22 July 2024
EMA/CHMP/304093/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 22-25 July 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

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

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

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

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

Disclaimers

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

Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

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

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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 July 2024. See July 2024 CHMP minutes (to be published post August 2024 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 22-25 July 2024

1.3. Adoption of the minutes

CHMP minutes for the 24-27 June 2024 meeting.

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

2. Oral Explanations

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No items

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Delgocitinib - EMEA/H/C/006109

Treatment of moderate to severe chronic hand eczema (CHE)

Scope: Opinion

Action: For adoption

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

3.1.2. Axitinib - EMEA/H/C/006206

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

Scope: Opinion

Action: For adoption

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

3.1.3. Ustekinumab - EMEA/H/C/006448

Treatment of Crohn’s disease, Ulcerative colitis, Plaque psoriasis, Paediatric plaque psoriasis and Psoriatic arthritis (PsA)

Scope: Opinion

Action: For adoption

3.1.4. Ustekinumab - EMEA/H/C/005805

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.05.2024. List of Questions adopted on 25.01.2024.

3.1.5. Trastuzumab - EMEA/H/C/006252

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

Scope: Opinion

Action: For adoption

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

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

Ipsen Pharma; treatment of primary biliary cholangitis (PBC)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.05.2024. List of Questions adopted on 22.02.2024.

3.1.7. Rituximab - EMEA/H/C/006224

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

Scope: Opinion

Action: For adoption

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

3.1.8. Odevixibat - EMEA/H/C/006462

Treatment of cholestatic pruritus in Alagille syndrome (ALGS)

Scope: Opinion

Action: For adoption

List of Questions adopted on 25.04.2024.

3.1.9. Lecanemab - EMEA/H/C/005966

A disease modifying treatment in adult patients with Mild Cognitive Impairment due to Alzheimer’s disease and Mild Alzheimer’s disease (Early Alzheimer’s disease)

Scope: Opinion, intervention by a third party

Action: For adoption

List of Outstanding Issues adopted on 27.06.2024, 21.03.2024, 09.11.2023. List of Questions adopted on 25.05.2023.

3.1.10. Toripalimab - EMEA/H/C/006120

Combination treatment for metastatic or recurrent locally advanced nasopharyngeal carcinoma and for metastatic or recurrent oesophageal squamous cell carcinoma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 30.03.2023.

3.1.11. Ustekinumab - EMEA/H/C/006544

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.05.2024.

3.1.12. Ranibizumab - EMEA/H/C/006528

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

Scope: Opinion

Action: For adoption

3.1.13. Ciclosporin - EMEA/H/C/006250

Treatment of dry eye disease in adult patients

Scope: Opinion

Action: For adoption

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

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

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

Scope: Opinion

Action: For adoption

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

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

Treatment of pulmonary arterial hypertension (PAH) in adults
patients

Scope: Opinion

Action: For adoption

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

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

3.2.1. Apremilast - EMEA/H/C/006193

Treatment of psoriatic arthritis, psoriasis, Behçet's disease

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.02.2024.

3.2.2. Levetiracetam - EMEA/H/C/006186

Treatment of partial onset seizures

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

3.2.3. Marstacimab - Orphan - EMEA/H/C/006240

Pfizer Europe Ma EEIG; Tradename is indicated for routine prophylaxis of bleeding episodes in patients with haemophilia A or haemophilia B

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.02.2024.

3.2.4. 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: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.04.2024.

3.2.6. Eplontersen - Orphan - EMEA/H/C/006295

AstraZeneca AB; indicated for the treatment of adult patients with polyneuropathy associated with hereditary transthyretin-mediated amyloidosis (ATTRv)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.02.2024.

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

3.3.1. Obecabtagene autoleucel - PRIME - Orphan - ATMP - EMEA/H/C/005907

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

Scope: List of questions

Action: For information

3.3.2. Deutetrabenazine - EMEA/H/C/006371

Treatment of tardive dyskinesia

Scope: List of questions

Action: For adoption

3.3.3. Ferric citrate coordination complex - EMEA/H/C/006402

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

Scope: List of questions

Action: For adoption

3.3.4. Human normal immunoglobulin - EMEA/H/C/006423

Replacement therapy (primary immunodeficiency syndromes and secondary hypogammaglobulinemia), immunomodulation (in primary immune thrombocytopenic purpura, Guillain Barré syndrome, Kawasaki disease and Multifocal Motor Neuropathy).

Scope: List of questions

Action: For adoption

3.3.5. Eltrombopag - EMEA/H/C/006459

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

Scope: List of questions

Action: For adoption

3.3.6. Mozafancogene autotemcel - PRIME - Orphan - ATMP - EMEA/H/C/005537

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

Scope: List of questions

Action: For information

3.3.7. Denosumab - EMEA/H/C/006398

Prevention of skeletal related events with advanced malignancies

Scope: List of questions

Action: For adoption

3.3.8. Denosumab - EMEA/H/C/006424

Treatment of osteoporosis and bone loss

Scope: List of questions

Action: For adoption

3.3.9. Denosumab - EMEA/H/C/006157

Prevention of skeletal related events with advanced malignancies

Scope: List of questions

Action: For adoption

3.3.10. Denosumab - EMEA/H/C/006399

Treatment of osteoporosis and bone loss

Scope: List of questions

Action: For adoption

3.3.11. 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*

Scope: List of questions

Action: For adoption

3.3.12. Denosumab - EMEA/H/C/006156

Treatment of osteoporosis and bone loss

Scope: List of questions

Action: For adoption

3.3.13. Atropine - EMEA/H/C/006324

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

Scope: List of questions

Action: For adoption

3.3.14. Sargramostim - EMEA/H/C/006411

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Treatment for exposure to myelosuppressive doses of radiation

Scope: List of questions

Action: For adoption

3.3.15. Aflibercept - EMEA/H/C/006192

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

Scope: List of questions

Action: For adoption

3.3.16. Denosumab - EMEA/H/C/006468

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

Scope: List of questions

Action: For adoption

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

Treatment of multiple sclerosis

Scope: List of questions

Action: For adoption

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

3.4.1. Bimatoprost - EMEA/H/C/005916

Indicated for the reduction of intraocular pressure (IOP) in adults with open angle glaucoma (OAG) or ocular hypertension (OHT) who are unsuitable for topical IOP-lowering medications

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

Action: For adoption

List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 20.07.2023.

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

Orphelia Pharma; treatment of neuroblastoma

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

Action: For adoption

List of Outstanding Issues adopted on 27. List of Questions adopted on 14.12.2023.

3.4.3. Donanemab - EMEA/H/C/006024

To slow disease progression in adult patients with Alzheimer’s disease (AD).

Scope: Third party intervention

Action: For information

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

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

Springworks Therapeutics Ireland Limited; treatment of desmoid tumours

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

Action: For adoption

List of Questions adopted on 27.06.2024.

3.4.5. Trastuzumab - EMEA/H/C/006219

Treatment of metastatic and early breast cancer

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

Action: For adoption

List of Questions adopted on 30.05.2024.

3.4.6. Resmetirom - EMEA/H/C/006220

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

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

Action: For adoption

List of Questions adopted on 27.06.2024.

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

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

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

Scope: Re-examination rapporteurs appointment, adoption of timetable

Action: For adoption

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

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

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

Scope: Re-examination rapporteurs were appointed in the July CHMP PROM meeting.

Action: For adoption

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

Opinion adopted on 27.06.2024. List of Outstanding Issues adopted on 25.04.2024, 12.10.2023. List of Questions adopted on 25.05.2023.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

Janssen-Cilag International N.V.;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan

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

Type II variation (C.I.6.a) to modify the approved therapeutic indication of the already authorised 25 mg film-coated tablets presentation to include, in combination with other antiretroviral medicinal products, treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve and virologically suppressed (HIV-1 RNA less than 50 copies per ml) paediatric patients from 2 to less than 12 years weighing at least 25 kg, based on final results from study studies TMC278-TiDP38-C213 Cohort 2. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. The updated RMP version 10.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to Annex II and to update the list of local representatives in the Package Leaflet."

Action: For adoption

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

4.1.2. Opsumit - Macitentan - EMEA/H/C/002697/X/0051/G

Janssen-Cilag International N.V.;

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

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (2.5 mg dispersible tablet) grouped with an extension of indication (C.I.6.a) to include, as monotherapy or in combination, the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged 1 month to less than 18 years of age of WHO Functional Class (FC) I to III for OPSUMIT, based on interim results from AC-055-312 study (TOMORROW). This is a multicentre, open-label, randomized study with single-arm extension period to assess the pharmacokinetics, safety, and efficacy of macitentan versus standard of care in children with pulmonary arterial hypertension. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC for film-coated tablets are

updated. The Package Leaflet and Labelling are updated in accordance. Version 14.1 of the RMP has also been submitted."

Action: For adoption

List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 22.02.2024.

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

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt

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

Action: For adoption

List of Outstanding Issues adopted on 30.05.2024. List of Questions adopted on 22.02.2024.

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

Boehringer Ingelheim International GmbH;

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

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

Action: For adoption

List of Outstanding Issues adopted on 30.05.2024, 21.03.2024. List of Questions adopted on 09.11.2023.

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

4.2.1. 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

List of Questions adopted on 25.04.2024.

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

GSK Vaccines S.r.l;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection). The RMP (version 11.0) is updated in accordance."

Action: For adoption

List of Questions adopted on 12.10.2023.

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

Boehringer Ingelheim International GmbH;

Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension application to add a new strength of 25 mg hard capsules, grouped with an extension of indication (C.I.6.a) to include treatment of fibrosing Interstitial Lung Diseases (ILDs) in children and adolescents from 6 to 17 years of age for Ofev, following the assessment of procedure X/0052/G, based on final results from study 1199-0337 (A Double Blind, Randomised, Placebo-controlled Trial to Evaluate the Dose-exposure and Safety of Nintedanib Per os on Top of Standard of Care for 24 Weeks, Followed by Open Label Treatment With Nintedanib of Variable Duration, in Children and Adolescents (6 to 17

Year-old) With Clinically Significant Fibrosing Interstitial Lung Disease), which is supplemented by the currently ongoing prospective Phase III extension trial 1199-0378 (An Open-label Trial of the Long-term Safety and Tolerability of Nintedanib Per os, on Top of Standard of Care, Over at Least 2 Years, in Children and Adolescents With Clinically Significant Fibrosing Interstitial Lung Disease). The main objective of the study 1199-0337 was to evaluate dose-exposure and safety of nintedanib in children and adolescents with fibrosing Interstitial Lung Disease (ILD). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 12.0 of the RMP has also been submitted."

Action: For adoption

List of Questions adopted on 22.02.2024.

4.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question

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

Pfizer Europe MA EEIG;

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

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

Action: For adoption

4.3.2. PREVYMIS - Letermovir - Orphan - EMEA/H/C/004536/X/0037/G

Merck Sharp & Dohme B.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Kirsti Villikka

Scope: "Extension applications to introduce a new pharmaceutical form (granules in sachet) associated with new strengths (20 and 120 mg) grouped with a type II variation (C.I.6.a) to include treatment of paediatric patients from birth up to 18 years old based on the final results from studies P030 and P031.
Study P030 was a Phase 2b, open-label, single-arm study to evaluate PK, efficacy, safety, and tolerability of LET when used for CMV prophylaxis in paediatric participants from birth to <18 years of age who are at risk of developing CS-CMVi following an allogeneic HSCT.
Study P031 was an open-label, single-dose, four-period, seven-treatment, crossover study

designed to evaluate the bioavailability of 2 paediatric formulations of MK-8228 (Formulations A and B) administered alone or in soft food (applesauce and vanilla pudding) compared to a currently marketed tablet formulation.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes."

Action: For adoption

4.3.3. Retsevmo - Selpercatinib - EMEA/H/C/005375/X/0031

Eli Lilly Nederland B.V.;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder

Scope: "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."

Action: For adoption

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

4.4.1. Lyrica - Pregabalin - EMEA/H/C/000546/X/0127

Upjohn EESV;

Rapporteur: Peter Mol, PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

List of Questions adopted on 30.05.2024.

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. ADCETRIS - Brentuximab vedotin - Orphan - EMEA/H/C/002455/II/0111

Takeda Pharma A/S;

PRAC Rapporteur: Bianca Mulder, PRAC Co-Rapporteur: Jan Mueller-Berghaus, PRAC-CHMP liaison: Peter Mol

Scope: "Extension of indication for ADCETRIS to include treatment for adult patients with previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone (BrECADD), based on final results from phase 3 study HD21 (NCT02661503). This study is titled Treatment Optimization Trial in the First-Line Treatment of Advanced-Stage Hodgkin Lymphoma; Comparison of 4-6 Cycles of Escalated BEACOPP With 4-6 Cycles of BrECADD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 20.0 of the RMP has also been submitted.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the SmPC."

Action: For adoption

5.1.2. Aflunov - Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - EMEA/H/C/002094/II/0086

Seqirus S.r.l;

Rapporteur: Maria Grazia Evandri, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include treatment of individuals 6 months of age and older for AFLUNOV, based on final results from study V87_30. This is a Phase 2, Randomized, Observer-Blind, Multicenter Study to Evaluate the Immunogenicity and Safety of Several Doses of Antigen and MF59 Adjuvant Content in a Monovalent H5N1 Pandemic Influenza Vaccine in Healthy Pediatric Subjects 6 Months to < 9 Years of Age.
As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 5.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC."

