenicity and safety study of a quadrivalent meningococcal conjugate vaccine versus Nimenrix, and when administered alone or concomitantly with 9vHPV and Tdap-IPV vaccines in healthy adolescents aged 10 to 17 years. In addition, the MAH took the opportunity to introduce minor updates to the PI and to update the list of local representatives in the Package Leaflet."

Request for Supplementary Information adopted on 04.04.2024.

Request for supplementary information adopted with a specific timetable.

Nexviadyme - Avalglucosidase alfa - EMEA/H/C/005501/II/0015

Sanofi B.V., Rapporteur: Christian Gartner, "Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update safety and efficacy information based on final results from study EFC14028 - COMparative Enzyme replacement Trial with neoGAA versus rhGAA (COMET), listed as a category 3 study in the RMP. This is a phase 3 randomized, multicenter, multinational, double-blinded study comparing the efficacy and safety of repeated biweekly infusions of

Positive Opinion adopted by consensus on 04.04.2024.

avalglucosidase alfa (neoGAA, GZ402666) and alglucosidase alfa in treatment of naive patients with late onset Pompe disease. In addition, the MAH took this opportunity to update the list of local representatives in the Package Leaflet.”
Opinion adopted on 04.04.2024.
Request for Supplementary Information adopted on 08.02.2024.

NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0062

Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt, “Submission of the final report from clinical study 2019nCoV-505 listed as a category 3 study in the RMP. This is a Phase 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 Matrix M Adjuvant in People Living with HIV.”
Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

Olumiant - Baricitinib - EMEA/H/C/004085/II/0046

Eli Lilly Nederland B.V., Rapporteur: Peter Mol, “Update of section 5.1 of the SmPC in order to add information on JIA-associated uveitis or chronic anterior antibody positive uveitis based on interim results from study I4VMC-JAHW; this is an open-label, active-controlled, safety, and efficacy study of oral baricitinib in patients from 2 years to less than 18 years old with active juvenile idiopathic arthritis-associated uveitis or chronic anterior antinuclear antibody-positive uveitis.”
Request for Supplementary Information adopted on 04.04.2024, 08.02.2024.

Request for supplementary information adopted with a specific timetable.

Pombiliti - Cipaglucosidase alfa - EMEA/H/C/005703/II/0010

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

**PONVORY - Ponesimod -
EMA/H/C/005163/II/0013**

Janssen-Cilag International N.V., Rapporteur:
Peter Mol, "Update of section 4.4 of the SmPC to
amend an existing warning on PML-IRIS based
on the cumulative review of literature. In
addition, the MAH took the opportunity to
update the list of local representatives in the
Package Leaflet, to introduce editorial changes
to the PI and to bring the PI in line with the
latest QRD template version 10.3."

Request for Supplementary Information adopted
on 11.04.2024, 25.01.2024.

Request for supplementary information adopted
with a specific timetable.

**QUVIVIQ - Daridorexant -
EMA/H/C/005634/II/0013/G**

Idorsia Pharmaceuticals Deutschland GmbH,
Rapporteur: Alexandre Moreau, "Update of
sections 4.4, 4.5 and 5.1 of the SmPC in order
to reflect the conclusions of studies ID-075-121,
ID-078-122 and ID-078-118, respectively. The
Package Leaflet was updated accordingly. Study
ID-078-121 is a randomized, double-blind,
placebo-controlled, 2-way crossover study to
investigate the effects of daridorexant on
nighttime respiratory function and sleep in
subjects with severe obstructive sleep apnea;
Study ID-078-122 is a prospective, open-label,
single-dose Phase 1 study to measure
daridorexant in breast milk of healthy lactating
women; and Study ID-078-118 is a single-
center, randomized, double-blind, single-dose,
3-way crossover study to compare the effects of
daridorexant and placebo on postural stability,
the auditory awakening threshold, and cognitive
function in the middle of the night following
evening administration to healthy adult and
elderly subjects."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted
on 07.03.2024, 01.02.2024.

Positive Opinion adopted by consensus on
11.04.2024.

**Reagila - Cariprazine -
EMA/H/C/002770/II/0034**

Gedeon Richter Plc., Rapporteur: Kristina
Dunder, PRAC Rapporteur: Ana Sofia Diniz
Martins, "Update of sections 4.3, 4.4 and 4.5 of
the SmPC in order to update an existing
contraindication and update drug-drug
interaction information with CYP3A4 inhibitors,
based on final results from study RGH-188-301

Positive Opinion adopted by consensus on
11.04.2024.

(CYPRESS) listed as a category 3 study in the RMP; this is an open-label, single-arm, fixed-sequence study to investigate the effect of erythromycin, a moderate CYP3A4 inhibitor on the pharmacokinetics of cariprazine in male patients with schizophrenia. The Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 08.02.2024, 26.10.2023.

**REKAMBYS - Rilpivirine -
EMA/H/C/005060/II/0020**

Positive Opinion adopted by consensus on 11.04.2024.

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, “Update of section 4.2 of the SmPC in order to update administration instructions to mitigate product leakage related to the correct use of the vial adapter, based on Human Factor studies. The Package Leaflet (Instructions for Use) is updated accordingly.”
Opinion adopted on 11.04.2024.

**Remsima - Infliximab -
EMA/H/C/002576/II/0133/G**

See 9.1

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 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 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 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."

Request for Supplementary Information adopted on 21.03.2024, 09.11.2023.

**Revestive - Teduglutide -
EMA/H/C/002345/II/0064, Orphan**

Takeda Pharmaceuticals International AG
Ireland Branch, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.4 of the SmPC in order to add the recommendation of upper GI endoscopy or other imaging before and during the treatment with teduglutide per clinical discretion as a precaution to 'Gastrointestinal neoplasia including hepatobiliary tract' based on the cumulative review of literature. In addition, the MAH took the opportunity to introduce minor editorial changes and to bring the PI in line with the latest QRD template."

**Reyataz - Atazanavir -
EMA/H/C/000494/II/0139**

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jean-Michel Race, "Update of sections 4.3 and 4.5 of the SmPC in order to reclassify the drug-drug-interaction information to a contraindication for the co-administration with antineoplastic agents (encorafenib and ivosidenib), as well as, for the co-administration with the anticonvulsant agents (carbamazepine, phenobarbital, and phenytoin); based on post-marketing data and literature. The Package Leaflet is updated accordingly."

RINVOQ - Upadacitinib -

Request for supplementary information adopted

EMA/H/C/004760/II/0050

AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to include long term efficacy and safety information (up to week 104 data) from study M19-944 (Study 1); this is a phase 3 randomized, placebo-controlled, double-blind program to evaluate efficacy and safety of upadacitinib in adult subjects with axial spondyloarthritis followed by a remission-withdrawal period."

Request for Supplementary Information adopted on 04.04.2024.

with a specific timetable.

SARCLISA - Isatuximab -**EMA/H/C/004977/II/0025**

Sanofi Winthrop Industrie, Rapporteur: Peter Mol, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to amend an existing warning on second primary malignancies and to update efficacy and safety information based on Overall Survival analysis from study EFC15246 (IKEMA - Randomized, open label, multicenter study assessing the clinical benefit of isatuximab combined with carfilzomib (Kyprolis) and dexamethasone versus carfilzomib with dexamethasone in patients with relapsed and/or refractory multiple myeloma previously treated with 1 to 3 prior lines). In addition, the MAH took this opportunity to introduce editorial changes to the PI."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 25.01.2024.

Positive Opinion adopted by consensus on 11.04.2024.

SARCLISA - Isatuximab -**EMA/H/C/004977/II/0028**

Sanofi Winthrop Industrie, Rapporteur: Peter Mol, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on final results from study ACT15378 (ISAKIDS). This was a Phase 2, single-arm, multicenter, open-label study evaluating the antitumor activity, safety, and PK of isatuximab in combination with standard salvage chemotherapies in paediatric participants with R/R ALL (including both T-ALL and B-ALL) and AML conducted in 3 separate cohorts. Male and female children from 28 days to less than 18 years of age with R/R T-ALL, B-ALL, or AML in first or second relapse were

Positive Opinion adopted by consensus on 04.04.2024.

eligible. Participants under 2 years of age could only be enrolled after the dose reassessment is completed on the first 20 participants who were 2 to less than 18 years of age.
The Package Leaflet is updated accordingly.”
Opinion adopted on 04.04.2024.

**Skilarence - Dimethyl fumarate -
EMA/H/C/002157/II/0034**

Almirall S.A, Rapporteur: Janet Koenig, “Update of section 5.1 of the SmPC in order to update long term efficacy and safety information based on final results from study M-41008-41 (Dimeskin 1); this is a phase IV non-randomised, non-interventional, open label study in adult patients with moderate to severe chronic plaque psoriasis to further assess long-term (12 months) efficacy and safety of Skilarence in routine daily practice in Spain.”
Request for Supplementary Information adopted on 14.12.2023.

**Sunlenca - Lenacapavir -
EMA/H/C/005638/II/0013**

Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, “Update of section 5.3 of the SmPC in order to update non-clinical information based on final results from study TX-200-2046 entitled, "104 Week Subcutaneous Injection Carcinogenicity and Toxicokinetic Study of GS-6207 Administered Every 13 Weeks in Wistar-Han Rats". In addition, the MAH took the opportunity introduce minor editorial changes to the PI.”
Request for Supplementary Information adopted on 11.04.2024, 18.01.2024.

Request for supplementary information adopted with a specific timetable.

**Tecentriq - Atezolizumab -
EMA/H/C/004143/II/0084**

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, “Update of section 4.8 of the SmPC in order to add ‘hypophysitis’ to the list of adverse drug reactions (ADRs) with frequency ‘uncommon’ based on interim results from study WO39391 (IMpassion030). This is a Phase III, randomized, open label study comparing atezolizumab in combination with adjuvant anthracycline/taxane-based chemotherapy versus chemotherapy alone in patients with operable triple-negative breast cancer; the package leaflet is updated accordingly. In addition, the MAH took the opportunity to

Positive Opinion adopted by consensus on 11.04.2024.

implement editorial changes to the SmPC, labelling and package leaflet.”
Opinion adopted on 11.04.2024.

**TEPMETKO - Tepotinib -
EMA/H/C/005524/II/0011**

Merck Europe B.V., Rapporteur: Filip Josephson, “Update of section 4.2 of the SmPC in order to add alternative methods of administration dispersed in water, as oral drinking suspension or via feeding tubes based on the available physicochemical and clinical pharmacology data. The Package Leaflet is updated accordingly.”
Request for Supplementary Information adopted on 22.02.2024.

**Ultomiris - Ravulizumab -
EMA/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 11.01.2024.

**Veltassa - Patiromer -
EMA/H/C/004180/II/0034/G**

Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Jayne Crowe, “Grouped application consisting of three Type II variations (C.I.4):
Update of sections 4.2 and 5.1 of the SmPC in order to update efficacy information based on final results from study PAT-CR-302 (Diamond); this is a Phase 3b international, double-blind, placebo-controlled, randomised withdrawal, parallel-group study of patiromer for the management of hyperkalaemia (HK) in patients receiving renin-angiotensin-aldosterone system inhibitors (RAASi) for the treatment of heart failure (HF). In addition, the MAH took the

opportunity to implement editorial changes to the SmPC.

Update of sections 4.8 and 5.1 of the SmPC in order to update safety information based on a pooled safety database. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.

Update of section 4.8 of the SmPC in order to add "Hypersensitivity" to the list of adverse drug reactions (ADRs) with frequency "not known", based on post-marketing data."

Request for Supplementary Information adopted on 25.01.2024, 14.09.2023.

**Verzenio - Abemaciclib -
EMA/H/C/004302/II/0033**

Eli Lilly Nederland B.V., Rapporteur: Filip Josephson, "Update of section 5.1 of the SmPC in order to include the final OS data based on final results from study MONARCH3 (I3Y-MC-JPBM). This is a randomized, double-blind, placebo-controlled, phase 3 trial of nonsteroidal aromatase inhibitors (anastrozole or letrozole) plus LY2835219, a CDK4/6 Inhibitor, or placebo in postmenopausal women with hormone receptor-positive, HER2-Negative locoregionally recurrent or metastatic breast cancer with no prior systemic therapy in this disease setting."

**Wegovy - Semaglutide -
EMA/H/C/005422/II/0019**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Update of sections 4.1, 4.4, 4.8 and 5.1 in order to include information in patients with obesity-related HFpEF, with and without type 2 diabetes based on the final reports from studies EX9536-4665 STEP-HFpEF, EX9536-4773 STEP HFpEF-DM and EX9536-4388 SELECT. In addition, the MAH took this opportunity to introduce editorial changes to the PI."
Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

**Xevudy - Sotrovimab -
EMA/H/C/005676/II/0027**

Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC with data on the in vitro activity of sotrovimab in a pseudotyped virus assay against the Omicron HV.1 and BA.2.86 spike variants (PC-23-0165)

Positive Opinion adopted by consensus on 18.04.2024.

and the Omicron HK.3 spike variant (PC-23-0179) as well as data on the in vitro activity of sotrovimab in an authentic virus assay against the SARS-COV-2 EG.5.1 variant (PC-23-0176) based on the relevant pharmacology study reports.”

Opinion adopted on 18.04.2024.

**XGEVA - Denosumab -
EMA/H/C/002173/II/0084**

Amgen Europe B.V., Rapporteur: Kristina Dunder, “Submission of the final report from study 20140114, listed as a category 3 study in the RMP. This is a long-term safety follow up study, that was conducted to continue to follow subjects with GCTB who were treated in Study 20062004 for an additional 5 or more years of long-term safety follow up and to further evaluate denosumab treatment in subjects with GCTB.”

Request for Supplementary Information adopted on 04.04.2024.

Request for supplementary information adopted with a specific timetable.

WS2612

Finlee-EMA/H/C/005885/WS2612/0003

Mekinist-

EMA/H/C/002643/WS2612/0062

Spexotras-

EMA/H/C/005886/WS2612/0001

Tafinlar-

EMA/H/C/002604/WS2612/0065

Novartis Europharm Limited, Lead Rapporteur: Peter Mol, “Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on Tumour lysis syndrome and add Tumour lysis syndrome to the list of adverse drug reactions (ADRs) with frequency Not known based on the review of MAH global database, clinical trials database and literature. 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 and to introduce editorial changes.”

WS2650

Imfinzi-EMA/H/C/004771/WS2650/0065

IMJUDO-

EMA/H/C/006016/WS2650/0006

AstraZeneca AB, Lead Rapporteur: Aaron Sosa Mejia, “Update of sections 4.2 and 4.4 of the SmPC in order to simplify current dosing

recommendations.”

B.5.3. CHMP-PRAC assessed procedures

Beyfortus - Nirsevimab -

EMA/H/C/005304/II/0018/G

Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Kimmo Jaakkola, “Grouped application comprising two type II variations as follows:

C.I.13: Submission of the final report from study D5290C00004 (MELODY) listed as a category 3 study in the RMP. This is a phase III study, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of MEDI8897, a monoclonal antibody with an extended half-life against respiratory syncytial virus, in healthy late preterm and term infants.

C.I.13: Submission of the final report from study D5290C00005 (MEDLEY) listed as a category 3 study in the RMP. This is a phase II/III study, randomized, double-blind, placebo-controlled study to evaluate the safety of Beyfortus (nirsevimab) in high-risk children.

The RMP version 2.3 has also been submitted.”

Request for Supplementary Information adopted on 07.03.2024, 08.02.2024.

BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - Positive Opinion adopted by consensus on 11.04.2024.

EMA/H/C/006058/II/0010

Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Zane Neikena, “Submission of the final report from study HIPRA-HH-5, “A phase III, open label, single arm, multi-center, trial to assess the safety and immunogenicity of a booster vaccination with a recombinant protein RBD fusion heterodimer candidate (PHH-1V) against SARS-COV-2, in adults vaccinated against COVID-19”. The RMP version 1.4 has also been submitted.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 11.01.2024.

Ilumetri - Tildrakizumab -

EMA/H/C/004514/II/0055

Almirall S.A, Rapporteur: Jan Mueller-Berghaus,

Request for supplementary information adopted with a specific timetable.

PRAC Rapporteur: Adam Przybylkowski
Request for Supplementary Information adopted
on 11.04.2024.

Inrebic - Fedratinib -

EMA/H/C/005026/II/0020, Orphan

Bristol-Myers Squibb Pharma EEIG, Rapporteur:
Peter Mol, PRAC Rapporteur: Sonja Hrabcik,
"Update of sections 4.2, 4.4 and 4.8 of the
SmPC in order to update information regarding
thiamine levels based on a review of the
primary results of the study FEDR-MF-002. This
is a Phase 3, multicenter, open-label,
randomized study to evaluate the efficacy and
safety of fedratinib compared with BAT in
subjects with DIPSS intermediate-2 or high-risk
primary MF, post-PV MF, or post-ET MF and
previously treated with ruxolitinib. The RMP
version 3 has also been submitted."

**JCOVDEN - COVID-19 Vaccine Janssen
(Ad26.COV2.S) -**

EMA/H/C/005737/II/0076

Janssen-Cilag International N.V., Rapporteur:
Christophe Focke, PRAC Rapporteur: Ulla
Wändel Liminga, "Update of sections 4.5, 4.8
and 5.1 of the SmPC in order to update
information regarding the co-administration of
JCOVDEN with influenza vaccine based on the
final report from study VAC31518COV3005
listed as a category 3 study in the RMP; this is a
randomized, double-blind, Phase 3 study to
evaluate safety, reactogenicity, and
immunogenicity of co-administration of
Ad26.COV2.S and influenza vaccines in healthy
adults 18 years of age and older. The Package
Leaflet is updated accordingly. Version 8.1 of
the RMP has also been submitted."

Request for supplementary information adopted
with a specific timetable.

Request for Supplementary Information adopted
on 11.04.2024.

Juluca - Dolutegravir / Rilpivirine -

EMA/H/C/004427/II/0057/G

ViiV Healthcare B.V., Rapporteur: Janet Koenig,
PRAC Rapporteur: Nathalie Gault, "Grouped
application comprising two type II variations as
follows:

C.I.13: Submission of the final report from
study 201636 (SWORD 1) listed as a category 3
study in the RMP. This is a phase III,
randomized, multicenter, parallel-group, non-
inferiority study evaluating the efficacy, safety,

and tolerability of switching to dolutegravir plus rilpivirine from current INI-, NNRTI-, or PI-based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed.