Action: For adoption

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

Request for Supplementary Information adopted on 25.04.2024.

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

Roche Registration GmbH;

Rapporteur: Thalia Marie Estrup Blicher

Scope: "C.I.6.a: Extension of indication to include paediatric patients (3 months to 18 years of age) for hepatic and cardiac transplants and to extend the indication for renal transplants for paediatric patients starting from 3 months, based on pharmacokinetic data, published literature and the Roche Global Safety Database. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly.
Type IB (C.I.z): To update section 4.2 of the SmPC for the CellCept 500 mg tablets formulation in order to be in line with the other three CellCept formulations. And for alignment with the current QRD guidance, the Package Leaflet was updated to cross reference section 2 in section 6 for sodium content.
In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and bring the PI in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024, 14.09.2023.

5.1.5. Dupixent - Dupilumab - EMEA/H/C/004390/II/0081

Sanofi Winthrop Industrie;

Rapporteur: Jan Mueller-Berghaus

Scope: "Extension of indication to include treatment of children aged 1 year and older to the already approved eosinophilic esophagitis (EoE) indication for Dupixent based on final results from study R668-EE-1877 (Part A, Part B, and Part A Addendum) - A Randomized,

Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Dupilumab in Pediatric Patients with Active Eosinophilic Esophagitis. 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."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

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

Ultragenyx Germany GmbH;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Mari Thorn

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

Action: For adoption

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

Sanofi Winthrop Industrie;

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

Scope: "Extension of indication to include treatment of Polymyalgia Rheumatica (PMR) in adult patients who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper for Kevzara, based on results from study EFC15160; this is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of sarilumab in patients with polymyalgia rheumatica; As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP is also submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

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

Request for Supplementary Information adopted on 25.04.2024.

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

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

5.1.10. 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, multicentre, randomized, open-label trial to evaluate efficacy and safety of ribociclib with ET versus ET alone as adjuvant treatment in patients with HR-positive, HER2-negative, early breast cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. 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."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024, 14.12.2023.

5.1.11. OPDIVO - Nivolumab - EMEA/H/C/003985/II/0140

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Carolina Prieto Fernandez, 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

Request for Supplementary Information adopted on 25.04.2024.

5.1.12. Otezla - Apremilast - EMEA/H/C/003746/II/0044/G

Amgen Europe B.V.;

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Monica Martinez Redondo

Scope: "A grouped application of a Type II Variation with two Type IA Variations, as follows: Type II (C.I.6.a): Extension of indication to include the treatment of moderate to severe chronic plaque psoriasis in children and adolescents from the age of 6 years who have a contraindication, have an inadequate response, or are intolerant to at least one other systemic therapy or phototherapy for OTEZLA, based on final results from study CC-10004-PPSO-003 as well as results from studies CC-10004-PPSO-001 and CC-10004-PPSO-004. CC-10004-PPSO-003 is a phase 3, multi-centre, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of apremilast (CC-10004) in paediatric subjects from 6 through 17 years of age with moderate to severe plaque psoriasis. As a consequence, sections 4.1, 4.2, 4.4 ,4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 15.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial and formatting changes to the PI and to update the list of local representatives in the Package Leaflet.
2 Type IA (B.II.e.5.a.1): Update of sections 6.5 and 8 of the SmPC to introduce two new pack sizes within approved range as a result of the indication update ."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

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

Request for Supplementary Information adopted on 25.04.2024.

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, multicentre 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

Request for Supplementary Information adopted on 25.04.2024.

5.1.15. Rybrevant - Amivantamab - EMEA/H/C/005454/II/0011

Janssen-Cilag International N.V.;

Rapporteur: Filip Josephson, Co-Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Gabriele Maurer

Scope: " Extension of indication to include amivantamab in combination with carboplatin and pemetrexed for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including a third-generation EGFR tyrosine kinase inhibitor (TKI) for RYBREVANT, based on the final results from study 61186372NSC3002 (MARIPOSA 2); this is a randomized, open label, multicentre Phase 3 study that compares efficacy and safety of amivantamab in combination with carboplatin and pemetrexed (ACP) with carboplatin and pemetrexed (CP). The primary objective of the MARIPOSA 2 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, 4.4, 4.8, 4.9, 5.1, 5.2, 6.6 and 9 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2 of the EU RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) is requesting an additional year of 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.

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

Sanofi Winthrop Industrie;

Rapporteur: Peter Mol, PRAC Rapporteur: Monica Martinez Redondo

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

Action: For adoption

5.1.17. Slenyto - Melatonin - EMEA/H/C/004425/II/0025

RAD Neurim Pharmaceuticals EEC SARL;

Rapporteur: Kristina Dunder, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Extension of indication to include treatment of neurogenetic disorders (e.g., Angelman syndrome, Rett syndrome, Tuberous sclerosis complex and Williams syndrome) for SLENYTO, based on Phase III study NEU_CH_7911, post-marketing data and literature; As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 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

Request for Supplementary Information adopted on 21.03.2024.

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

AstraZeneca AB;

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy for TAGRISSO as monotherapy, based on results from study D5160C00048 (LAURA); this is a Phase III, randomised, double-blind, placebo-controlled, multicentre international study of osimertinib as maintenance therapy in patients with locally advanced unresectable EGFR mutation-positive non-small cell lung cancer

(stage III) whose disease has not progressed following definitive platinum-based chemoradiation therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 17.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

Action: For adoption

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, multicentre, 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 25.04.2024, 14.12.2023.

5.1.20. 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 27.06.2024, 25.04.2024, 25.01.2024.

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

Pierre Fabre Medicament;

Lead Rapporteur: Janet Koenig, PRAC Rapporteur: Rugile Pilviniene

Scope: "Extension of indication to include binimetinib in combination with encorafenib for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with a BRAF V600 mutation for MEKTOVI and BRAFTOVI based on results from study PHAROS (Study ARRAY-818-202) at the primary completion date; this is a Phase II, open-label, multicentre, non-comparative study (interventional). As a consequence, sections 4.1, 4.4, 4.8, 5.1, 5.2, 9 and 10 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection for MEKTOVI.
", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024, 25.01.2024.

5.1.22. WS2672
OPDIVO - Nivolumab - EMEA/H/C/003985/WS2672/0141
Yervoy - Ipilimumab - EMEA/H/C/002213/WS2672/0111

Bristol-Myers Squibb Pharma EEIG;

Lead Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

Scope: "A Worksharing application for OPDIVO and YERVOY, as follows:
Extension of indication to include OPDIVO in combination with ipilimumab in the first-line treatment of adult patients with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) unresectable or metastatic colorectal cancer, based on interim results from study CA2098HW; this is a phase 3 randomised clinical trial of nivolumab alone, nivolumab in combination with ipilimumab, or investigator's choice chemotherapy in participants with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 37.0 of the RMP has also been submitted.
Extension of indication to include YERVOY in combination with nivolumab in the first-line treatment of adult patients with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) unresectable or metastatic colorectal cancer, based on interim results from study CA2098HW; this is a phase 3 randomised clinical trial of nivolumab alone, nivolumab in combination with ipilimumab, or investigator's choice chemotherapy in participants with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 41.0 of the RMP has also been submitted."

Action: For adoption

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."

Scope: Third party intervention

Action: For information

Request for Supplementary Information adopted on 30.05.2024, 22.02.2024.

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

Proveca Pharma Limited;

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

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

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024.

The CHMP adopted the request via written procedure on 3 July 2024 for an extension to the clock stop to respond to the request for supplementary information adopted in May 2024.

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006536

To detect ITD and TKD mutations in the FLT3 gene in patients with acute myelogenous leukaemia (AML).

Scope: Opinion

Action: For adoption

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

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

Scope: Opinion

Action: For adoption

6.3.3. In vitro diagnostic medical device - EMEA/H/D/006543

Qualitative immunohistochemical assay using mouse monoclonal anti-claudin 18, clone 43 14A, intended for laboratory use in the assessment of claudin 18 (CLDN18) protein in formalin-fixed, paraffin-embedded (FFPE) gastric adenocarcinoma including gastroesophageal junction (GEJ) tissue specimens by light microscopy.

Scope: Opinion

Action: For adoption

6.3.4. In vitro diagnostic medical device - EMEA/H/D/006545

Laboratory use in the assessment of folate receptor alpha (FOLR1) protein in formalin-fixed

paraffin embedded (FFPE) epithelial ovarian, fallopian tube or primary peritoneal cancer tissue specimens by light microscopy

Scope: Opinion

Action: For adoption

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

None

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. Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0013

Gilead Sciences Ireland Unlimited Company

Rapporteur: Filip Josephson

Scope: "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."

Action: For adoption

Request for Supplementary Information adopted on 13.06.2024, 11.04.2024, 18.01.2024.

9.1.2. Wegovy - Semaglutide - EMEA/H/C/005422/II/0019

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: "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."

Action: For adoption

Request for Supplementary Information adopted on 11.04.2024.

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

Orexigen Therapeutics Ireland Limited

Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig

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

Action: For adoption

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

9.1.4. Alofisel - Darvadstrocel - EMEA/H/C/004258/II/0051/G - Orphan -ATMP

Takeda Pharma A/S

Rapporteur: Maria Luttgen, CHMP Coordinator: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer

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

3 x (C.I.13): Submission of interim results from studies Darvadstrocel-3003 and Alofisel-5003 (INSPIRE) and final results from study Darvadstrocel-3002 to support the benefit-risk assessment of darvadstrocel based on all new available clinical data.
The RMP version 8.0 has also been submitted."

Action: For adoption

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

PTC Therapeutics International Limited

Scope: Re-examination request, appointment of re-examination rapporteurs

Action: For adoption

10. Referral procedures

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

July 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

Information related to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to contain commercially confidential information

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 July 2024

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

Agenda of the June 2024 PDCO plenary meeting

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Reports from the BWP meeting for CHMP adoption

Action: For adoption

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 08-11 July 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

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

Explanatory notes

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

Oral explanations *(section 2)*

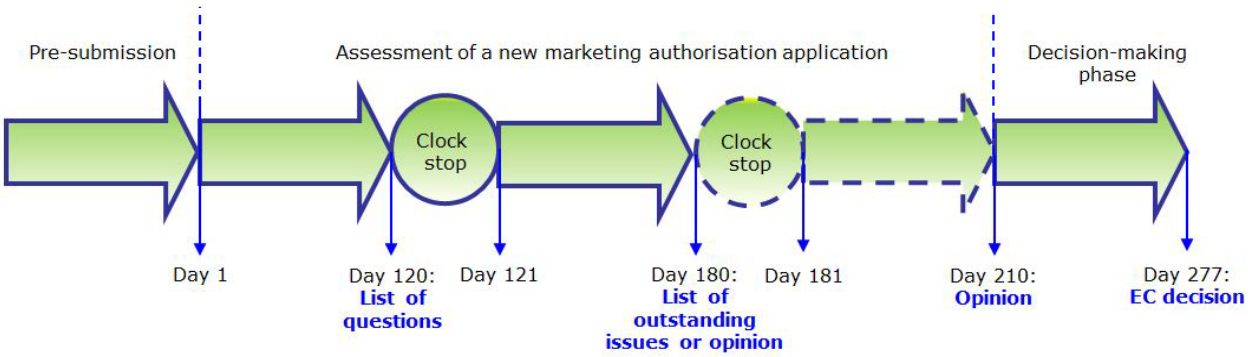
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 July 2024
EMA/CHMP/304099/2024

Annex to 22-25 July 2024 CHMP Agenda

Pre-submission and post-authorisations issues

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Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for July 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

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

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

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

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

Obizur - Susoctocog alfa - EMEA/H/C/002792/S/0056
Baxalta Innovations GmbH, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Gabriele Maurer

Request for Supplementary Information adopted on 30.05.2024.

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

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

Arsenic trioxide Accord - Arsenic trioxide - EMEA/H/C/005175/R/0009
Accord Healthcare S.L.U., Generic of TRISENOX, Rapporteur: Alar Irs, PRAC Rapporteur: Tiphaine Vaillant
Request for Supplementary Information adopted on 30.05.2024.

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

Bortezomib Fresenius Kabi - Bortezomib - EMEA/H/C/005074/R/0010
Fresenius Kabi Deutschland GmbH, Generic of VELCADE, Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Amelia Cupelli
Request for Supplementary Information adopted on 30.05.2024.

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

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

Mayzent - Siponimod - EMEA/H/C/004712/R/0029

Novartis Europharm Limited, Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Maria del Pilar Rayon

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

RINVOQ - Upadacitinib - EMEA/H/C/004760/R/0051
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Petar Mas
Request for Supplementary Information adopted on 30.05.2024.

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

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

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

B.2.3. Renewals of Conditional Marketing Authorisations

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

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

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

Signal of Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)
Glofitamab - COLUMVI (CAP)
Rapporteur: Aaron Sosa Mejia, PRAC
Rapporteur: Jana Lukacisinova
PRAC recommendation on a variation
Action: For adoption

Signal of aspiration and pneumonia aspiration
Exenatide, liraglutide, dulaglutide, semaglutide, lixisenatide, tirzepatide - OZEMPIC, RYBELSUS, WEGOVY, SAXENDA, VICTOZA, XULTOPHY, BYDUREON, BYETTA, TRULICITY, LYXUMIA, SULIQUA
Rapporteur: multiple, PRAC Rapporteur: multiple
PRAC recommendation on a variation
Action: For adoption

Signal of granuloma
Human Papillomavirus 9-valent Vaccine (recombinant, adsorbed), human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed - GARDASIL 9 , GARDASIL
Rapporteur: Kristina Dunder, PRAC
Rapporteur: Jean-Michel Dogné, Ulla Wändel Liminga
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 July 2024 meeting:

EMEA/H/C/PSUSA/00003085/202312
(ustekinumab)
CAPS:
Stelara (EMEA/H/C/000958) (Ustekinumab), Janssen-Cilag International N.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "01/01/2023 To: 31/12/2023"

EMEA/H/C/PSUSA/00010930/202312
(berotralstat)
CAPS:
Orladeyo (EMEA/H/C/005138) (Berotralstat), BioCryst Ireland Limited, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Julia Pallos, "03/12/2022 To: 02/12/2023"

EMEA/H/C/PSUSA/00010955/202312
(roxadustat)

CAPS:
Evrenzo (EMEA/H/C/004871) (Roxadustat), Astellas Pharma Europe B.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Anna Mareková, "17/06/2023 To: 16/12/2023"

EMEA/H/C/PSUSA/00010989/202312
(enfortumab vedotin)
CAPS:
Padcev (EMEA/H/C/005392) (Enfortumab vedotin), Astellas Pharma Europe B.V., Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Eva Jirsová, "17/12/2022 To: 17/12/2023"

EMEA/H/C/PSUSA/00010999/202312
(mosunetuzumab)
CAPS:
Lunsumio (EMEA/H/C/005680) (Mosunetuzumab), Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, "02/06/2023 To: 02/12/2023"

EMEA/H/C/PSUSA/00011007/202312
(budesonide (for centrally authorised products indicated for primary immunoglobulin A nephropathy only))
CAPS:
Kinpeygo (EMEA/H/C/005653) (Budesonide), STADA Arzneimittel AG, Rapporteur: Christian Gartner, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "14/06/2023 To: 14/12/2023"

B.4. EPARs / WPARs

Avzivi – Bevacizumab – EMEA/H/C/005574

FGK Representative Service GmbH, treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer; first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer; first line treatment of patients with advanced and/or metastatic renal cell cancer, Similar biological application (Article 10(4) of Directive No 2001/83/EC)

Balversa - Erdafitinib - EMEA/H/C/006050 For information only. Comments can be sent to Janssen-Cilag International N.V., treatment of

adult patients with locally advancedunresectableor metastatic urothelial carcinoma (UC), New active substance (Article 8(3) of Directive No 2001/83/EC)	the PL in case necessary.
Enzalutamide Viatris - Enzalutamide - EMEA/H/C/006299 Viatris Limited, treatment of prostate cancer, Generic, Generic of Xtandi, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
EURneffy - Epinephrine - EMEA/H/C/006139 Ars Pharmaceuticals Irl Limited, Treatment of allergic reactions (anaphylaxis) and idiopathic or exercise induced anaphylaxis, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Masitinib AB Science - Masitinib - EMEA/H/C/005897, Orphan AB Science, in combination with riluzole for the treatment of adult patients with amyotrophic lateral sclerosis (ALS), 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.
mRESVIA - Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation - EMEA/H/C/006278 Moderna Biotech Spain S.L., Prevention of lower respiratory tract disease (LRTD) and acute respiratory disease (ARD) caused by respiratory syncytial virus (RSV), 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.
Nilotinib Accord - Nilotinib - EMEA/H/C/006315 Accord Healthcare S.L.U., treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (CML), Generic, Generic of Tasigna, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Ordspono - Odronextamab - EMEA/H/C/006215, Orphan Regeneron Ireland Designated Activity Company, treatment of blood cancers (follicular lymphoma (FL) or diffuse large B cell lymphoma (DLBCL) and large B cell lymphoma), 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.

Piasky - Crovalimab - EMEA/H/C/006061 Roche Registration GmbH, treatment of paroxysmal nocturnal haemoglobinuria, 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.
STEQEYMA - Ustekinumab - EMEA/H/C/005918 Celltrion Healthcare Hungary Kft., treatment of adult patients with moderately to severely active Crohn's disease, treatment of adult patients with moderately to severely active Crohn's disease, plaque psoriasis, paediatric plaque psoriasis and Psoriatic arthritis (PsA), 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.
Syfovre - Pegcetacoplan - EMEA/H/C/005954 Apellis Europe B.V., Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD), 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.
Tauvid - Flortaucipir (18F) - EMEA/H/C/006064 Eli Lilly Nederland B.V., indicated for Positron Emission Tomography (PET) imaging of the brain, 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.
Winrevair - Sotatercept - EMEA/H/C/005647, Orphan Merck Sharp & Dohme B.V., treatment of pulmonary arterial hypertension 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.
Zegalogue – Dasiglucagon – EMEA/H/C/006214 Zealand Pharma A/S, treatment of severe hypoglycemia in patients with diabetes, 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.

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

Afstyla - Lonoctocog alfa -	Positive Opinion adopted by consensus on

EMEA/H/C/004075/II/0055 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 11.07.2024.	11.07.2024.
Benlysta - Belimumab - EMEA/H/C/002015/II/0130 GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0022/G Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher	
BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/II/0016 Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, Co-Rapporteur: Daniela Philadelphy	
Bortezomib SUN - Bortezomib - EMEA/H/C/004076/II/0023 Sun Pharmaceutical Industries Europe B.V., Generic of VELCADE, Rapporteur: Margareta Bego Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Brineura - Cerliponase alfa - EMEA/H/C/004065/II/0045/G, Orphan BioMarin International Limited, Rapporteur: Martina Weise	
BroPair Spiromax - Salmeterol / Fluticasone propionate - EMEA/H/C/005591/II/0011 Teva B.V., Rapporteur: John Joseph Borg Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Cablivi - Caplacizumab - EMEA/H/C/004426/II/0049/G, Orphan Ablynx NV, Rapporteur: Filip Josephson Opinion adopted on 04.07.2024.	Positive Opinion adopted by consensus on 04.07.2024.
Cresemba - Isavuconazole - EMEA/H/C/002734/II/0046, Orphan Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Patrick Vrijlandt	
Darzalex - Daratumumab - EMEA/H/C/004077/II/0073/G, Orphan Janssen-Cilag International N.V., Rapporteur:	

Aaron Sosa Mejia Request for Supplementary Information adopted on 06.06.2024.	
DuoTrav - Travoprost / Timolol - EMEA/H/C/000665/II/0068/G Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes Opinion adopted on 04.07.2024. Request for Supplementary Information adopted on 16.05.2024.	Positive Opinion adopted by consensus on 04.07.2024.
Emtricitabine/Tenofovir disoproxil Mylan – Emtricitabine/Tenofovir disoproxil - EMA/VR/0000177324 Mylan Pharmaceuticals Limited, Rapporteur: Vilma Petrikaite, Type II -Quality	
Emtricitabine/Tenofovir disoproxil Mylan – Emtricitabine/Tenofovir disoproxil - EMA/VR/0000177462 Mylan Pharmaceuticals Limited, Rapporteur: Bruno Sepodes, type II -Quality	
Entyvio - Vedolizumab - EMEA/H/C/002782/II/0083/G Takeda Pharma A/S, Rapporteur: Paolo Gasparini	
Esperoct - Turoctocog alfa pegol - EMEA/H/C/004883/II/0024/G Novo Nordisk A/S, Rapporteur: Daniela Philadelphy	
Fluad Tetra - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0053 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Flucelvax Tetra - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/II/0045 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 27.06.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Fluenz - Influenza vaccine (live attenuated, nasal) - EMEA/H/C/006514/II/0001 AstraZeneca AB, Rapporteur: Christophe Focke Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.

Gardasil 9 - Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0074 Merck Sharp & Dohme B.V., Rapporteur: Kristina Dunder	
Gilenya - Fingolimod - EMEA/H/C/002202/II/0088 Novartis Europharm Limited, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 25.04.2024.	
Herzuma - Trastuzumab - EMEA/H/C/002575/II/0061/G Celltrion Healthcare Hungary Kft., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 18.07.2024, 11.04.2024.	Request for supplementary information adopted with a specific timetable.
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0150/G CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 18.07.2024. Request for Supplementary Information adopted on 21.03.2024.	Positive Opinion adopted by consensus on 18.07.2024.
Imfinzi - Durvalumab - EMEA/H/C/004771/II/0067/G AstraZeneca AB, Rapporteur: Aaron Sosa Mejia	
IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0104/G Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus	
Inhixa - Enoxaparin sodium - EMEA/H/C/004264/II/0109 Techdow Pharma Netherlands B.V., Rapporteur: Christian Gartner Request for Supplementary Information adopted on 20.06.2024.	
Juluca - Dolutegravir / Rilpivirine - EMEA/H/C/004427/II/0059/G ViiV Healthcare B.V., Rapporteur: Janet Koenig	
Kengrexal - Cangrelor - EMEA/H/C/003773/II/0033 Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt	

Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0155 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini Request for Supplementary Information adopted on 04.07.2024.	Request for supplementary information adopted with a specific timetable.
Klisyri - Tirbanibulin - EMEA/H/C/005183/II/0014/G Almirall, S.A., Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 14.03.2024.	
Leqvio - Inclisiran - EMEA/H/C/005333/II/0027/G Novartis Europharm Limited, Rapporteur: Martina Weise Opinion adopted on 04.07.2024. Request for Supplementary Information adopted on 30.05.2024.	Positive Opinion adopted by consensus on 04.07.2024.
LIVOGIVA - Teriparatide - EMEA/H/C/005087/II/0012 Theramex Ireland Limited, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 04.07.2024.	Request for supplementary information adopted with a specific timetable.
M-M-RvaxPro - Measles, mumps and rubella vaccine (live) - EMEA/H/C/000604/II/0124/G Merck Sharp & Dohme B.V., Rapporteur: Jan Mueller-Berghaus	
Mircera - Methoxy polyethylene glycol-epoetin beta - EMEA/H/C/000739/II/0099/G Roche Registration GmbH, Rapporteur: Antonio Gomez-Outes Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 16.05.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Mounjaro - Tirzepatide - EMEA/H/C/005620/II/0022 Eli Lilly Nederland B.V., Rapporteur: Martina Weise Request for Supplementary Information adopted on 20.06.2024.	
Nustendi - Bempedoic acid / Ezetimibe - EMEA/H/C/004959/II/0046 Daiichi Sankyo Europe GmbH, Rapporteur:	

Patrick Vrijlandt	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0063/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 04.07.2024, 25.04.2024.	Request for supplementary information adopted with a specific timetable.
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0070/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 20.06.2024.	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0071/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0075 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt	
Pegasys - Peginterferon alfa-2a - EMEA/H/C/000395/II/0120 Pharmaand GmbH, Rapporteur: Filip Josephson	
Pemetrexed Accord - Pemetrexed - EMEA/H/C/004072/II/0028 Accord Healthcare S.L.U., Generic of Alimta, Rapporteur: John Joseph Borg Opinion adopted on 18.07.2024. Request for Supplementary Information adopted on 15.02.2024.	Positive Opinion adopted by consensus on 18.07.2024.
Praluent - Alirocumab - EMEA/H/C/003882/II/0091/G Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 18.07.2024.	Request for supplementary information adopted with a specific timetable.
Puregon - Follitropin beta - EMEA/H/C/000086/II/0130 Organon N.V., Rapporteur: Finbarr Leacy	
Qarziba - Dinutuximab beta - EMEA/H/C/003918/II/0056/G, Orphan Recordati Netherlands B.V., Rapporteur: Peter Mol	Positive Opinion adopted by consensus on 11.07.2024.

Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 02.05.2024, 15.02.2024.	
Ranivisio - Ranibizumab - EMEA/H/C/005019/II/0015/G Midas Pharma GmbH, Rapporteur: Jan Mueller-Berghaus	
Rezzayo - Rezafungin - EMEA/H/C/005900/II/0002, Orphan Mundipharma GmbH, Rapporteur: Bruno Sepodes Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Rystiggo - Rozanolixizumab - EMEA/H/C/005824/II/0003, Orphan UCB Pharma, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 18.07.2024.	Positive Opinion adopted by consensus on 18.07.2024.
Ryzneuta - Efbemalenograstim alfa - EMEA/H/C/005828/II/0001 Evive Biotechnology Ireland Limited, Rapporteur: Vilma Petrikaite Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Seffalair Spiromax - Salmeterol / Fluticasone propionate - EMEA/H/C/004881/II/0011 Teva B.V., Rapporteur: John Joseph Borg Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0004, Orphan Reata Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Soliris - Eculizumab - EMEA/H/C/000791/II/0132, Orphan Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez	
Spectrila - Asparaginase - EMEA/H/C/002661/II/0040 medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Christian Gartner Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Tabrecta - Capmatinib - EMEA/H/C/004845/II/0007/G Novartis Europharm Limited, Rapporteur:	Positive Opinion adopted by consensus on 18.07.2024.