C.I.13: Submission of the final report from study 201637 (SWORD 2) listed as a category 3 study in the RMP. This is a phase III, randomized, multicenter, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of switching to dolutegravir plus rilpivirine from current INI-, NNRTI-, or PI-based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed. The RMP version 7.0 has also been submitted.” Request for Supplementary Information adopted on 07.03.2024.

Jyseleca - Filgotinib -

EMA/H/C/005113/II/0031/G

Galapagos N.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas, “Grouped application comprising two variations as follows:

Type II (C.I.4): Update of sections 4.8 and 5.1 of the SmPC to update the safety mean duration exposure and efficacy information based on final results (up to Week 432) from study GLPG0634-CL-205 (DARWIN 3) listed as a category 3 study in the RMP (MEA/009); this is a phase II, open-label, long-term follow-up safety and efficacy study to evaluate the long-term safety and tolerability of filgotinib for the treatment of Rheumatoid Arthritis in patients who received treatment in their parent studies. The RMP version 6.1 has also been submitted.

Type IA (A.6): To change the ATC code for Janus-associated kinase (JAK) inhibitor from L04AA45 filgotinib to L04AF04 filgotinib.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 07.03.2024.

Positive Opinion adopted by consensus on 11.04.2024.

Leqvio - Inclisiran -

EMA/H/C/005333/II/0021

Novartis Europharm Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Kimmo Jaakkola, “Submission of the final report from study ORION-8 - A long-term extension trial of the Phase III lipid-lowering trials to assess the effect of long-term dosing of inclisiran given as subcutaneous injections in subjects with high

Request for supplementary information adopted with a specific timetable.

cardiovascular risk and elevated LDL-C, listed as a category 3 study in the RMP. The RMP version 3.0 has also been submitted.”

Request for Supplementary Information adopted on 11.04.2024.

LUMYKRAS - Sotorasib -

EMA/H/C/005522/II/0010/G

Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, “Update of sections 4.2, 4.4, 4.8, 5.2 and 5.3 of the SmPC in order to change in the recommended dose and to update safety and efficacy information based on results from study 20190009 (CodeBreak 200) listed as a specific obligation in the Annex II, in order to fulfil SOB/001; and results from study 20170543 (CodeBreak 100) Phase 2 Part B. Study 20190009 is a Phase 3 Multicenter, Randomized, Open Label, Active-controlled, Study of AMG 510 Versus Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC Subjects With Mutated KRAS p.G12C; while study 20170543 is a Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumors With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the SmPC.”

Request for Supplementary Information adopted on 14.12.2023, 25.05.2023.

Lupkynis - Voclosporin -

EMA/H/C/005256/II/0013

Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Adam Przybylkowski, “Update of section 4.6 of the SmPC in order to updated breast-feeding information based on final results from study AUR-VCS-2021-04. This study is a single-center, open-label, Phase 1, lactation study to investigate the amount of voclosporin excreted in breast milk following a single oral dose of 23.7 mg voclosporin in healthy, lactating,

Request for supplementary information adopted with a specific timetable.

female volunteers. The Package Leaflet is updated accordingly. The updated RMP version 5.0 has also been submitted.”
Request for Supplementary Information adopted on 11.04.2024.

MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine - EMEA/H/C/005084/II/0027

Positive Opinion adopted by consensus on 11.04.2024.

Sanofi Pasteur, Rapporteur: Daniela Philadelphly, PRAC Rapporteur: Jean-Michel Dogné, “Submission of the final report from study MET52, listed as a category 3 study in the RMP. This was a Phase III, open-label, randomised, parallel-group, active-controlled, multi-centre study to evaluate the immunogenicity and describe the safety of MenACYW conjugate vaccine when administered concomitantly with a Meningococcal Group B vaccine and other routine paediatric vaccines as part of the National Immunisation Schedule in healthy infants and toddlers in the United Kingdom. The RMP version 2.0 has also been submitted.”
Opinion adopted on 11.04.2024.
Request for Supplementary Information adopted on 11.01.2024.

Phesgo - Pertuzumab / Trastuzumab - EMEA/H/C/005386/II/0023/G

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Gabriele Maurer, “A grouped application comprised of 2 Type II variations and 1 Type IA variation, as follows:
Type II variation (C.I.4): Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information, based on the final report from study WO40324 (FeDeriCa) listed as a category 3 study in the RMP. This is a phase 3, randomized, multicenter, open-label, two-arm study to evaluate the pharmacokinetics, efficacy, and safety of subcutaneous administration of the fixed-dose combination of pertuzumab and trastuzumab in combination with chemotherapy in patients with HER2-positive early breast cancer.
Type II variation (C.I.4): Update of section 4.8 of the SmPC in order to only present specific Phesgo safety data by updating the summary of safety profile and the tabulated list of adverse reactions to reflect this information. The

Package Leaflet is updated accordingly.
Type IA variation (A.6): To change the ATC code of pertuzumab and trastuzumab from L01XY02 to L01FY01.
The RMP version 3.0 has also been submitted.
In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information and to update the list of local representatives in the Package Leaflet.”

Prevenar 20 - Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) -

EMA/H/C/005451/II/0023

Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphia, PRAC Rapporteur: Jean-Michel Dogné, “Submission of the final current B7471015 study protocol, the Statistical Analysis Plan (SAP) and the final country feasibility assessment report for Apexnar. The RMP (version 5.0) is updated accordingly.”
Opinion adopted on 11.04.2024.

Positive Opinion adopted by consensus on 11.04.2024.

Ronapreve - Casirivimab / Imdevimab -
EMA/H/C/005814/II/0015

Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Ulla Wändel Liminga, “Update of section 4.6 of the SmPC in order to update information on pregnancy based on a comprehensive analysis of the results from the drug pregnancy registry cohort (PDC study GV44373), listed as a category 3 PASS in the RMP, as well as data from clinical studies and post-marketing surveillance. The RMP version 3.0 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.”
Request for Supplementary Information adopted on 07.03.2024.

See 9.1

Spikevax - COVID-19 mRNA vaccine -
EMA/H/C/005791/II/0120

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen, “Submission of the final report from study mRNA-1273-P301; this is a Phase 3, randomised, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of Spikevax in adults aged 18

Positive Opinion adopted by consensus on 11.04.2024.

years and older, listed as a category 3 study in the RMP. The RMP version 8.2 has also been approved.”

Opinion adopted on 11.04.2024.

**Spravato - Esketamine -
EMA/H/C/004535/II/0020**

Janssen-Cilag International N.V., Rapporteur: Martina Weise, PRAC Rapporteur: Kirsti Villikka, “Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on severe hepatic impairment and to include the long-term safety information based on final results from study 54135419TRD3008 (An Open-label Long-term Extension Safety Study of Esketamine Nasal Spray in Treatment-resistant Depression), listed as a category 3 study in the RMP; This was a multicenter, open-label, long-term extension safety study to evaluate safety, tolerability, and efficacy of esketamine in participants with TRD. The RMP version 5.1 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 11.01.2024.

Positive Opinion adopted by consensus on 11.04.2024.

**TAKHZYRO - Lanadelumab -
EMA/H/C/004806/II/0040, Orphan**

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder, PRAC Rapporteur: Kirsti Villikka, “Update of section 4.4 of the SmPC in order to remove the information related to non-availability of clinical data on the use of lanadelumab in HAE patients with normal C1-INH activity, based on results from studies CASPIAN (SHP643-303) and CASPIAN OLE (TAK-743-3001). CASPIAN (SHP643-303) is a Phase 3, multicenter, randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of lanadelumab for prevention against acute attacks of nonhistaminergic angioedema with Normal C1 Inhibitor (C1-INH); and CASPIAN OLE (TAK-743-3001) is an open-label study to evaluate the long term safety and efficacy of lanadelumab for prevention against acute attacks of Nonhistaminergic Angioedema with Normal C1-Inhibitor (C1-INH).

The RMP version 4.0 has also been submitted.

Request for supplementary information adopted with a specific timetable.

In addition, the MAH took the opportunity to implement editorial changes to the SmPC and the Package Leaflet.”

Request for Supplementary Information adopted on 11.04.2024.

**Tecvayli - Teclistamab -
EMA/H/C/005865/II/0009**

Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Jana Lukacisinova, “Update of section 4.4 of the SmPC in order to update the warning on Progressive Multifocal Leukoencephalopathy (PML) based on a cumulative safety review. The Package Leaflet is updated accordingly. The RMP version 4.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor updates to the PI and to update the list of local representatives in the Package Leaflet.”

Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

**VPRIV - Velaglucerase alfa -
EMA/H/C/001249/II/0063**

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, “Update of section 4.2 of the SmPC in order to add information to support at-home self-administration of VPRIV by a trained patient and/or a caregiver based on post-marketing data and literature. The Package Leaflet and Annex IID are updated accordingly. The updated RMP version 13.0 has also been submitted.”

Request for Supplementary Information adopted on 14.12.2023.