Carolina Prieto Fernandez Opinion adopted on 18.07.2024. Request for Supplementary Information adopted on 16.05.2024, 18.01.2024.	
Travatan - Travoprost - EMEA/H/C/000390/II/0071/G Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes Opinion adopted on 04.07.2024. Request for Supplementary Information adopted on 16.05.2024.	Positive Opinion adopted by consensus on 04.07.2024.
TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0033 Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 02.05.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Tysabri - Natalizumab - EMEA/H/C/000603/II/0143/G Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 23.05.2024.	
Uzpruvo - Ustekinumab - EMEA/H/C/006101/II/0002/G STADA Arzneimittel AG, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0144 MCM Vaccine B.V., Rapporteur: Christophe Focke	
VEGZELMA - Bevacizumab - EMEA/H/C/005534/II/0010/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Voxzogo - Vosoritide - EMEA/H/C/005475/II/0015, Orphan BioMarin International Limited, Rapporteur: Martina Weise	

WS2529 **Keppra-EMEA/H/C/000277/WS2529/0200** UCB Pharma S.A., Lead Rapporteur: Karin Janssen van Doorn, Lead PRAC Rapporteur: Jo Robays Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
WS2634 **Hexacima-EMEA/H/C/002702/WS2634/0154** **Hexyon-EMEA/H/C/002796/WS2634/0158** Sanofi Pasteur Europe, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 30.05.2024, 04.04.2024.	Positive Opinion adopted by consensus on 11.07.2024.
WS2642/G **Riltrava Aerosphere-EMEA/H/C/005311/WS2642/0011/G** **Trixeo Aerosphere-EMEA/H/C/004983/WS2642/0018/G** AstraZeneca AB, Lead Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 16.05.2024.	
WS2692/G **Hexacima-EMEA/H/C/002702/WS2692/0157/G** **Hexyon-EMEA/H/C/002796/WS2692/0161/G** Sanofi Pasteur Europe, Lead Rapporteur: Jan Mueller-Berghaus	

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

Alecensa - Alectinib - EMEA/H/C/004164/II/0048 Roche Registration GmbH, Rapporteur: Filip Josephson, "To update sections 4.4 and 4.6 of the SmPC to update the safety information to amend the duration of the period for which female patients of child-bearing potential must use highly effective contraceptive methods following the last dose of Alecensa, and must be informed of potential harm to the fetus in the event of pregnancy, from 3 months to 5 weeks based on the latest guidelines on contraception requirements for drugs with aneugenic	

potential. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

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

Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to change posology recommendations in individuals 16 years of age and older, amend an existing warning on hypersensitivity and anaphylaxis, delete insomnia and back pain from the list of adverse drug reactions (ADRs), change frequency of odynophagia, abdominal pain and injection site hypersensitivity from Uncommon to Rare and update immunogenicity information based on final results from study HIPRA-HH-2 (PART A and PART B) listed as a category 3 study in the RMP; HIPRA-HH-2 was a Phase IIb, double-blind, randomised, active-controlled, multi-centre, non-inferiority trial in adults fully vaccinated against COVID-19. The objective was to assess immunogenicity and safety of a booster vaccination with a recombinant protein RBD fusion heterodimer vaccine candidate (PHH-1V) against SARS-CoV-2 (Part A). An extension to the study was introduced to add a fourth dose as described below (Part B)."
Request for Supplementary Information adopted on 06.06.2024, 21.03.2024.

Cablivi - Caplacizumab - EMEA/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.

Cablivi - Caplacizumab -

EMEA/H/C/004426/II/0050, Orphan Ablynx NV, Rapporteur: Filip Josephson, "Update of section 4.2 of the SmPC in order to include further administration instructions in case the first intravenous dose of caplacizumab is missed and plasma exchange is already administered, based on final results from study ALX0681-C103; this is a Phase 1, single-centre, randomized, double-blind, placebo controlled, 2 part study that evaluated the safety, tolerability, PK/PD profile, and immunogenicity of single IV and SC doses (Part I) or multiple SC doses once daily for 7 days (Part II) of caplacizumab in Japanese and White healthy volunteers. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
CAMZYOS - Mavacamten - EMEA/H/C/005457/II/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-centre, 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." Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Dengvaxia - Dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0030 Sanofi Pasteur, Rapporteur: Christophe Focke, "Submission of the final report from study CYD50 (Safety and Immunogenicity of a Tetravalent Dengue Vaccine in HIV Positive Adults Aged 18 to 50 Years in Brazil) listed as a category 3 study in the RMP. This was a randomized, observer-blind, placebo-controlled, multi-center, Phase II study planned in 150 HIV-positive adults, treated with antiretrovirals, and previously exposed to dengue."	Positive Opinion adopted by consensus on 18.07.2024.

Opinion adopted on 18.07.2024.

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

Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.), Rapporteur: Kristina Dunder, "Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding renal impairment based on final results from study MIT-Do001-C103. This is a Phase 1, open-label, sequential group, single-dose study to evaluate the pharmacokinetics and safety of estetrol monohydrate (E4) in female subjects with varying degrees of renal function. The Package Leaflet is updated accordingly."

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

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

Edarbi - Azilsartan medoxomil - EMEA/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 25.04.2024, 25.01.2024.

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

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

Erleada - Apalutamide - EMEA/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."
Request for Supplementary Information adopted on 20.06.2024.

Evrysdi - Risdiplam - EMEA/H/C/005145/II/0022

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

in Type 2 and 3 Spinal Muscular Atrophy Patients." Request for Supplementary Information adopted on 13.06.2024.	
Evrysdi - Risdiplam - EMEA/H/C/005145/II/0025 Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Update of sections 4.4, 4.5 and 5.3 of the SmPC in order to remove the warning on retinal toxicity, based on thorough ophthalmological monitoring in clinical studies to date." Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Fexinidazole Winthrop - Fexinidazole - EMEA/H/W/002320/II/0017 Sanofi Winthrop Industrie, Rapporteur: Fátima Ventura, "Update of sections 4.2, 4.3, 4.4 and 5.2 of the SmPC in order to add PK information in participants with mild and moderate hepatic impairment based on final results from study POP17145 - A multicentric, open-label, non-randomized, pharmacokinetic and tolerability study of fexinidazole given as an oral single 1200 mg dose in participants with mild and moderate hepatic impairment, and in matched participants with normal hepatic function. The Package Leaflet is updated accordingly."	
Fexinidazole Winthrop - Fexinidazole - EMEA/H/W/002320/II/0018 Sanofi Winthrop Industrie, Rapporteur: Fátima Ventura, "Update of sections 4.5 and 5.2 of the SmPC in order to update information regarding the interaction with CYP3A4/3A5 drugs based mainly on final results from study INT17144; this is an open-label, non-randomized, two-treatment, one-sequence crossover pharmacokinetic interaction study of 5-day repeated oral doses of fexinidazole on a single oral dose of midazolam used as probe substrate for CYP3A4 in healthy male and female participants."	
Kalydeco - Ivacaftor - EMEA/H/C/002494/II/0124 Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Antonio Gomez-Outes, "Submission of the final report from Post-Authorisation Effectiveness Study (PAES) Study VX15-770-125. This is an observational study to evaluate the long-term effectiveness and safety of	Positive Opinion adopted by consensus on 11.07.2024.

Kalydeco in children with cystic fibrosis who have a specified CFTR gating mutation and are aged 2 through 5 years at therapy initiation. Study 125 has been removed from the Annex II.D of the product information." Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 14.03.2024.	
Kisqali - Ribociclib - EMEA/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." Opinion adopted on 04.07.2024. Request for Supplementary Information adopted on 25.04.2024.	Positive Opinion adopted by consensus on 04.07.2024.
Lorviqua - Lorlatinib - EMEA/H/C/004646/II/0034 Pfizer Europe MA EEIG, Rapporteur: Aaron Sosa Mejia, "Submission of the final report from study B7461001. This was a Phase 1/2, open-label, multicentre, multiple-dose, dose escalation, safety, PK, pharmacodynamics, and anti-cancer efficacy exploration study of lorlatinib as a singleagent in participants with advanced ALK-positive or advanced ROS1-positive NSCLC."	
Lydisilka - Drospirenone / Estetrol - EMEA/H/C/005382/II/0025 Estetra SRL, Rapporteur: Kristina Dunder, "Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding renal impairment based on final results from study MIT-Do001-C103. This is a Phase 1, open-label, sequential group, single-dose study to evaluate the pharmacokinetics and safety of estetrol monohydrate (E4) in female subjects with varying degrees of renal function. The Package Leaflet is updated accordingly."	

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

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

Lysodren - Mitotane - EMEA/H/C/000521/II/0029/G

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

Mavenclad - Cladribine - EMEA/H/C/004230/II/0032

Merck Europe B.V., Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.4 of the SmPC in order to update an existing warning on infections. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce an editorial update to the PI."
Request for Supplementary Information adopted on 08.02.2024.

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

Sanofi Pasteur, Rapporteur: Daniela Philadelphy, "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-centre, 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.	
MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine - EMEA/H/C/005084/II/0034/G Sanofi Pasteur, Rapporteur: Daniela Philadelphy, "Grouped application comprising two type II variations as follows: C.I.4 - Update of section 5.1 of the SmPC in order to add 5 years persistence of immune response based on final results from study MEQ00066. MEQ00066 was a Phase III, two--stage, randomized, open-label, multi-center trial to evaluate the immunogenicity and safety of a single dose of MenACYW conjugate vaccine at least 3 years after a prior dose of either MenACYW conjugate vaccine or Menomune. C.I.4 – Update of section 5.1 of the SmPC in order to add immune persistence and booster response data in children based on interim results from study MEQ00073. MEQ00073 is a Phase IIIb, open-label, multi-center study to evaluate the immunogenicity and safety of a booster dose of MenQuadfi administered to children and describe 5- and/or 10-year immune persistence of MenQuadfi after primary vaccination. Annex II is also being updated. In addition, the MAH took the opportunity to introduce editorial changes to the PI." Request for Supplementary Information adopted on 18.07.2024.	Request for supplementary information adopted with a specific timetable.
Mounjaro - Tirzepatide - EMEA/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." Request for Supplementary Information adopted on 13.06.2024.	
MULTAQ - Dronedarone - EMEA/H/C/001043/II/0053 Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt, "Update of section 4.6 of the SmPC in order to update recommendations on contraception, pregnancy and lactation, and to propose pregnancy testing prior to treatment. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Nexavar - Sorafenib - EMEA/H/C/000690/II/0059, Orphan Bayer AG, Rapporteur: Filip Josephson, "Update of section 5.3 of the SmPC in order to update preclinical safety data on carcinogenicity studies based on final results from studies T4079666 - Carcinogenicity Study in CD-1 Mice (2 Years Administration by Diet) and T8076320 - Carcinogenicity Study in Wistar Rats (2 Years Administration in the Diet with Dose Adjustment). In addition, the MAH took the opportunity to introduce editorial changes to the PI and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 04.07.2024.	Request for supplementary information adopted with a specific timetable.
Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0135	Positive Opinion adopted by consensus on 11.07.2024.

Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang, "Update of section 5.1 of the SmPC in order to update immunogenicity response information based on results from Study C0921062 and following EMEA/H/C/002226/P46/057 procedure. Study C0921062 is a Phase 3b, open-label, with a single-arm design study, to evaluate the safety and immunogenicity of a single dose of Nimenrix in infants at 3 months of age, followed by a booster dose at 12 months of age. In addition, the MAH took the opportunity to implement editorial changes in the SmPC" Opinion adopted on 11.07.2024.	
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.	
Opfolda - Miglustat - EMEA/H/C/005695/II/0013 Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, "Update of section 4.8 SmPC in order to update the frequency of adverse drug reactions and to add ''paraesthesia'' to the list of adverse drug reactions (ADRs) with frequency ''common'' based on an updated pooled analysis (Pool 2) of integrated safety data of Phase 2/3 studies (Study ATB200-02, Study ATB200-03 and Study ATB200-07). The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
OZAWADE - Pitolisant - EMEA/H/C/005117/II/0007 Bioprojet Pharma, Rapporteur: Peter Mol, "Submission of the final report from study P21-03. This is an open label, single centre, drug-drug interaction study to evaluate the effect of a	

combination of itraconazole and paroxetine treatment on the pitolisant pharmacokinetics at steady-state in eighteen healthy male Caucasian subjects." Request for Supplementary Information adopted on 02.05.2024, 01.02.2024.	
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0052/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "A grouped application comprised of 2 Type II Variations, as follows: C.I.4: Update of section 4.5 of the SmPC in order to include more detailed dosing information within the clinical comments for the drug-drug interactions (DDIs) related to venetoclax, apixaban, saxagliptin and cariprazine and to remove the reference to the dabigatran SmPC in the dabigatran DDI clinical comments. C.I.4: Update of section 5.2 of the SmPC in order to include additional information related to the rosuvastatin DDI, based on the final results from study C4671052; this is a phase 1, randomized, fixed sequence, multiple dose, open-label study to estimate the effect of nirmatrelvir/ritonavir on rosuvastatin pharmacokinetics in healthy adult participants." Request for Supplementary Information adopted on 11.07.2024, 02.05.2024.	Request for supplementary information adopted with a specific timetable.
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0056 Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Update of section 4.6 of the SmPC in order to update information on breastfeeding based on final results from study C4671039 listed as a category 3 study in the RMP (MEA/018.2); this is a Phase I, multiple dose, pharmacokinetic and safety study in healthy lactating adult women. The package leaflet is updated accordingly." Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Piqray - Alpelisib - EMEA/H/C/004804/II/0025 Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update the frequency of Adverse Drug Reactions and safety information based on final results from	Positive Opinion adopted by consensus on 11.07.2024.

study CBYL719C2301 (SOLAR-1). This is a randomized, double-blind, placebo-controlled, international, multicentre, Phase III study to determine the efficacy and safety of treatment with alpelisib plus fulvestrant versus placebo plus fulvestrant in men and postmenopausal women with hormone receptor-positive, HER2-negative advanced breast cancer which progressed on or after AI (Aromatase Inhibitor) treatment. The Package Leaflet is updated accordingly." Opinion adopted on 11.07.2024.	
Pombiliti - Cipaglucosidase alfa - EMEA/H/C/005703/II/0012 Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, "Update of section 4.8 of the SmPC in order to update the frequency of adverse drug reactions and to add swelling face to the list of adverse drug reactions (ADRs) with frequency Uncommon based on the updated integrated analysis of safety data for Pool 2 (All Studies ATB200-02/03/07). The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
PONVORY - Ponesimod - EMEA/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 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.	
Prevenar 20 - Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0026 Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphy, "Update of sections 4.2 and 5.1 of the SmPC in order to introduce a vaccination schedule for children 12 months to 23 months of age transitioning from another pneumococcal conjugate vaccine and to update clinical information based on the final results from the	

paediatric study B7471027; this is a phase 3, randomized, partially double-blind trial to evaluate the safety and immunogenicity of 20-valent pneumococcal conjugate vaccine in healthy toddlers 12 through 23 months of age with 2 prior infant doses of Prevenar 13. The Package Leaflet is updated accordingly."	
Pylclari - Piflufolastat (18F) - EMEA/H/C/005520/II/0004 Curium Pet France, Rapporteur: Antonio Gomez-Outes, "Update of section 11 of the SmPC in order to update information on dosimetry data based on results obtained with a new generation software. In addition, the MAH took the opportunity to implement editorial changes to the SmPC." Opinion adopted on 18.07.2024.	Positive Opinion adopted by consensus on 18.07.2024.
Repatha - Evolocumab - EMEA/H/C/003766/II/0069 Amgen Europe B.V., Rapporteur: Patrick Vrijlandt, "Update of section 5.1 of the SmPC to include Real World Data information based on final results from study 20130296; this is an observational study to describe the clinical characteristics of patients on initiation of Repatha, with a secondary objective to describe the treatment patterns of Repatha use over time." Request for Supplementary Information adopted on 14.03.2024.	
Revestive - Teduglutide - EMEA/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 as a precaution to 'Gastrointestinal neoplasia including hepatobiliary tract' based on the cumulative review of literature. Furthermore, section 4.8 is updated with information about location of the small intestinal polyps. In addition, the MAH took the opportunity to introduce minor editorial changes and to bring the PI in line with the latest QRD template." Opinion adopted on 04.07.2024. Request for Supplementary Information adopted on 25.04.2024.	Positive Opinion adopted by consensus on 04.07.2024.

Saxenda - Liraglutide - EMEA/H/C/003780/II/0041 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Update of section 4.8 of the SmPC in order to add 'intestinal obstruction' to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI in order to align with the latest QRD requirements." Opinion adopted on 18.07.2024.	Positive Opinion adopted by consensus on 18.07.2024.
Skilarence - Dimethyl fumarate - EMEA/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 25.04.2024, 14.12.2023.	
Soliris - Eculizumab - EMEA/H/C/000791/II/0131, Orphan Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, "Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic information based on final results from study ECU-MG-303; this is a Phase 3, open-label, multicenter study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of eculizumab in pediatric patients with refractory generalized myasthenia gravis (gMG). In addition, the MAH took the opportunity to introduce minor changes to the PI." Request for Supplementary Information adopted on 18.07.2024.	Request for supplementary information adopted with a specific timetable.
Sunlenca - Lenacapavir - EMEA/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	See 9.1

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 13.06.2024, 11.04.2024, 18.01.2024.	
Trumenba - Meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0052 Pfizer Europe MA EEIG, Rapporteur: Patrick Vrijlandt, "Update of sections 4.2 and 4.8 of the SmPC in order to add information regarding fever in infants 2 months of age based on final results from study C3511002; this is a Phase 2b trial to assess the safety, tolerability, and immunogenicity of MenABCWY in healthy infants 2 and 6 months of age. In addition, the MAH is taking this opportunity to implement a minor editorial update to SmPC Section 4.4 to add a 'Traceability' subheading, in line with the QRD product information template version 10.3. Furthermore, as suggested by PEI in the linguistic review phase of variation procedure EMEA/H/C/004051/II/0037, the MAH is adding an 'Excipients' subheading to SmPC Section 4.4." Request for Supplementary Information adopted on 30.05.2024, 21.03.2024.	
Verzenios - Abemaciclib - EMEA/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." Opinion adopted on 04.07.2024. Request for Supplementary Information adopted on 25.04.2024.	Positive Opinion adopted by consensus on 04.07.2024.
Wegovy - Semaglutide - EMEA/H/C/005422/II/0019 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt,	See 9.1

"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.	
Wegovy - Semaglutide - EMEA/H/C/005422/II/0022 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Update of section 4.8 of the SmPC in order to add "Dysaesthesia" to the list of adverse drug reactions (ADRs) with frequency "common" based on post marketing data and literature. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 18.07.2024.	Request for supplementary information adopted with a specific timetable.
Xeljanz - Tofacitinib - EMEA/H/C/004214/II/0059 Pfizer Europe MA EEIG, Rapporteur: Paolo Gasparini, "Update of section 4.4 of the SmPC in order to update serious infections section based on post marketing data and literature. In addition, the MAH has taken the opportunity to implement changes to improve readability and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 13.06.2024, 14.03.2024.	
XGEVA - Denosumab - EMEA/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 04.07.2024, 04.04.2024.	Request for supplementary information adopted with a specific timetable.
Xultophy - Insulin degludec / Liraglutide - EMEA/H/C/002647/II/0052 Novo Nordisk A/S, Rapporteur: Kristina Dunder,	Request for supplementary information adopted with a specific timetable.

"Update of section 4.8 of the SmPC in order to add 'intestinal obstruction' to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI in order to align with the latest QRD requirements." Request for Supplementary Information adopted on 18.07.2024.	
WS2647 **Mekinist-** **EMEA/H/C/002643/WS2647/0066** **Tafinlar-** **EMEA/H/C/002604/WS2647/0071** Novartis Europharm Limited, Lead Rapporteur: Peter Mol, "Update of section 5.1 of the SmPC for Tafinlar and Mekinist in order to update efficacy information based on final results from study CDRB436F2301 (COMBI-AD); this is a phase 3 randomized double blind study of dabrafenib in combination with trametinib versus two placebos in the adjuvant treatment of high-risk BRAF V600 mutation-positive melanoma after surgical resection. The RMP version 11.1 for Tafinlar and version 19.2 for Mekinist have also been submitted. In addition, MAH took the opportunity to introduce minor editorial changes to the Product Information." Request for Supplementary Information adopted on 27.06.2024.	
WS2683 **Relvar Ellipta-** **EMEA/H/C/002673/WS2683/0068** **Revinty Ellipta-** **EMEA/H/C/002745/WS2683/0065** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Antonio Gomez-Outes, "Update of section 5.1 of the SmPC in order to update the results of study HZA107116 - A randomised, double-blind, parallel group, multicentre, stratified, study evaluating the efficacy and safety of once daily fluticasone furoate/vilanterol inhalation powder compared to once daily fluticasone furoate inhalation powder in the treatment of asthma in participants aged 5 to 17 years old (inclusive) currently uncontrolled on inhaled corticosteroids." Opinion adopted on 04.07.2024.	Positive Opinion adopted by consensus on 04.07.2024.

Request for Supplementary Information adopted on 30.05.2024.	
WS2691 **Hycamtin-EMEA/H/C/000123/WS2691/0102** Sandoz Pharmaceuticals d.d., Lead Rapporteur: Filip Josephson, "Update of section 4.6 of the SmPC in order to update recommendations on duration of contraception in males and females, in line with the SWP/NcWP recommendations (EMA/CHMP/SWP/74077/2020 rev. 1*) on the duration of contraception following the end of treatment with a genotoxic drug and based on the proposed wording suggested in the CMDh report for EMA/CMDh/409368/2021. The Package Leaflet is updated accordingly." Opinion adopted on 04.07.2024.	Positive Opinion adopted by consensus on 04.07.2024.
WS2693 **Finlee-EMEA/H/C/005885/WS2693/0007** **Spexotras-EMEA/H/C/005886/WS2693/0006** Novartis Europharm Limited, Lead Rapporteur: Filip Josephson, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to add photosensitivity to the list of adverse drug reactions (ADRs) with frequency Common respectively and to update efficacy and safety information on paediatric population based on final results from study CDRB436G2201; this is a phase II open-label global study to evaluate the effect of dabrafenib in combination with trametinib in children and adolescent patients with BRAF V600 mutation positive Low Grade Glioma (LGG) or relapsed or refractory High Grade Glioma (HGG). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes." Opinion adopted on 18.07.2024.	Positive Opinion adopted by consensus on 18.07.2024.
WS2701 **Ofev-EMEA/H/C/003821/WS2701/0061** **Vargatef-EMEA/H/C/002569/WS2701/0053** Boehringer Ingelheim International GmbH, Lead Rapporteur: Finbarr Leacy, "Update of sections 4.4 and 4.8 of the SmPC in order to add 'posterior reversible encephalopathy syndrome (PRES)' to the list of adverse drug reactions (ADRs) with frequency 'Not known' based on	Positive Opinion adopted by consensus on 04.07.2024.

postmarketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and update the list of representatives." Opinion adopted on 04.07.2024.	
WS2707 **Celldemic-** **EMEA/H/C/006052/WS2707/0001** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2707/0003** Seqirus Netherlands B.V., Lead Rapporteur: Daniela Philadelphy, "Submission of the final report from extension study V89_18E1 (NCT05422326). This is a Phase 2, Randomized, Study to Evaluate Safety and Immunogenicity of One or Two Heterologous Booster Vaccinations With an MF59-adjuvanted, Cell Culture-derived H5N6 Influenza Vaccine in Adults Primed With MF59-adjuvanted, Cell Culture-derived H5N1 Influenza Vaccine or Unprimed. "	

B.5.3. CHMP-PRAC assessed procedures

Akeega - Niraparib / Abiraterone acetate - **EMEA/H/C/005932/II/0003** Janssen-Cilag International N.V., Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Jan Neuhauser, "Update of sections 4.8 and 5.1 of the SmPC in order to update the frequency of adverse drug reactions and to update information from MAGNITUDE study based on final results from study 64091742PCR3001 (MAGNITUDE) listed as a PAES in the Annex II. This was a phase 3, randomized, placebo-controlled, double-blind study of niraparib in combination with abiraterone acetate and prednisone versus abiraterone acetate and prednisone for treatment of subjects with metastatic prostate cancer. The MAH took this opportunity to make an alignment of wording between sections 4.2 and 4.4 of the SmPC. The Annex II and Package Leaflet are updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took this opportunity to update the list of local representatives in the Package Leaflet, and to introduce editorial changes to the PI." Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.

Request for Supplementary Information adopted on 16.05.2024.	
Dapivirine Vaginal Ring 25 mg - Dapivirine - EMEA/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. " Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 13.06.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Fintepla - Fenfluramine - EMEA/H/C/003933/II/0022/G, Orphan UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, "A grouped application comprised of three Type II variations, as follows: C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to modify the list of adverse drug reactions based on a revised safety ADR methodology for Dravet and Lennox-Gastaut syndromes, which includes pooled analyses encompassing studies ZX008-1503 and ZX008-1601 cohort B. The Package Leaflet is updated accordingly. C.I.4: Update of section 5.1 of the SmPC in order to update clinical efficacy information for Dravet syndrome based on final results from study ZX008-1503 listed as a category 3 study in the RMP. This is an open-label extension trial to assess the long-term safety of ZX008 (fenfluramine hydrochloride) oral solution as an adjunctive therapy in children and young adults with Dravet syndrome. C.I.4: Update of section 5.1 of the SmPC in	

order to update clinical efficacy information for Lennox-Gastaut syndrome based on final results from study ZX008-1601 Part 1 cohort B and interim results for study ZX008-1601 Part 2 cohort B. Study 1601 Part 1 was an international, randomized, double-blind, parallel-group, placebo-controlled study in subjects with LGS 2 to 35 years of age, while study 1601 Part 2 is a long-term, open-label, flexible-dose extension for subjects who completed study 1601 Part 1. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information, including to section 4.2 of the SmPC" Request for Supplementary Information adopted on 27.06.2024, 21.03.2024.	
ILARIS - Canakinumab - EMEA/H/C/001109/II/0085 Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0100 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Update of section 5.1 of the SmPC in order to add vaccine effectiveness data, and the removal of the two open specific obligations (POX-MVA-039 (SOB02) and SEMVAc (SOB03)), based on the IMVANEX vaccine effectiveness data in real-world use during the 2022 monkeypox outbreak. Consequently, the MAH proposes a switch from exceptional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 30.05.2024, 21.03.2024.	
JCOVDEN - COVID-19 Vaccine Janssen (Ad26.COV2.S) - EMEA/H/C/005737/II/0076	Positive Opinion adopted by consensus on 11.07.2024.