**Vyvgart - Efgartigimod alfa -
EMA/H/C/005849/II/0014, Orphan**

Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald, “Update of section 4.4 of the SmPC in order to amend an existing warning on infusion reactions and hypersensitivity reactions, and update of section 5.1 of the SmPC to update the mechanism of action of efgartigimod in relation to albumin; based on final results from study ARGX-113-1705 listed a category 3 study in the RMP. This is a long-term, single-arm, open-label, multicenter, phase 3 follow-on study of ARGX-113-1704 to evaluate the safety and tolerability

Positive Opinion adopted by consensus on 11.04.2024.

of ARGX-113 in patients with myasthenia gravis having generalized muscle weakness. The Applicant took advantage to update the PI with relevant information about sodium content as requested during the post-linguistic review of procedure II-06, to update the PI on some information about additional suppliers in the important instructions for use in line with the input received from one Member State reporting the unavailability of some suppliers in the country and to update the list of local representatives of the Marketing Authorisation Holder. The RMP has been updated to RMP version 2.4.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 07.03.2024, 11.01.2024.

**ZTALMY - Ganaxolone -
EMA/H/C/005825/II/0004/G, Orphan**

Marinus Pharmaceuticals Emerald Limited,
Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, “A grouped application comprised of 8 Type II variations as follows: The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to introduce updates to the PI that reflect clarifications and typographical corrections, including to sections 4.2 and 4.4 of the SmPC.”
Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

**ZTALMY - Ganaxolone -
EMA/H/C/005825/II/0006, Orphan**

Marinus Pharmaceuticals Emerald Limited,
Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, “Update of section 5.1 of the SmPC in order to update open-label data based on the final report from study 1042-CDD-3001 OLE listed as a category 3 study in the RMP. This was the open-label portion of the pivotal study 1042-CDD-3001; a double-blind, randomized, placebo-controlled trial of adjunctive ganaxolone treatment in children and young adults with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) followed by long-term open-label treatment. The RMP version 1.4 has also been submitted.”
Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

WS2619/G

Request for supplementary information adopted

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

with a specific timetable.

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

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

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

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

The RMP version 11.1 has also been submitted."

Request for Supplementary Information adopted on 11.04.2024.

WS2670
Finlee-EMA/H/C/005885/WS2670/0004
Spexotras-

EMA/H/C/005886/WS2670/0003
Novartis Europharm Limited, Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: Ulla Wändel Liminga, "To include into the product information for dabrafenib and trametinib to include the signal "peripheral neuropathy" in line with the PRAC recommended wording from EMA/PRAC/289010/2023, EPITT No. 19947."

B.5.4. PRAC assessed procedures

PRAC Led
AJOVY - Fremanezumab -
EMA/H/C/004833/II/0047

Positive Opinion adopted by consensus on 11.04.2024.

TEVA GmbH, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of the final report from the PASS study TV48125-MH-50039 listed as a category 3 study in the RMP. This is a long-term, prospective, observational study to evaluate the safety, including cardiovascular safety, of fremanezumab in patients with migraine in routine clinical practice. The RMP version 6.0 has also been submitted."
Opinion adopted on 11.04.2024

PRAC Led
Bavencio - Avelumab -

Request for supplementary information adopted with a specific timetable.

EMA/H/C/004338/II/0044/G

Merck Europe B.V., PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Grouped application comprising of four variations as follows:

Type II (C.I.11.b): To update Annex II and the RMP version 7.1 for Bavencio to change the classification of "safety in patients with autoimmune disease" to the important identified risk "other immune mediated adverse reactions" along with removal of the patient information brochure from the educational material, following the PRAC assessment report PSUSA/00010635/202303.

Type IA (A.6): To change ATC level name from Other antineoplastic agents, monoclonal antibodies to Antineoplastic agents, monoclonal antibodies, PD-1/PDL-1 (Programmed cell death protein 1/death ligand 1) inhibitors in Section 5.1 of the Summary of Product Characteristics (SmPC). The ATC code remains unchanged.

Type IA (C.I.z): To update the statement for "infusion-related reactions" in section 4.4 of the SmPC and to align terminology with the RMP for the term "immune-related" versus "immune-mediated".

Type IAIN (C.I.12): To remove from the Product Information the black symbol and explanatory statements for medicinal products subject to additional monitoring.

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

Request for Supplementary Information adopted on 11.04.2024"

PRAC Led

Benlysta - Belimumab -**EMA/H/C/002015/II/0116**

GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report for the Belimumab Pregnancy registry (BEL114256) listed as a category 3 study in the RMP. This is a non-interventional study to evaluate pregnancy and infant outcomes for pregnancies in women with systemic lupus erythematosus (SLE) exposed to commercially supplied belimumab within the 4 months preconception and/or during pregnancy. In

Positive Opinion adopted by consensus on 11.04.2024.

addition, the BPR protocol planned to collect pregnancy and infant outcomes for pregnancies in women with SLE and SABLE (Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus) protocol who were not exposed to belimumab and enrolled in BPR. As a result, section 4.6 of the SmPC was updated. In addition, RMP version 45.0 has been submitted.”

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 26.10.2023.

PRAC Led

COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) -

EMA/H/C/005735/II/0206/G

BioNTech Manufacturing GmbH, PRAC

Rapporteur: Liana Martirosyan, PRAC-CHMP

liaison: Patrick Vrijlandt, “A grouped application comprised of 3 Type II variations as follows:

C.I.13: Submission of the final report from study C4591012 listed as a category 3 study in the RMP. This is a non-interventional Post-Emergency Use Authorization active safety surveillance study among individuals in the Veteran’s Affairs health system receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) vaccine. The RMP version 11.2 has also been submitted.

C.I.11.b: Submission of an updated RMP version 11.2 in order to implement changes to an agreed post-authorisation study (C4591052 protocol amendments 1 & 2) in the RMP, where there is an impact on the description of the study.

C.I.11.b: Submission of an updated RMP version 11.2 in order to implement changes to an agreed post-authorisation study (C4591021 protocol amendment 4) in the RMP, where there is an impact on the description of the study.

In addition, the MAH took the opportunity to update the milestones for the two studies C4591022 and C4591051 in the RMP.”

Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led

DaTSCAN - Ioflupane (123I) -

EMA/H/C/000266/II/0067

GE Healthcare B.V., Rapporteur: Alexandre

Request for supplementary information adopted with a specific timetable.

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."
Request for Supplementary Information adopted on 11.04.2024.

PRAC Led

Enbrel - Etanercept -

EMA/H/C/000262/II/0254

Pfizer Europe MA EEIG, Rapporteur: Antonio Gómez Outes, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gómez Outes, "Update of section 4.8 of the SmPC in order to update the frequency of Adverse Drug Reaction (ADR) 'Glomerulonephritis' from 'Not Known' to 'Rare' following PSUSA/00010795/202302 procedure, based on available evidence from clinical trials, literature, and post-marketing data. The Package Leaflet is updated accordingly. Minor editorial changes have also been introduced."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 07.03.2024.

Positive Opinion adopted by consensus on 11.04.2024.

PRAC Led

Flixabi - Infliximab -

EMA/H/C/004020/II/0084/G

Samsung Bioepis NL B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "A grouped application comprised of two Type II variations as follows:
C.I.13: Submission of the final report from study CEDUR listed as a category 3 study in the RMP. This is a nationwide German IBD registry to describe the long-term effectiveness of treatment with IBD therapies such as drug survival, effectiveness, side effects of treatment combination, and disease activity achieved.
C.I.13: Submission of the final report from study CREDIT listed as a category 3 study in the RMP. This is a Czech Register of IBD Patients on Biological Therapy to monitor effectiveness of

Positive Opinion adopted by consensus on 11.04.2024.

total population of IBD patients on biological medication in the Czech Republic and regular analytical evaluation of the effectiveness. The RMP version 13.0 has also been submitted.”
Opinion adopted on 11.04.2024.

PRAC Led

**Humira - Adalimumab -
EMA/H/C/000481/II/0218**

AbbVie Deutschland GmbH & Co. KG, PRAC
Rapporteur: Mari Thorn, PRAC-CHMP liaison:
Kristina Dunder, “Submission of the final report for study P10-023 listed as a category 3 study in the RMP. This is a 10-year, post marketing, observational registry to assess long term safety of Humira (adalimumab) in adult patients with chronic plaque psoriasis (Ps).”
Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led

**MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine -
EMA/H/C/005084/II/0031**

Sanofi Pasteur, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, “Update of section 4.8 of the SmPC in order to add ‘Hypersensitivity including anaphylaxis’ to the list of adverse drug reactions (ADRs) with frequency not known, based on a cumulative review of cases of hypersensitivity/allergic reaction (including anaphylaxis) following the request by PRAC in the Assessment Report for PSUSA/00010044/202304. The Package Leaflet is updated accordingly.”
Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led

**Mysimba - Naltrexone hydrochloride /
Bupropion hydrochloride -
EMA/H/C/003687/II/0066**

Orexigen Therapeutics Ireland Limited, PRAC
Rapporteur: Martin Huber, PRAC-CHMP liaison:
Janet Koenig, “Submission of final report from study NB-453 study, listed as a category 3 study in the RMP. This is a noninterventional qualitative research using online focus groups to assess understanding, attitude and behaviour for usage of the Mysimba Physician Prescribing Checklist (PPC) among physicians in the

Request for supplementary information adopted with a specific timetable.

European Union (EU), following a previous cross-sectional survey that aimed at evaluating the effectiveness of the same PPC (Study NB-452). The RMP version 12.10 has also been submitted.”

Request for Supplementary Information adopted on 11.04.2024, 11.01.2024.