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, "Update of section 4.5 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."
Opinion adopted on 11.07.2024.
Request for Supplementary Information adopted on 11.04.2024.

LUMYKRAS - Sotorasib - EMEA/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 Multicentre, 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 Tumours 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 25.04.2024, 14.12.2023, 25.05.2023.

Nyxoid - Naloxone - EMEA/H/C/004325/II/0019 Mundipharma Corporation (Ireland) Limited, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Liana Martirosyan, "Submission of the interim report from the PAES MR903-9501 listed as an obligation in the Annex II, supported by Real World Evidence from literature and European Take-Home Naloxone programs (THN) demonstrating the effectiveness of Nyxoid in a real-world setting. Study MR903-9501 is a non-interventional multi-national, prospective, mixed methods study of the effectiveness of naloxone (including intranasal Nyxoid) administration by lay people in reversing opioid overdose. The Annex II and the RMP version 3.0 are updated accordingly. In addition, the MAH took the opportunity to introduce minor administrative changes to the Package Leaflet."	
Ocrevus - Ocrelizumab - EMEA/H/C/004043/II/0041 Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.6 and 5.3 of the SmPC in order to amend the recommendations for breast-feeding during ocrelizumab therapy, based on newly available clinical data. The Package Leaflet is updated accordingly. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0057/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Martin Huber, "Grouped application consisting of: C.I.4: Update of sections 4.2, 4.4, 4.8 and 5.2 of the SmPC in order to provide a new dosing recommendation in patients with severe renal impairment based on final results from study C4671028; this is a Phase 1, Open-Label, Non-Randomized Study to Investigate the Safety and PK Following Multiple Oral Doses of PF-07321332 (Nirmatrelvir)/Ritonavir in Adult Participants With COVID-19 and Severe Renal Impairment Either on Hemodialysis or Not on Hemodialysis. The Package Leaflet and Labelling	

are updated accordingly. The updated RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. ”	
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, multicentre, 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.” Request for Supplementary Information adopted on 25.04.2024.	
Retsevmo - Selpercatinib - EMEA/H/C/005375/II/0032 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder, “Update of sections 4.8, 5.1 and 5.2 of the SmPC based on efficacy, safety and pk information from study LIBRETTO-531 (JZJB) listed as a specific obligation in the Annex II; This study is a Phase 3 confirmatory study comparing selpercatinib to physicians’ choice of cabozantinib or vandetanib in patients with progressive advanced, kinase inhibitor naive	Positive Opinion adopted by consensus on 11.07.2024.

RET-mutant medullary thyroid cancer (MTC). The Package Leaflet and Annex II are updated accordingly. The RMP version 12.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Opinion adopted on 11.07.2024.	
Rybelsus - Semaglutide - EMEA/H/C/004953/II/0041 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Mari Thorn, "Update of section 4.6 of the SmPC in order to update information on breast-feeding based on final results from study NN9924-4669. This was an open-label, single-armed, multiple-dose, multi-centre study evaluating the semaglutide and SNAC concentrations in breastmilk from healthy lactating women dosed once daily with oral semaglutide for 10 days (3 mg for 5 days followed by 7 mg for 5 days). The primary endpoints were evaluated during a 24 hours pharmacokinetic (PK) sampling period after the 10th dose. The package leaflet is updated accordingly. The RMP version 9.0 has also been submitted." Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0136 Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen Request for Supplementary Information adopted on 27.06.2024.	
Tecvayli - Teclistamab - EMEA/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." Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.

Request for Supplementary Information adopted on 11.04.2024.	
VELSIPITY - Etrasimod - EMEA/H/C/006007/II/0002/G Pfizer Europe MA EEIG, Rapporteur: Martina Weise, PRAC Rapporteur: Mari Thorn, "A grouped application comprised of two Type II variations, as follows: C.I.4: Update of sections 4.2, 4.3 and 5.2 of the SmPC in order to amend recommendation regarding administration to patients with severe hepatic impairment and remove contraindication for severe hepatic impairment, based on in vitro studies to further characterise the drug-drug interaction (DDI) potential of metabolites M3 and M6. The Annex II and Package Leaflet are updated accordingly. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.13: Submission of the final report from study 24GR036 (hERG Channel Automated Patch-Clamp Test); this is an assessment of the effects of PF-08034694, PF-08034742, PF-08039030, and PF-08039032 on the Kv11.1 (hERG) potassium current."	
VPRIV - Velaglucerase alfa - EMEA/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 25.04.2024, 14.12.2023.	
Zeposia - Ozanimod - EMEA/H/C/004835/II/0024/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, "Grouped application comprising two variations as follows: Type II (C.I.4) – Update of section 4.4 in order to amend a prior warning on liver function as liver injury based on the cumulative review of	Positive Opinion adopted by consensus on 11.07.2024.

the MAH safety database, clinical trials, and literature search. Update of section 4.8 to add liver injury with frequency rare and to move alanine aminotransferase increased, gamma-glutamyl transferase increased, and blood bilirubin increased from the SOC "Investigations" to the SOC "Hepatobiliary disorders" with frequency "common". The PL has been updated accordingly. The RMP has been updated to version 8.1. Type IA (A.6) – To change the ATC code from L04AA38 to L04AE02." Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 13.06.2024.	
ZTALMY - Ganaxolone - EMEA/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: 1 Type II (C.I.4): Update of section 5.2 of the SmPC in order to update ganaxolone metabolite pattern at steady state based on re-analysis of 1042-TQT-1001 listed as a category 3 study in the RMP to evaluate the ganaxolone steady-state metabolite. 7 Type II (C.I.13): Submission of the final non-clinical study reports for the in vitro DDI potential and in vivo PK of the metabolite M17 listed as category 3 studies in the RMP. 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.	
WS2664 **Ebymect-EMEA/H/C/004162/WS2664/0066** **Qtern-EMEA/H/C/004057/WS2664/0043** **Xigduo-EMEA/H/C/002672/WS2664/0076** AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Bianca Mulder, "Update of sections 4.2, 4.4, 4.5, 4.8, 5.1 and 6.1 of the SmPC in order to align dapagliflozin related information in Fixed Dose Combination with Forxiga. The Package Leaflet is updated accordingly. The RMPs version 15.1 (Xigduo and	

Wbymect) and 9.1 (Qtern) has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI." Request for Supplementary Information adopted on 13.06.2024.	
WS2695 **Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-EMEA/H/W/005362/WS2695/0015** **Qdenga-EMEA/H/C/005155/WS2695/0016** Takeda GmbH, Lead Rapporteur: Sol Ruiz, Lead PRAC Rapporteur: Liana Martirosyan, "Update of section 4.4 and 4.8 of the SmPC in order to add anaphylactic reaction to the list of adverse drug reactions (ADRs) with frequency not known, based on post-authorization experience. The Package Leaflet is updated accordingly. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
WS2702 **Ongentys-EMEA/H/C/002790/WS2702/0066** **Ontilyv-EMEA/H/C/005782/WS2702/0021** Bial - Portela & Cª, S.A., Lead Rapporteur: Martina Weise, Lead PRAC Rapporteur: Maria del Pilar Rayon, "Update of section 4.8 of the SmPC in order to add 'fall' and 'fatigue' to the list of adverse drug reactions (ADRs) with frequency uncommon based on the cumulative review of literature. The Package Leaflet is updated accordingly. The Ongentys RMP version 6.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes to the PI." Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-EMEA/H/W/005362/WS2593/0012 **Qdenga-**	Request for supplementary information adopted with a specific timetable.

EMEA/H/C/005155/WS2593/0013 Takeda GmbH, Lead Rapporteur: Sol Ruiz, Lead PRAC Rapporteur: Liana Martirosyan, "Update of section 4.5 of the SmPC in order to add co-administration information with HPV vaccine based on final results from study DEN-308 listed as a category 3 study in the RMP (MEA003/MEA004); this is a Phase 3, open-label, randomized trial to investigate the immunogenicity and safety of the co-administration of a subcutaneous dengue tetravalent vaccine (live, attenuated) (TDV) and an intramuscular recombinant 9-valent human papillomavirus (9vHPV) vaccine in subjects aged ≥9 to <15 years in an endemic country for dengue; the Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes and to update the text on PSUR submissions in Annex II for Dengue tetravalent vaccine." Request for Supplementary Information adopted on 11.07.2024, 16.05.2024, 07.03.2024.	

B.5.4. PRAC assessed procedures

PRAC Led **Bavencio - Avelumab - EMEA/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	Positive Opinion adopted by consensus on 11.07.2024.

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." Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 11.04.2024.	
PRAC Led **Beovu - Brolucizumab - EMEA/H/C/004913/II/0028** Novartis Europharm Limited, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 4.8 of the SmPC in order to add 'Scleritis' to the list of adverse drug reactions (ADRs) with frequency 'Not known', following the recommendation by PRAC in the outcome for the signal assessment of Scleritis. The Package Leaflet is updated accordingly." Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 16.05.2024.	Positive Opinion adopted by consensus on 11.07.2024.
PRAC Led **BLINCYTO - Blinatumomab - EMEA/H/C/003731/II/0054, Orphan** Amgen Europe B.V., PRAC Rapporteur: Jana Lukacisinova, PRAC-CHMP liaison: Petr Vrbata, "To update sections 4.2, 4.4, 4.8 of the SmPC to include Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS); and to update section D of Annex II to remove educational materials for physicians, pharmacists and nurses and to include ICANS within neurologic events in educational material for patient/caregivers and patient alert card following the outcome of PSUR procedure EMEA/H/C/PSUSA/00010460/202212. The Package Leaflet is updated accordingly. The RMP version 17.0 has also been submitted." Request for Supplementary Information adopted on 11.07.2024, 08.02.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led	Positive Opinion adopted by consensus on

Humira - Adalimumab - EMEA/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)." Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 11.04.2024.	11.07.2024.
PRAC Led **Mysimba - Naltrexone hydrochloride / Bupropion hydrochloride - EMEA/H/C/003687/II/0063** Orexigen Therapeutics Ireland Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "To update sections 4.3, 4.4 and 4.5 of the SmPC to update and streamline the relevant wording on opioids following the assessment of PSUSA/00010366/202209 procedure. The Package Leaflet is updated accordingly. The RMP version 12.9 has also been submitted." Request for Supplementary Information adopted on 16.05.2024, 09.02.2024, 31.08.2023.	See 9.1
PRAC Led **NeoRecormon - Epoetin beta - EMEA/H/C/000116/II/0126** Roche Registration GmbH, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of an updated RMP version 4.0 in order to align with GVP Module V (Rev. 2)." Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.
PRAC Led **Oxbryta - Voxelotor - EMEA/H/C/004869/II/0011, Orphan** Pfizer Europe Ma EEIG, PRAC Rapporteur: Jo Robays, PRAC-CHMP liaison: Christophe Focke, "Submission of an updated RMP version 1.2 in order to include the current data for the main existing treatment options and to extend the submission deadline for Study GBT440-0122 (C5341029) and for Study GBT440-034 (C5341022)." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 11.07.2024.	
PRAC Led **Piqray - Alpelisib - EMEA/H/C/004804/II/0024** Novartis Europharm Limited, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Peter Mol, "Submission of an updated RMP version 8.0 in order to remove the PASS CBYL719C2404 (Cat. 3) RMP commitment (MEA 002)." Request for Supplementary Information adopted on 11.07.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0131** Moderna Biotech Spain S.L., PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report from study mRNA-1273-919 - An Observational Study to Assess Maternal and Infant Outcomes Following Exposure to Spikevax During Pregnancy, listed as a category 3 study in the RMP." Request for Supplementary Information adopted on 11.07.2024, 13.06.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **VEYVONDI - Vonicog alfa - EMEA/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." Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 11.04.2024.	Positive Opinion adopted by consensus on 11.07.2024.
PRAC Led **VITRAKVI - Larotrectinib - EMEA/H/C/004919/II/0036** Bayer AG, PRAC Rapporteur: Rugile Pilviniene, PRAC-CHMP liaison: Vilma Petrikaite, "Submission of an updated RMP version 2.1 in order to adjust the sample size for the non-interventional PASS ON-TRK as well as to update epidemiological, clinical trial and post-marketing data."	Positive Opinion adopted by consensus on 11.07.2024.

Opinion adopted on 11.07.2024.	
PRAC Led **WS2615** **Abseamed-** **EMEA/H/C/000727/WS2615/0108** **Binocrit-** **EMEA/H/C/000725/WS2615/0108** **Epoetin alfa Hexal-** **EMEA/H/C/000726/WS2615/0108** Sandoz GmbH, Lead PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from the non-interventional post authorization safety study (NI-PASS) HX575-507, listed as a category 3 study in the RMP. The NI-PASS study HX575-507 was conducted to address a post-authorisation measure (MEA 13.5) to evaluate the safety profile of HX575 administered s.c. in patients with chronic kidney disease (CKD)-induced anaemia under real-life conditions. The RMP version 19.1 is accepted." Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 16.05.2024, 08.02.2024.	Positive Opinion adopted by consensus on 11.07.2024.
PRAC Led **WS2705** **Lixiana-EMEA/H/C/002629/WS2705/0050** **Roteas-EMEA/H/C/004339/WS2705/0036** Daiichi Sankyo Europe GmbH, Lead PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Alexandre Moreau, "Submission of a Summary of Changes for the DSE-EDO-05-14-EU clinical study report, as an erratum detailing the updates. DSE-EDO-05-14-EU is a non-interventional Post-Authorisation Safety Study (PASS) on Edoxaban treatment in routine clinical practice for patients with acute venous thromboembolism in Europe (ETNA-VTE-Europe) which was listed as a category 3 study in the RMP (MEA 007)." Opinion adopted on 11.07.2024.	Positive Opinion adopted by consensus on 11.07.2024.

B.5.5. CHMP-CAT assessed procedures

Abecma - Idecabtagene vicleucel - EMEA/H/C/004662/II/0047, Orphan, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur:	

Rune Kjeken, CHMP Coordinator: Ingrid Wang, "- To update section 6.6 of the SmPC - "Special precautions for disposal and other handling", and corresponding section of the Package Leaflet, to clarify dose preparation and administration instructions of the thawed finished product (IV administration set fitted with a non-leukodepleting in-line filter which can be used to reduce visible cellular aggregates that do not disperse after gentle manual mixing)."
Request for Supplementary Information adopted on 24.05.2024.

Abecma - Idecabtagene vicleucel - EMEA/H/C/004662/II/0048, Orphan, ATMP
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang
Opinion adopted on 19.07.2024.
Request for Supplementary Information adopted on 21.06.2024.

Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0037/G, ATMP
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini
Request for Supplementary Information adopted on 21.06.2024, 15.03.2024.

Hemgenix - Etranacogene dezaparvovec - EMEA/H/C/004827/II/0014/G, Orphan, ATMP
CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy

Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/II/0067/G, ATMP
Amgen Europe B.V., Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lähteenvuo, "A grouped application as follows: Type II (C.I.4): Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update paediatric information based on the paediatric study 20110261, which was previously submitted in procedure II/0063. This is a phase 1, multicentre, open-label study of talimogene laherparepvec in paediatric subjects with advanced non-CNS tumours that were amenable to direct injection in the clinical setting. The Package Leaflet is updated accordingly. In

addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the Product Information. Type IA (A.6): To change the ATC Code of Antineoplastic cell and gene therapy from L01XX51 to L01XL02.”	
Upstaza - Eladocagene exuparvovec - EMEA/H/C/005352/II/0022/G, Orphan, ATMP PTC Therapeutics International Limited, Rapporteur: Joseph DeCourcey, CHMP Coordinator: Finbarr Leacy	
Yescarta - Axicabtagene ciloleucel - EMEA/H/C/004480/II/0077, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus	
WS2613 **Tecartus- EMEA/H/C/005102/WS2613/0046** **Yescarta- EMEA/H/C/004480/WS2613/0078** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus Opinion adopted on 04.07.2024.	Positive Opinion adopted by consensus on 04.07.2024.

B.5.6. CHMP-PRAC-CAT assessed procedures

Alofisel - Darvadstrocel - EMEA/H/C/004258/II/0051/G, Orphan, ATMP Takeda Pharma A/S, Rapporteur: Maria Luttgen, CHMP Coordinator: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer, “A grouped application comprised of 4 Type II Variations, as follows: (C.I.4): Update of sections 4.8 and 5.1 of the SmPC in order to update the safety information, based on pooled safety data from the two phase 3 controlled studies (ADMIRE-CD & ADMIRE-CD II) and to update efficacy information based on final results from study ADMIRE-CD II, listed as an obligation in the Annex II. ADMIRE-CD II (Cx601-0303) is a Phase III randomised double blind, placebo-controlled study to assess efficacy and safety of Cx601, adult allogeneic expanded adipose-derived stem cells (eASC) for	See 9.1

the treatment of complex perianal fistula(s) in patients with Crohn's disease. The Annex II is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI, including to section 4.2 of the SmPC and to the Package Leaflet. 3 x (C.I.13): Submission of interim results from studies Darvadstrocel-3003 and Alofisel-5003 (INSPIRE) and final results from study Darvadstrocel-3002 to support the benefit-risk assessment of darvadstrocel based on all new available clinical data. The RMP version 8.0 has also been submitted."	

B.5.7. PRAC assessed ATMP procedures

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

WS2688 **Corlentor-** **EMEA/H/C/000598/WS2688/0063** **Ivabradine Anpharm-** **EMEA/H/C/004187/WS2688/0023** **Procoralan-** **EMEA/H/C/000597/WS2688/0062** Les Laboratoires Servier, Lead Rapporteur: Patrick Vrijlandt, Quality"	
WS2694/G **GONAL-f-** **EMEA/H/C/000071/WS2694/0170/G** **Pergoveris-** **EMEA/H/C/000714/WS2694/0092/G** Merck Europe B.V., Lead Rapporteur: Thalia Marie Estrup Blicher, Quality Opinion adopted on 11.07.2024. Request for Supplementary Information adopted on 06.06.2024.	Positive Opinion adopted by consensus on 11.07.2024.
WS2715 **M-M-RvaxPro-** **EMEA/H/C/000604/WS2715/0125** **ProQuad-** **EMEA/H/C/000622/WS2715/0167** Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus, "To introduce editorial changes in sections 3.2.S.4.1 and 3.2.S.4.5."	
WS2725/G **Efficib-** **EMEA/H/C/000896/WS2725/0115/G**	Positive Opinion adopted by consensus on 18.07.2024.

Janumet- **EMEA/H/C/000861/WS2725/0113/G** **Ristfor-** **EMEA/H/C/001235/WS2725/0102/G** **Velmetia-** **EMEA/H/C/000862/WS2725/0121/G** Merck Sharp & Dohme B.V., Lead Rapporteur: Patrick Vrijlandt, Quality Opinion adopted on 18.07.2024.	
WS2728 **Blitzima-** **EMEA/H/C/004723/WS2728/0075** **Truxima-** **EMEA/H/C/004112/WS2728/0078** Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz, Quality	
WS2734/G **Nuwiq-** **EMEA/H/C/002813/WS2734/0062/G** **Vihuma-** **EMEA/H/C/004459/WS2734/0044/G** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus, Quality	

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

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

Cimzia - Certolizumab pegol - **EMEA/H/C/001037/II/0110** UCB Pharma S.A., Rapporteur: Kristina Dunder, "Update of sections 4.2 and 4.6 of the SmPC in order to update information on pregnancy based on final results from study UP0085, OTIS Phase I report and post marketing data. UP0085 is a Phase 1b, prospective, longitudinal, interventional, open-label study evaluating the impact of pregnancy on the PK of CZP. OTIS Phase I report presents the formal analysis of pregnancy outcome and infant and child follow-up data from the OTIS CZP Pregnancy Registry (RA0023). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4." Request for Supplementary Information adopted on 13.06.2024.	Request by the applicant for an extension to the clock stop to respond to the RSI adopted in June 2024.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

Belantamab mafodotin - EMEA/H/C/006511 treatment of multiple myeloma	
In vitro diagnostic medical device - EMEA/H/D/006587 To detect G719X substitution mutations in exon 18, deletion mutations in exon 19, T790M and S768I substitution mutations in exon 20, insertion mutations in exon 20, and L858R and L861Q substitution mutations in exon 21.	
Aflibercept - EMEA/H/C/006282 treatment of age-related macular degeneration (AMD) and visual impairment	
Ustekinumab - EMEA/H/C/006467 treatment of Crohn's Disease and Ulcerative colitis, treatment of plaque psoriasis, arthritis psoriatic	
Nintedanib - EMEA/H/C/006486 treatment of Idiopathic Pulmonary Fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) and systemic sclerosis associated interstitial lung disease (SSc-ILD)	
ACELLULAR PERTUSSIS VACCINE - EMEA/H/C/006304 indicated as active booster immunization against pertussis of persons aged 11 years onwards and passive protection against pertussis in early infancy following maternal immunization during pregnancy	
Vimseltinib - EMEA/H/C/006363, Orphan Deciphera Pharmaceuticals (Netherlands) B.V., Treatment of adult patients with tenosynovial giant cell tumour (TGCT) who are not amenable to surgery	
Chikungunya virus virus-like particle - EMEA/H/C/005470, Article 28 prevention of disease caused by chikungunya (CHIKV) virus	**Accelerated review**
Human albumin solution - EMEA/H/D/006540 Ex vivo heart perfusion	

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

Xofluza - Baloxavir marboxil - EMEA/H/C/004974/X/0022
Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Sonja Hrabcik, "Extension application to add a new pharmaceutical form (granules) associated with three new strengths (10, 30 and 40 mg) packaged in sachet (PET/alu/PET)."

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

Repotrectinib - EMEA/H/C/006005
Treatment of ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) and for solid tumours
List of Questions adopted on 25.04.2024.

Givinostat - EMEA/H/C/006079, Orphan
Italfarmaco S.p.A., treatment of Duchenne muscular dystrophy (DMD)
List of Questions adopted on 14.12.2023.

Garadacimab - EMEA/H/C/006116, Orphan
CSL Behring GmbH, routine prevention of attacks of hereditary angioedema (HAE)
List of Questions adopted on 21.03.2024.

In vitro diagnostic medical device - EMEA/H/D/006536
to detect ITD and TKD mutations in the FLT3 gene in patients with acute myelogenous leukemia (AML).
Request for Supplementary Information adopted on 27.06.2024.

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.
Request for Supplementary Information adopted on 27.06.2024, 30.05.2024.

Trabectedin - EMEA/H/C/006433
treatment of soft tissue sarcoma and combination with PLD treatment of relapsed platinum-sensitive ovarian cancer, treatment soft tissue sarcoma and combination with PLD treatment of relapsed platinum-sensitive ovarian cancer

List of Questions adopted on 30.05.2024.

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
List of Questions adopted on 25.04.2024.

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

MVABEA - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343/S/0022
Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné

Qarziba - Dinutuximab beta - EMEA/H/C/003918/S/0063, Orphan
Recordati Netherlands B.V., Rapporteur: Peter Mol, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Gabriele Maurer

ZABDENO - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337/S/0020
Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné

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

Arsenic trioxide Mylan - Arsenic trioxide - EMEA/H/C/005235/R/0012
Mylan Ireland Limited, Generic of TRISENOX, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Tiphaine Vaillant

Azacitidine betapharm - Azacitidine - EMEA/H/C/005075/R/0020
betapharm Arzneimittel GmbH, Rapporteur: Petr Vrbata, PRAC Rapporteur: Bianca Mulder

ELREXFIO - Elranatamab - EMEA/H/C/005908/R/0003
Pfizer Europe Ma EEIG, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Barbara Kovacic Bytyqi

Enhertu - Trastuzumab - EMEA/H/C/005124/R/0047
Daiichi Sankyo Europe GmbH, Rapporteur:

Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre

Fetcroja - Cefiderocol - EMEA/H/C/004829/R/0022
Shionogi B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber

Fluad Tetra - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/R/0055
Seqirus Netherlands B.V., Rapporteur: Sol Ruiz, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné

GoResp Digihaler - Budesonide / Formoterol fumarate dihydrate - EMEA/H/C/004882/R/0016
Teva Pharma B.V., Rapporteur: John Joseph Borg, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Krazati - Adagrasib - EMEA/H/C/006013/R/0006
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Kimmo Jaakkola

LUMYKRAS - Sotorasib - EMEA/H/C/005522/R/0018
Amgen Europe B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Spevigo - Spesolimab - EMEA/H/C/005874/R/0008
Boehringer Ingelheim International GmbH, Rapporteur: Kristina Dunder, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Nathalie Gault

Tecartus - Brexucabtagene autoleucel - EMEA/H/C/005102/R/0047, Orphan, ATMP
Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Rune Kjeken, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder

Tigecycline Accord - Tigecycline - EMEA/H/C/005114/R/0007
Accord Healthcare S.L.U., Generic of Tygacil, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Maria del Pilar Rayon

Vaxchora - Cholera vaccine, oral, live - EMEA/H/C/003876/R/0024
Bavarian Nordic A/S, Rapporteur: Ingrid Wang, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Jean-Michel Dogné

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

Benlysta - Belimumab - EMEA/H/C/002015/II/0133
GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn, "Extension of indication to include treatment of paediatric patients from 5 years of age with active, autoantibody-positive systemic lupus erythematosus (SLE) for BENLYSTA, based on final results from study 200908; this is a worldwide population pharmacokinetic analysis of subcutaneous administered belimumab plus standard therapy to pediatric patients aged 5-17 years with systematic lupus erythematous (SLE), which was aimed to describe the pharmacokinetic (PK) analysis of belimumab to support an appropriate weight-based dosing regimen for subcutaneous administration in paediatric patients aged 5-17 years with SLE. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 46.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Bridion - Sugammadex - EMEA/H/C/000885/II/0047
Merck Sharp & Dohme B.V., Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, "Extension of indication to include treatment of paediatric patients from birth to less than 2 years of age for Bridion based on final results from paediatric study PN169 (MK-8616-P169); this is a Phase 4 double-blinded, randomized, active comparator-controlled clinical trial to study the efficacy, safety, and pharmacokinetics of sugammadex (MK-8616) for reversal of

neuromuscular blockade in paediatric participants aged birth to <2 years. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, to implement minor editorial corrections and to update the information intended for healthcare professionals (HCPs) at the end of the Package Leaflet."