PRAC Led

NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0060

Novavax CZ, a.s., PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, “Submission of an updated RMP version 4.3 after approval of adapted COVID-19 vaccine by new strain, Omicron XBB.1.5.” Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 07.03.2024.

Positive Opinion adopted by consensus on 11.04.2024.

PRAC Led

Prolia - Denosumab - EMEA/H/C/001120/II/0100

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

Request for Supplementary Information adopted on 11.04.2024, 11.01.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led

RAYVOW - Lasmiditan - EMEA/H/C/005332/II/0007

Eli Lilly Nederland B.V., PRAC Rapporteur: Anna Mareková, PRAC-CHMP liaison: Frantisek Drafi, “Submission of the final report from study H8H-MC-B005, listed as a category 3 study in the RMP (MEA/003). This is a Real-World Observational Study to Assess Drug Utilisation Patterns in the US Among Migraine Patients Treated with Lasmiditan. The RMP version 2.1 is submitted alongside the final study report.”

Request for Supplementary Information adopted on 11.04.2024.

Request for supplementary information adopted with a specific timetable.

PRAC Led Positive Opinion adopted by consensus on 11.04.2024.

SARCLISA - Isatuximab - EMEA/H/C/004977/II/0027

Sanofi Winthrop Industrie, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Carolina Prieto Fernandez, "Update of section 4.8 of the SmPC in order to add 'Thrombocytopenia' and 'Anaemia' to the list of adverse drug reactions (ADRs) and to amend the frequency of all remaining ADRs with their appropriate frequencies, following PRAC request in the outcome of the PSUSA procedure PSUSA/00010851/202303."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 07.03.2024.

PRAC Led Positive Opinion adopted by consensus on 11.04.2024.

SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0049, Orphan

Clinuvel Europe Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "To remove study CUV-RCR-001 (Scenesse (Afamelanotide 16mg) Retrospective Chart Review) listed as an obligation in the Annex II of the Product Information. This is a retrospective study comparing long term safety data and outcome endpoints in patients receiving and not receiving Scenesse, or having discontinued Scenesse use. The Annex II and the RMP (version 9.11) are updated accordingly."

Opinion adopted on 11.04.2024.

Request for Supplementary Information adopted on 08.02.2024.

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

Sprycel - Dasatinib - EMEA/H/C/000709/II/0090

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Aaron Sosa Mejia, "Submission of an updated RMP version 18.0 in order to reflect the proposed revised commitments to assess the growth and development disorders and bone mineral metabolism disorders in paediatric subjects."

Request for Supplementary Information adopted on 11.04.2024, 30.11.2023.

PRAC Led Request for supplementary information adopted

**VEYVONDI - Vonicog alfa -
EMA/H/C/004454/II/0033**

Baxalta Innovations GmbH, PRAC Rapporteur:
Mari Thorn, PRAC-CHMP liaison: Kristina
Dunder, "Submission of the final report from
study TAK-577-4005 listed as a category 3
PASS in the RMP. This is a non-interventional
retrospective cohort study that evaluated the
safety of VEYVONDI in real-world clinical
practice. The RMP version 5.0 has also been
submitted."

Request for Supplementary Information adopted
on 11.04.2024.

with a specific timetable.

PRAC Led

**Vyndaqel - Tafamidis -
EMA/H/C/002294/II/0091/G, Orphan**

Pfizer Europe MA EEIG, PRAC Rapporteur:
Tiphaine Vaillant, PRAC-CHMP liaison: Jean-
Michel Race, "A grouped application comprised
of two Type II Variations, as follows:
C.I.4: Update of the Annex II based on final
results from study B3461001 (THAOS) listed as
a category 3 study in the RMP. This is a global,
multi-center, longitudinal, observational survey
of patients with documented transthyretin gene
mutations or wild-type transthyretin
amyloidosis.

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

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

Request for Supplementary Information adopted
on 11.04.2024.

Request for supplementary information adopted
with a specific timetable.

PRAC Led

WS2519/G

Advagraf-

EMA/H/C/000712/WS2519/0071/G

Modigraf-

EMA/H/C/000954/WS2519/0046/G

Astellas Pharma Europe B.V., Lead PRAC
Rapporteur: Eamon O Murchu, PRAC-CHMP
liaison: Jayne Crowe, "A grouped application
consisting of:

Type II (C.I.13): Submission of the final report

Request for supplementary information adopted
with a specific timetable.

from study F506-PV-0001 listed as a category 3 study in the RMP for Advagraf and Modigraf.

This is a non-interventional post-authorization safety study (NI-PASS) of outcomes associated with the use of tacrolimus around conception, or during pregnancy or lactation using data from Transplant Pregnancy Registry International (TPRI). The RMP version 5.0 has also been submitted.

Type IB (C.I.11.z): To include the feasibility assessment of using alternative secondary-use data sources to replicate the Transplant Pregnancy Registry International (TPRI) study as a category 3 additional pharmacovigilance activity in the RMP, including the milestones for the progress report and the final report of the feasibility assessment, related to EMEA/H/C/000712/MEA/032 and EMEA/H/C/000954/MEA/024.”

Request for Supplementary Information adopted on 11.04.2024, 26.10.2023.

B.5.5. CHMP-CAT assessed procedures

CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0023, Orphan, ATMP

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

Request for Supplementary Information adopted on 19.01.2024, 06.10.2023.

ROCTAVIAN - Valoctocogene roxaparvovec - EMEA/H/C/005830/II/0010, Orphan, ATMP

BioMarin International Limited, Rapporteur: Violaine Closson Carella, CHMP Coordinator: Jean-Michel Race, , “Submission of the final report from study BMN270-302 listed as a category 3 study in the RMP. This is a phase 3 open-label, single-arm study to evaluate the efficacy and safety of BMN 270, an adeno-associated virus vector-mediated gene transfer of human factor VIII at a dose of 4E13 vg/kg in hemophilia A patients with residual FVIII levels ≤ 1 IU/dL receiving prophylactic FVIII infusions.”

WS2607

Tecartus-

EMEA/H/C/005102/WS2607/0039

Yescarta-**EMA/H/C/004480/WS2607/0067**Kite Pharma EU B.V., Lead Rapporteur: Jan
Mueller-BerghausRequest for Supplementary Information adopted
on 19.01.2024.

WS2646**Tecartus-****EMA/H/C/005102/WS2646/0042****Yescarta-****EMA/H/C/004480/WS2646/0073**Kite Pharma EU B.V., Lead Rapporteur: Jan
Mueller-Berghaus

Opinion adopted on 04.04.2024.

Positive Opinion adopted by consensus on
04.04.2024.

B.5.6. CHMP-PRAC-CAT assessed procedures

WS2632**Tecartus-****EMA/H/C/005102/WS2632/0041****Yescarta-****EMA/H/C/004480/WS2632/0072**Kite Pharma EU B.V., Lead Rapporteur: Jan
Mueller-Berghaus, "Update of sections 4.2 and
5.1 of the SmPC in order to update the safety
monitoring timelines based on data from clinical
studies, postmarketing studies, and literature.
The Package Leaflet is updated accordingly. In
addition, the MAH took the opportunity to
implement editorial changes to sections 2.2, 6.3
and 6.6 and to update sections 4.4 and 4.5 of
the SmPC to align the language across both
products."

B.5.7. PRAC assessed ATMP procedures

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

WS2618**Dengue Tetravalent Vaccine (Live,
Attenuated) Takeda-****EMA/H/W/005362/WS2618/0013****Qdenga-****EMA/H/C/005155/WS2618/0014**Takeda GmbH, Lead Rapporteur: Sol Ruiz
Opinion adopted on 18.04.2024.Request for Supplementary Information adopted
on 15.02.2024.Positive Opinion adopted by consensus on
18.04.2024.

<p>WS2629/G Eviplera- EMA/H/C/002312/WS2629/0115/G Stribild- EMA/H/C/002574/WS2629/0122/G Truvada- EMA/H/C/000594/WS2629/0180/G Viread- EMA/H/C/000419/WS2629/0211/G Gilead Sciences Ireland UC, Lead Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 08.02.2024.</p>	<p>Positive Opinion adopted by consensus on 04.04.2024.</p>
<p>WS2633/G Hexacima- Hexyon- Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller- Berghaus Opinion adopted on 18.04.2024.</p>	<p>Positive Opinion adopted by consensus on 18.04.2024.</p>
<p>WS2639 Glyxambi- EMA/H/C/003833/WS2639/0059 Jentadueto- EMA/H/C/002279/WS2639/0072 Trajenta- EMA/H/C/002110/WS2639/0054 Boehringer Ingelheim International GmbH, Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 18.04.2024.</p>	<p>Positive Opinion adopted by consensus on 18.04.2024.</p>
<p>WS2640 Infanrix hexa- EMA/H/C/000296/WS2640/0343 GlaxoSmithKline Biologicals SA, Lead Rapporteur: Christophe Focke</p>	<p>Positive Opinion adopted by consensus on 04.04.2024.</p>
<p>WS2645/G Avamys- EMA/H/C/000770/WS2645/0052/G Elebrato Ellipta- EMA/H/C/004781/WS2645/0039/G Relvar Ellipta- EMA/H/C/002673/WS2645/0066/G Revinty Ellipta- EMA/H/C/002745/WS2645/0063/G Trelegy Ellipta- EMA/H/C/004363/WS2645/0036/G GlaxoSmithKline Trading Services Limited, Lead Rapporteur: Finbarr Leacy</p>	<p>Request for supplementary information adopted with a specific timetable.</p>

Request for Supplementary Information adopted on 11.04.2024.

WS2648/G
Mircera-
EMA/H/C/000739/WS2648/0098/G

Positive Opinion adopted by consensus on 04.04.2024.

NeoRecormon-
EMA/H/C/000116/WS2648/0123/G
Roche Registration GmbH, Lead Rapporteur:
Martina Weise
Opinion adopted on 04.04.2024.

WS2654
Aerius-EMA/H/C/000313/WS2654/0106
Azomyr-
EMA/H/C/000310/WS2654/0110
Neoclarityn-
EMA/H/C/000314/WS2654/0104

Request for supplementary information adopted with a specific timetable.

Organon N.V., Duplicate, Duplicate of Alex (SRD), Azomyr, Opulis (SRD), Lead Rapporteur: Christophe Focke, "To update section 4.4 of the SmPC and section 2 of the package leaflet to correct the content of benzyl alcohol from 0.75 mg to 0.375 mg and the content of propylene glycol from 100.75 mg to 100.19 mg to comply with the Annex to the European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use".

In addition, the MAH has taken the opportunity to update section 4.8 of the SmPC and section 4 of the package leaflet to correct the link to QRD Appendix V for the national reporting system. Furthermore, the MAH has taken the opportunity to update the package leaflet with details of the local representative for Austria. Lastly, the MAH has taken the opportunity to introduce minor editorial corrections to the PI in the following language: CS."

Request for Supplementary Information adopted on 04.04.2024.

WS2657
HyQvia-EMA/H/C/002491/WS2657/0097
Kiovig-EMA/H/C/000628/WS2657/0127

Request for supplementary information adopted with a specific timetable.

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

WS2660/G
Entresto-

Positive Opinion adopted by consensus on 04.04.2024.

EMA/H/C/004062/WS2660/0059/G

Neparvis-

EMA/H/C/004343/WS2660/0057/G

Novartis Europharm Limited, Lead Rapporteur:

Patrick Vrijlandt

Opinion adopted on 04.04.2024.

WS2661

Mirapexin-

EMA/H/C/000134/WS2661/0108

Sifrol-EMA/H/C/000133/WS2661/0099

Boehringer Ingelheim International GmbH, Lead

Rapporteur: Thalia Marie Estrup Blicher

Request for Supplementary Information adopted

on 29.02.2024.

WS2662/G

Edistride-

EMA/H/C/004161/WS2662/0066/G

Forxiga-

EMA/H/C/002322/WS2662/0087/G

AstraZeneca AB, Lead Rapporteur: Kristina

Dunder

WS2674

Nuwiq-EMA/H/C/002813/WS2674/0060

Vihuma-

EMA/H/C/004459/WS2674/0042

Octapharma AB, Lead Rapporteur: Jan Mueller-

Berghaus

Opinion adopted on 04.04.2024.

WS2675

Hefiya-EMA/H/C/004865/WS2675/0053

Hyrimoz-

EMA/H/C/004320/WS2675/0052

Sandoz GmbH, Duplicate of Hyrimoz, Lead

Rapporteur: Christian Gartner, "

Opinion adopted on 04.04.2024.

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

Clopidogrel Zentiva - Clopidogrel -

EMA/H/C/000975/II/0089

Zentiva k.s., Duplicate of Clopidogrel BMS

(SRD), Informed Consent of Iscover,

Rapporteur: Bruno Sepodes, Withdrawal request

submitted on 03.04.2024.

Bylvay - Odevixibat -

EMA/H/C/004691/II/0020, Orphan

Ipsen Pharma, Rapporteur: Patrick Vrijlandt

Positive Opinion adopted by consensus on
04.04.2024.

Positive Opinion adopted by consensus on
04.04.2024.

The MAH withdrew the procedure on
03.04.2024.

The MAH withdrew the procedure on
11.04.2024.

Withdrawal request submitted on 11.04.2024.

**BUCCOLAM - Midazolam -
EMA/H/C/002267/II/0062/G**

Neuraxpharm Pharmaceuticals S.L., Rapporteur:
Peter Mol

The MAH withdrew the procedure on
18.04.2024.

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

**Cablivi - Caplacizumab -
EMA/H/C/004426/II/0048, Orphan**

Ablynx NV, Rapporteur: Filip Josephson,
"Update of sections 4.2, 4.8 and 5.1 of the
SmPC in order to update efficacy and safety
information on paediatric patients based on
results from study OBS17325 - Retrospective
Data Collection of Pediatric Patients with
Immune Thrombotic Thrombocytopenic Purpura
(iTTP) Treated with Caplacizumab. The primary
objective of this study was to describe the
effectiveness and safety of caplacizumab in
pediatric patients with iTTP."
Request for Supplementary Information adopted
on 14.03.2024.

Request by the applicant for an extension to the
clock stop to respond to the RSI adopted in
March 2024.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

**Obecabtagene autoleucel -
EMA/H/C/005907, Orphan, ATMP**

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

Deutetrabenazine - EMA/H/C/006371

treatment of tardive dyskinesia

**Ferric citrate coordination complex -
EMA/H/C/006402**

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

**Human normal immunoglobulin -
EMA/H/C/006423**

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

Multifocal Motor Neuropathy)

Eltrombopag - EMEA/H/C/006459

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

Mozafancogene autotemcel -

EMEA/H/C/005537, Orphan, ATMP

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

Influenza vaccine (live attenuated, nasal) -

EMEA/H/C/006514

Prophylaxis of influenza

Denosumab - EMEA/H/C/006398

prevention of skeletal related events with advanced malignancies

Denosumab - EMEA/H/C/006424

treatment of osteoporosis and bone loss

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

Denosumab - EMEA/H/C/006157

prevention of skeletal related events with advanced malignancies

Denosumab - EMEA/H/C/006399

treatment of osteoporosis and bone loss

Ustekinumab - EMEA/H/C/006544

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

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

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

Denosumab - EMEA/H/C/006156

treatment of osteoporosis and bone loss

Atropine sulfate - EMEA/H/C/006324

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

Aflibercept - EMEA/H/C/006192

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

Denosumab - EMEA/H/C/006468

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

Tegomil fumarate - EMEA/H/C/006427

treatment of multiple sclerosis

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

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

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

**PREVYMIS - Letermovir -
EMEA/H/C/004536/X/0037/G, Orphan**

Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Kirsti Villikka, "Extension applications to introduce a new pharmaceutical form (granules in sachet) associated with new strengths (20 and 120 mg) grouped with a type II variation (C.I.6.a) to

include treatment of paediatric patients from birth up to 18 years old based on the final results from studies P030 and P031. Study P030 was a Phase 2b, open-label, single-arm study to evaluate PK, efficacy, safety, and tolerability of LET when used for CMV prophylaxis in pediatric participants from birth to <18 years of age who are at risk of developing CS-CMV following an allogeneic HSCT. Study P031 was an open-label, single-dose, four-period, seven-treatment, crossover study designed to evaluate the bioavailability of 2 pediatric formulations of MK-8228 (Formulations A and B) administered alone or in soft food (applesauce and vanilla pudding) compared to a currently marketed tablet formulation. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes.”

**Retsevmo - Selpercatinib -
EMA/H/C/005375/X/0031**

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder, “Extension application to introduce a new pharmaceutical form (film-coated tablets) associated with new strengths (40 mg, 80 mg, 120 mg and 160 mg). The RMP (version 7.1) is updated in accordance.”

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

Delgocitinib - EMA/H/C/006109

treatment of moderate to severe chronic hand eczema (CHE)
List of Questions adopted on 14.12.2023.

**Edurant - Rilpivirine -
EMA/H/C/002264/X/0042/G**

Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan, “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.”
List of Questions adopted on 14.12.2023.

Eliquis - Apixaban -

EMA/H/C/002148/X/0089/G

Bristol-Myers Squibb / Pfizer EEIG, Rapporteur:
Patrick Vrijlandt, Co-Rapporteur: Christophe Focke, PRAC Rapporteur: Bianca Mulder,
“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.”
List of Questions adopted on 14.12.2023.

Ustekinumab - EMEA/H/C/005805

treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, Crohn’s Disease and Ulcerative colitis
List of Questions adopted on 25.01.2024.

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)
List of Questions adopted on 14.12.2023.

Elafibranor - EMEA/H/C/006231, Orphan

Ipsen Pharma, treatment of primary biliary cholangitis (PBC)
List of Questions adopted on 22.02.2024.

Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated - EMEA/H/C/005797

prevention of disease caused by chikungunya (CHIKV) virus
List of Questions adopted on 20.02.2024.

Avacincaptad pegol - EMEA/H/C/006153

is indicated for the treatment of adults with geographic atrophy (GA) secondary to age-related macular degeneration (AMD)
List of Questions adopted on 14.12.2023.

Zapomeran - EMEA/H/C/006207

active immunisation to prevent COVID-19
List of Questions adopted on 14.12.2023.

In vitro diagnostic medical device - EMEA/H/D/006470

to detect amplification of the HER2/neu gene via quantitative fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer and adenocarcinomas of the stomach (including gastroesophageal junction) tissue specimens
Request for Supplementary Information adopted

on 21.03.2024.

**Rybelsus - Semaglutide -
EMA/H/C/004953/X/0039**

Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt,
"Extension application to add two new strengths
(25 mg and 50 mg) tablets."

List of Questions adopted on 22.02.2024.

**Lutetium (177Lu) chloride -
EMA/H/C/005882**

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

List of Questions adopted on 14.12.2023.

Ciclosporin - EMA/H/C/006250

Treatment of dry eye disease in adult patients

List of Questions adopted on 14.12.2023.

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

**Evoltra - Clofarabine -
EMA/H/C/000613/S/0081**

Sanofi B.V., Rapporteur: Alexandre Moreau,
PRAC Rapporteur: Tiphaine Vaillant

**Lamzede - Velmanase alfa -
EMA/H/C/003922/S/0035, Orphan**

Chiesi Farmaceutici S.p.A., Rapporteur: Patrick
Vrijlandt, PRAC Rapporteur: Jan Neuhauser

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

**AYVAKYT - Avapritinib -
EMA/H/C/005208/R/0034, Orphan**

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

**BAQSIMI - Glucagon -
EMA/H/C/003848/R/0015**

Amphastar France Pharmaceuticals, Rapporteur:
Karin Janssen van Doorn, Co-Rapporteur:
Martina Weise, PRAC Rapporteur: Eamon O
Murchu

**Cegfila - Pegfilgrastim -
EMA/H/C/005312/R/0020**

Mundipharma Corporation (Ireland) Limited,
Duplicate, Duplicate of Pelmeg, Rapporteur:
Karin Janssen van Doorn, Co-Rapporteur:

Christian Gartner, PRAC Rapporteur: Bianca Mulder

**Clopidogrel/Acetylsalicylic acid Viatrix -
Clopidogrel / Acetylsalicylic acid -
EMA/H/C/004996/R/0012**

Mylan Pharmaceuticals Limited, Generic,
Generic of DuoPlavin, Rapporteur: Kristina Nadrah, PRAC Rapporteur: Carla Torre

**Evenity - Romosozumab -
EMA/H/C/004465/R/0025**

UCB Pharma S.A., Rapporteur: Kristina Dunder,
PRAC Rapporteur: Tiphaine Vaillant

**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, PRAC Rapporteur: Ulla Wändel Liminga

**Quofenix - Delafloxacin -
EMA/H/C/004860/R/0026**

A. Menarini Industrie Farmaceutiche Riunite s.r.l., Rapporteur: Janet Koenig, PRAC Rapporteur: Petar Mas

**Rhokiinsa - Netarsudil -
EMA/H/C/004583/R/0022**

Santen Oy, Rapporteur: Jayne Crowe, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Maria del Pilar Rayon

**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

**Spravato - Esketamine -
EMA/H/C/004535/R/0023**

Janssen-Cilag International N.V., Rapporteur: Martina Weise, PRAC Rapporteur: Kirsti Villikka

**Tepkinly - Epcoritamab -
EMA/H/C/005985/R/0004, Orphan**

AbbVie Deutschland GmbH & Co. KG,

Rapporteur: Peter Mol, PRAC Rapporteur:
Monica Martinez Redondo

**VITRAKVI - Larotrectinib -
EMA/H/C/004919/R/0035**

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

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

**Darzalex - Daratumumab -
EMA/H/C/004077/II/0072, Orphan**

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

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

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

MMY2040 (PLEIADES) is a randomised, open-label, multicentre phase 2 study to evaluate subcutaneous daratumumab in combination with standard multiple myeloma treatment regimens. The D-VRd cohort included adult subjects with newly diagnosed multiple myeloma, who were evaluated for clinical benefit in terms of very good partial response or better (VGPR) rate. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”

**Esperoct - Turoctocog alfa pegol -
EMA/H/C/004883/II/0023**

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

**Jaypirca - Pirtobrutinib -
EMA/H/C/005863/II/0002**

Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Edward Laane, PRAC Rapporteur: Bianca Mulder, “Extension of indication to include treatment of adult patients with chronic lymphocytic leukemia (CLL) who have been previously treated with a Bruton’s tyrosine kinase (BTK) inhibitor for JAYPIRCA, based on interim results from study LOXO-BTK-20020 (BRUIN CLL-321); this is a phase 3 open-label, randomized study of LOXO-305 versus investigator’s choice of idelalisib plus rituximab or bendamustine plus rituximab in BTK inhibitor pretreated CLL/SLL. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The

Package Leaflet is updated in accordance.
Version 1.1 of the RMP has also been submitted.
As part of the application the MAH is requesting
a 1-year extension of the market protection.”
Request for 1 year of data exclusivity for a new
indication (Article 10(5) of Directive
2001/83/EC).

**Keytruda - Pembrolizumab -
EMA/H/C/003820/II/0153**

Merck Sharp & Dohme B.V., Rapporteur: Paolo
Gasparini, PRAC Rapporteur: Bianca Mulder,
“Extension of indication for KEYTRUDA in
combination with carboplatin and paclitaxel to
include first-line treatment of primary advanced
or recurrent endometrial carcinoma in adults,
based on final results from study KEYNOTE-868.
This is a randomized Phase 3, placebo-
controlled, double-blind study of pembrolizumab
vs placebo in combination with chemotherapy
(paclitaxel plus carboplatin) for newly diagnosed
Stage III/Stage IVA, Stage IVB, or recurrent
endometrial cancer.
As a consequence, sections 4.1 and 5.1 of the
SmPC are updated. Version 46.1 of the RMP has
also been submitted.”

**Tevimbra - Tislelizumab -
EMA/H/C/005919/II/0008**

Beigene Ireland Limited, Rapporteur: Jan
Mueller-Berghaus, PRAC Rapporteur: Bianca
Mulder, “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.”

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

**Besremi - Ropeginterferon alfa-2b -
EMA/H/C/004128/II/0033/G**

AOP Orphan Pharmaceuticals GmbH,
Rapporteur: Janet Koenig

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

Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola

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

Janssen-Cilag International N.V., Rapporteur: Aaron Sosa Mejia

**Erbix - Cetuximab -
EMA/H/C/000558/II/0098/G**

Merck Europe B.V., Rapporteur: Filip Josephson

**Flixabi - Infliximab -
EMA/H/C/004020/II/0086**

Samsung Bioepis NL B.V., Rapporteur: Jan Mueller-Berghaus

**Inhixa - Enoxaparin sodium -
EMA/H/C/004264/II/0109**

Techdow Pharma Netherlands B.V., Duplicate of Thorinane (EXP), Rapporteur: Christian Gartner

**Leqvio - Inclisiran -
EMA/H/C/005333/II/0027/G**

Novartis Europharm Limited, Rapporteur: Martina Weise

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

MediWound Germany GmbH, Rapporteur: Janet Koenig

**Skyclarys - Omaveloxolone -
EMA/H/C/006084/II/0003/G, Orphan**

Reata Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher

**Spikevax - COVID-19 mRNA vaccine -
EMA/H/C/005791/II/0132/G**

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus

**Tysabri - Natalizumab -
EMA/H/C/000603/II/0143/G**

Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus

**Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) -
EMA/H/C/003982/II/0141**

MCM Vaccine B.V., Rapporteur: Christophe Focke

Vaxneuvance - Pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed) -

EMA/H/C/005477/II/0020

Merck Sharp & Dohme B.V., Rapporteur: Patrick Vrijlandt

Xenpozyme - Olipudase alfa - EMA/H/C/004850/II/0009, Orphan

Sanofi B.V., Rapporteur: Patrick Vrijlandt

Ximluci - Ranibizumab - EMA/H/C/005617/II/0010

STADA Arzneimittel AG, Rapporteur: Jayne Crowe

Zilbrysq - Zilucoplan - EMA/H/C/005450/II/0002

UCB Pharma S.A., Rapporteur: Kristina Dunder

WS2663/G

Infanrix hexa-

EMA/H/C/000296/WS2663/0344/G

GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS2684

Nuwiq-EMA/H/C/002813/WS2684/0061

Vihuma-EMA/H/C/004459/WS2684/0043

Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

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

Arixtra - Fondaparinux sodium -

EMA/H/C/000403/II/0092

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

**Cimzia - Certolizumab pegol -
EMA/H/C/001037/II/0110**

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

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

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

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

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC in order to update the statement relating to guanylate cyclase-C (GCC) receptor expression in the paediatric population to reflect current clinical data, including final results from study MCP-103-311; this is a non-interventional clinical research study to characterize GCC mRNA expression in duodenal and colonic mucosal biopsies in children aged 0 to 17 years. In addition, the MAH took the

opportunity to introduce minor editorial changes to the Product Information and to bring it in line with the latest QRD template.”

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

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

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

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

**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.”

**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.”

**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.”

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

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

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

Eli Lilly Nederland B.V., Rapporteur: Martina

Weise, "A grouped application consisting of two Type II variations, as follows:

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

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

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

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

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

Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, "A grouped application comprised of three Type II Variations and one Type IA Variation, as follows:
3 Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to update clinical safety information based on final results from the three studies: study WA21092 (OPERA I), study WA21093 (OPERA II) and study WA25046 (ORATORIO). Study WA21092 (OPERA I) and study WA21093 (OPERA II) are randomized, double-blind, double-dummy, parallel-group studies to evaluate the efficacy and safety of ocrelizumab in comparison to interferon beta-1a (Rebif) in patients with relapsing multiple sclerosis (RMS), while study WA25046 (ORATORIO) is a phase 3, multicentre, randomized, parallel-group, double blinded, placebo controlled study to evaluate the efficacy

and safety of ocrelizumab in adults with primary progressive multiple sclerosis (PPMS). In addition, the MAH took the opportunity to introduce minor editorial change to the Product Information.

Type IA (A.6): Change the ATC Code of ocrelizumab from L04AA36 to L04AG08.”

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.”

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.”

Rystiggo - Rozanolixizumab -

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

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

**Sivextro - Tedizolid phosphate -
EMA/H/C/002846/II/0053**

Merck Sharp & Dohme B.V., Rapporteur: Bruno Sepodes, “Update of section 5.1 of the SmPC in order to implement the revised EUCAST MIC breakpoints of tedizolid. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”

**Spikevax - COVID-19 mRNA vaccine -
EMA/H/C/005791/II/0130**

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, “To delete the following presentations from the Spikevax marketing authorization. The SmPC, Package Leaflet and Labelling section of the Product Information are updated accordingly.”

**Spravato - Esketamine -
EMA/H/C/004535/II/0024**

Janssen-Cilag International N.V., Rapporteur: Martina Weise, “Update of section 4.8 of the SmPC in order to add ‘hypotension’ to the list of adverse drug reactions (ADRs) with frequency uncommon, based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI.”

**TAVNEOS - Avacopan -
EMA/H/C/005523/II/0013, Orphan**

Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder

**Tevimbra - Tislelizumab -
EMA/H/C/005919/II/0009**

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

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

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

VANFLYTA - Quizartinib -

EMA/H/C/005910/II/0002

Daiichi Sankyo Europe GmbH, Rapporteur: Peter Mol, "To update section 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."

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."

Xevudy - Sotrovimab -

EMA/H/C/005676/II/0028

Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC with data on the in vitro activity of sotrovimab in a pseudotyped virus assay against the Omicron XBB.1.16.6 and FL.1.5.1 spike variants (PC-23-0155), and the Omicron JN.1(PC-24-0103) spike variant; data on the in vitro activity of sotrovimab in an authentic virus assay against the SARS-CoV-2 XBB.2.3 variant (PC-23-0154), FL.1.5.1 and BA.2.86 variants (PC-23-0180); data on the in

in vitro activity of sotrovimab in an authentic virus assay against the SARS-CoV-2 XBB.2.3 variant (PC-23-0154), FL.1.5.1 and BA.2.86 variants (PC-23-0180) and data on the epitope conservation and sotrovimab activity against pseudotyped virus encoding epitope variants (PC-7831-0143v21) based on the relevant pharmacology study reports.”

WS2658

Braftovi-

EMA/H/C/004580/WS2658/0039

Mektovi-

EMA/H/C/004579/WS2658/0031

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

WS2683

Relvar Ellipta-

EMA/H/C/002673/WS2683/0068

Revinty Ellipta-

EMA/H/C/002745/WS2683/0065

GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Antonio Gómez 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.6.10. CHMP-PRAC assessed procedures

Beovu - Brolucizumab -

EMA/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 brolocizumab 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 brolocizumab 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."

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

Samsung Bioepis NL B.V., Rapporteur: Christian Gartner, PRAC Rapporteur: Ulla Wandel Liminga

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

International Partnership for Microbicides
Belgium AISBL, Rapporteur: Patrick Vrijlandt,
PRAC Rapporteur: Jan Neuhauser, "A grouped application consisting of:
Type II (C.I.4): Update of section 4.6 of the SmPC in order to update information on breastfeeding based on final results from study MTN-043 (B-PROTECTED) listed as a category 3 study in the RMP (MEA/009). MTN-043 is a Phase 3b, randomized, open-label, safety, and drug detection study of dapivirine vaginal ring and oral truvada in breastfeeding mother-infant pairs. The Package Leaflet is updated accordingly. The RMP version 1.4 has also been submitted. In addition, the MAH took the opportunity to update Annex II of the PI.
Type IB (C.I.11.z): Submission of an updated RMP version 1.4 in order to request a change on

the due date for the MTN-034 (REACH) study.”

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

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

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

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

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

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

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

The Package Leaflet and Annex II are updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes.”

**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."

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

Pfizer Europe MA EEIG, Rapporteur: Martina
Weise, PRAC Rapporteur: Mari Thorn, "Update of
section 4.4 to modify the macular oedema
warning based on the evaluation of the cases of

MO/cystoid MO reported in the etrasimod clinical studies and other S1P labels in the EU. The Package Leaflet and Annex II are updated in accordance. RMP version 1.1 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes to the PI.”

Zeposia - Ozanimod -

EMA/H/C/004835/II/0024/G

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

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

The RMP version 8.0 also been submitted.

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

WS2664

Ebymect-

EMA/H/C/004162/WS2664/0066

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

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

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

B.6.11. PRAC assessed procedures

PRAC Led

BESPONSA - Inotuzumab ozogamicin -

EMA/H/C/004119/II/0028, Orphan

Pfizer Europe MA EEIG, PRAC Rapporteur:

Gabriele Maurer, PRAC-CHMP liaison: Jan

Mueller-Berghaus, “Submission of the final

report from study B1931028; this is a non-

interventional post-authorization safety study

(PASS) of inotuzumab ozogamicin to characterize complications post-hematopoietic stem cell transplantation (HSCT) following inotuzumab ozogamicin treatment in adult and pediatric patients with B-cell precursor acute lymphoblastic leukemia (ALL). The RMP version 3.0 has also been submitted.”

PRAC Led

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

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

PRAC Led

**Gilenya - Fingolimod -
EMA/H/C/002202/II/0090/G**

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

PRAC Led

**Olumiant - Baricitinib -
EMA/H/C/004085/II/0047**

Eli Lilly Nederland B.V., PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa

Balkowiec Iskra, "Submission of the final report from non-interventional Study I4V-MC-B012 listed as a category 3 study in the RMP. This is a post-marketing safety surveillance of baricitinib in three European registries. The RMP version 23.1 has also been submitted."

PRAC Led

**Reyataz - Atazanavir -
EMA/H/C/000494/II/0140**

Bristol-Myers Squibb Pharma EEIG, PRAC
Rapporteur: Nathalie Gault, PRAC-CHMP liaison:
Jean-Michel Race, "Update of section 4.4 of the SmPC in order to clarify and update the warning regarding dyslipidaemia in relation to other comparators, following PRAC's recommendation in the outcome of procedure PSUSA/00000258/202106. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

PRAC Led

**Spikevax - COVID-19 mRNA vaccine -
EMA/H/C/005791/II/0131**

Moderna Biotech Spain S.L., PRAC Rapporteur:
Marie Louise Schougaard Christiansen, PRAC-
CHMP liaison: Thalia Marie Estrup Blicher,
"Submission of the final report from study mRNA-1273-919 - An Observational Study to Assess Maternal and Infant Outcomes Following Exposure to Spikevax During Pregnancy, listed as a category 3 study in the RMP."

PRAC Led

**Uptravi - Selexipag -
EMA/H/C/003774/II/0045**

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

PRAC Led

Xeljanz - Tofacitinib -**EMA/H/C/004214/II/0062**

Pfizer Europe MA EEIG, PRAC Rapporteur: Liana Martirosyan, PRAC-CHMP liaison: Peter Mol, "Submission of the final report from study A3921203 (Tofacitinib Pregnancy Exposure Registry OTIS Autoimmune Diseases in Pregnancy Project) listed as a category 3 study in the RMP; this is a prospective, observational cohort study of pregnancy outcomes in women with a disease for which tofacitinib had an approved indication."

PRAC Led

Xeljanz - Tofacitinib -**EMA/H/C/004214/II/0063**

Pfizer Europe MA EEIG, PRAC Rapporteur: Liana Martirosyan, PRAC-CHMP liaison: Peter Mol, "Submission of an updated RMP version 32.0 in order to propose the removal of category 3 study A3921329 (A Long-Term, Observational Study within the CorEvitas [formerly Corrona] Inflammatory Bowel Disease (IBD) Registry to Characterize the Safety of Tofacitinib in Patients with Ulcerative Colitis in the Post-Approval Setting). In addition, the MAH took the opportunity to update the RMP with some other minor updates."

B.6.12. 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)."

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

Janssen-Cilag International NV, Rapporteur: 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

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

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

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

WS2662/G

Edistride-

EMA/H/C/004161/WS2662/0066/G

Forxiga-

EMA/H/C/002322/WS2662/0087/G

AstraZeneca AB, Lead Rapporteur: Kristina
Dunder

WS2669

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

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

Baxalta Innovations GmbH, Lead Rapporteur:
Jan Mueller-Berghaus

WS2677

Mircera-EMA/H/C/000739/WS2677/0100

NeoRecormon-

EMA/H/C/000116/WS2677/0124

Roche Registration GmbH, Lead Rapporteur:

Martina Weise

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

WS2685

Mekinist-

EMA/H/C/002643/WS2685/0065

Tafinlar-

EMA/H/C/002604/WS2685/0070

Novartis Europharm Limited, Lead Rapporteur:
Filip Josephson, "To update the product
information section 4.2 with the pharmaceutical
form capsule and tablets, respectively and
section 5.2 with pharmacokinetic exposure at
weight adjusted dosage for adolescents."

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

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