FABHALTA - Iptacopan - EMEA/H/C/005764/II/0001, Orphan

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

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

AstraZeneca AB, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: David Olsen, "Extension of indication to include treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy for IMFINZI, based on final results from study

D933QC00001 (ADRIATIC); this is a phase III, randomized, double-blind, placebo-controlled, multi-centre, global study to assess the efficacy and safety of durvalumab monotherapy and durvalumab in combination with tremelimumab compared to placebo as consolidation treatment in patients with LS-SCLC whose disease had not progressed following definitive platinum-based chemoradiation therapy (ADRIATIC). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 12,s1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to Annex II. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

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

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

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

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas, "Extension of indication to include treatment of giant cell arteritis (GCA) in adult patients for RINVOQ based on final results from study M16-852. This is a phase 3, global, multicentre, randomized, double-blind, PBO-controlled study evaluating the efficacy and safety of upadacitinib in subjects with GCA. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2

of the SmPC are updated. The Package Leaflet is updated in accordance. Version 15.0 of the RMP has also been submitted."

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

Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Paolo Gasparini, PRAC Rapporteur: Miroslava Gocova, "Extension of indication to include treatment of schizophrenia in adolescent patients aged from 13 years to 17 years for RXULTI, based on results from the following clinical studies: one phase 1 dose-escalation trial (Trial 331-10-233) and two phase 3 clinical trials (Trial 331-10-234 and Trial 331-10-236). In addition, a paediatric extrapolation study was completed (Study 331-201-00185). These studies investigated the efficacy and safety of brexpiprazole in paediatric patients (13-17 years old) with schizophrenia. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, and to bring the PI in line with the latest QRD template version 10.4."

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

Merck Sharp & Dohme B.V., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, "Extension of indication to include treatment of paediatric patients aged from birth to less than 12 years for SIVEXTRO, based on final results from studies MK-1986-013, MK-1986-014 and MK-1986-018. MK-1986-013 is a single-dose trial to evaluate pharmacokinetics (PK) and safety of oral and intravenous (IV) administration of tedizolid phosphate in patients from 2 years to <12 years of age; MK-1986-014 is an open-label, multicentre, 2-part, single and multiple dose study to assess the PK of tedizolid phosphate and its active metabolite, tedizolid, and the safety of tedizolid phosphate following single and multiple dose IV and single oral dose. MK-1986-018 is a randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in patients from birth to less than 12 years of age; As a

consequence, sections 4.1, 4.2, 4.4, 4.8, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to implement minor editorial corrections."

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

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

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

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

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

WS2717
OPDIVO-
EMEA/H/C/003985/WS2717/0146
Yervoy-EMEA/H/C/002213/WS2717/0115
Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Carolina Prieto Fernandez, Lead PRAC Rapporteur: Bianca Mulder, "A Worksharing application for OPDIVO and YERVOY, as follows:
Extension of indication to include a new indication for OPDIVO in combination with ipilimumab as first line treatment of adult patients with unresectable or advanced hepatocellular carcinoma (HCC) based on study CA2099DW. This is a phase 3 randomised, multi-centre, open label study of Nivolumab in combination with Ipilimumab compared to Sorafenib or Lenvatinib as first-line treatment in participants with advanced HCC. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 41.0 of the RMP has also been submitted.
Extension of indication to include a new indication for YERVOY in combination with ipilimumab as first line treatment of adult patients with unresectable or advanced hepatocellular carcinoma (HCC) based on study CA2099DW. This is a phase 3 randomised, multi-centre, open label study of Nivolumab in combination with Ipilimumab compared to Sorafenib or Lenvatinib as first-line treatment in participants with advanced HCC. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 44.0 of the RMP has also been submitted.**"**

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Aranesp - Darbepoetin alfa -
EMEA/H/C/000332/II/0166/G
Amgen Europe B.V., Rapporteur: Martina Weise

Azacitidine Mylan - Azacitidine -
EMEA/H/C/004984/II/0020
Mylan Ireland Limited, Generic of Vidaza, Rapporteur: Hrefna Gudmundsdottir

Azarga - Brinzolamide / Timolol -
EMEA/H/C/000960/II/0051/G
Novartis Europharm Limited, Rapporteur: Thalia Marie Estrup Blicher

Azopt - Brinzolamide -
EMEA/H/C/000267/II/0078/G
Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes

Dynastat - Parecoxib -
EMEA/H/C/000381/II/0093
Pfizer Europe MA EEIG, Rapporteur: Finbarr Leacy

Empliciti - Elotuzumab -
EMEA/H/C/003967/II/0040/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol

Enjaymo - Sutimlimab -
EMEA/H/C/005776/II/0016, Orphan
Sanofi B.V., Rapporteur: Kristina Dunder

Entyvio - Vedolizumab -
EMEA/H/C/002782/II/0084/G
Takeda Pharma A/S, Rapporteur: Paolo Gasparini

GONAL-f - Follitropin alfa -
EMEA/H/C/000071/II/0172/G
Merck Europe B.V., Rapporteur: Patrick Vrijlandt

Idefirix - Imlifidase -
EMEA/H/C/004849/II/0024/G, Orphan
Hansa Biopharma AB, Rapporteur: Martina Weise

Insuman - Insulin human -
EMEA/H/C/000201/II/0150
Sanofi-Aventis Deutschland GmbH, Rapporteur: Karin Janssen van Doorn

Kauliv - Teriparatide -
EMEA/H/C/004932/II/0004
Strides Pharma (Cyprus) Limited, Rapporteur: Martina Weise

Kisqali - Ribociclib -
EMEA/H/C/004213/II/0054/G
Novartis Europharm Limited, Rapporteur: Filip Josephson

Lutetium (177Lu) chloride Billev - Lutetium (177Lu) chloride -
EMEA/H/C/005859/II/0005/G

Billev Pharma ApS, Rapporteur: Antonio Gomez-Outes

NexoBrid - Concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0069
MediWound Germany GmbH, Rapporteur: Janet Koenig

Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0136/G
Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang

Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0046/G
AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus

Ontruzant - Trastuzumab - EMEA/H/C/004323/II/0050/G
Samsung Bioepis NL B.V., Rapporteur: Karin Janssen van Doorn

Opdualag - Nivolumab / Relatlimab - EMEA/H/C/005481/II/0009/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol

Phesgo - Pertuzumab / Trastuzumab - EMEA/H/C/005386/II/0025/G
Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia

Qarziba - Dinutuximab beta - EMEA/H/C/003918/II/0062/G, Orphan
Recordati Netherlands B.V., Rapporteur: Peter Mol

Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0030/G
Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson

Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0032/G
Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson

Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0033/G

Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson

Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0034
Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson

Retacrit - Epoetin zeta - EMEA/H/C/000872/II/0119
Pfizer Europe MA EEIG, Rapporteur: Martina Weise

Rimmyrah - Ranibizumab - EMEA/H/C/006055/II/0001
Qilu Pharma Spain S.L., Rapporteur: Jan Mueller-Berghaus

Ryeqo - Relugolix / Estradiol / Norethisterone acetate - EMEA/H/C/005267/II/0025
Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt

Semglee - Insulin glargine - EMEA/H/C/004280/II/0050
Biosimilar Collaborations Ireland Limited, Rapporteur: Martina Weise

Silapo - Epoetin zeta - EMEA/H/C/000760/II/0074
STADA Arzneimittel AG, Rapporteur: Martina Weise

Skyrizi - Risankizumab - EMEA/H/C/004759/II/0049/G
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy

Stimufend - Pegfilgrastim - EMEA/H/C/004780/II/0008
Fresenius Kabi Deutschland GmbH, Rapporteur: Christian Gartner

Synflorix - Pneumococcal polysaccharide conjugate vaccine (adsorbed) - EMEA/H/C/000973/II/0185/G
GlaxoSmithkline Biologicals SA, Rapporteur: Kristina Dunder

Tyruko - Natalizumab - EMEA/H/C/005752/II/0004
Sandoz GmbH, Rapporteur: Christian Gartner

Vaxelis - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA),

poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/003982/II/0146
MCM Vaccine B.V., Rapporteur: Christophe Focke

Vyepti - Eptinezumab - EMEA/H/C/005287/II/0020
H. Lundbeck A/S, Rapporteur: Jan Mueller-Berghaus

Wakix - Pitolisant - EMEA/H/C/002616/II/0039, Orphan
Bioprojet Pharma, Rapporteur: Jean-Michel Race

Wakix - Pitolisant - EMEA/H/C/002616/II/0040/G, Orphan
Bioprojet Pharma, Rapporteur: Jean-Michel Race

Zerbaxa - Ceftolozane / Tazobactam - EMEA/H/C/003772/II/0046/G
Merck Sharp & Dohme B.V., Rapporteur: Ingrid Wang

Zynlonta - Loncastuximab tesirine - EMEA/H/C/005685/II/0015/G
Swedish Orphan Biovitrum AB (publ), Rapporteur: Aaron Sosa Mejia

WS2710
Infanrix hexa-EMEA/H/C/000296/WS2710/0346
GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke

WS2727
Esperoct-EMEA/H/C/004883/WS2727/0025
NovoEight-EMEA/H/C/002719/WS2727/0044
NovoSeven-EMEA/H/C/000074/WS2727/0125
NovoThirteen-EMEA/H/C/002284/WS2727/0032
Refixia-EMEA/H/C/004178/WS2727/0038
Novo Nordisk A/S, Lead Rapporteur: Jan Mueller-Berghaus

WS2735/G
Blitzima-EMEA/H/C/004723/WS2735/0076/G
Truxima-EMEA/H/C/004112/WS2735/0079/G
Celltrion Healthcare Hungary Kft., Lead

Rapporteur: Sol Ruiz

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

AGAMREE - Vamorolone - EMEA/H/C/005679/II/0005, Orphan
Santhera Pharmaceuticals (Deutschland) GmbH, Rapporteur: Martina Weise, "Update of sections 4.4 and 5.2 of the SmPC in order to update information on biotransformation based on results from clinical and non-clinical studies."

Aldurazyme - Laronidase - EMEA/H/C/000477/II/0090
Sanofi B.V., Rapporteur: Alexandre Moreau, "Update of section 4.8 of the SmPC in order to update information on immunogenicity, based on results of completed clinical studies as well as results from the MPS I Registry."

AQUIPTA - Atogepant - EMEA/H/C/005871/II/0005
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Janet Koenig, "Update of sections 4.3, 4.4 and 4.8 of the SmPC in order to update the contraindication and warning on hypersensitivity reactions to include anaphylaxis and dyspnoea and to add them to the list of adverse drug reactions (ADRs) with frequency not known, based on a comprehensive safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce minor editorial changes to the PI."

Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0024
Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher, "Update of sections 2, 4.4 and 4.8 of the SmPC in order to add warning on excipient with known effect and hypersensitivity including anaphylaxis, and to add 'hypersensitivity' to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

Bosulif - Bosutinib - EMEA/H/C/002373/II/0060

Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on cardiovascular toxicity and to add cardiac failure and cardiac ischaemic events to the list of adverse drug reactions (ADRs) with frequency common, based on an updated safety review. The Package Leaflet is updated accordingly."

Brilique - Ticagrelor - EMEA/H/C/001241/II/0063

AstraZeneca AB, Rapporteur: Patrick Vrijlandt, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information between ticagrelor and rosuvastatin based on literature. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Cyramza – Ramucirumab - EMA/VR/0000221685

Eli Lilly Nederland B.V. Rapporteur: Peter Mol, "Update of section 5.1 of the SmPC in order to update overall survival information based on final results from study I4T-MC-JVCY; this is a Phase 3, Multi-Centre, Randomized, Double-Blind Study of Erlotinib in Combination with Ramucirumab or Placebo in Previously Untreated Patients with EGFR Mutation-Positive Metastatic Non-small Cell Lung Cancer. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI."

COMIRNATY - COVID-19 mRNA vaccine - EMEA/H/C/005735/II/0217

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "Submission of the final and supplemental reports from study C4591031 Substudy E, listed as a category 3 study in the RMP. This was a interventional, randomized, observer-blinded substudy to evaluate the safety, tolerability, and immunogenicity of high dose BNT162b2 OMI (60 µg), high-dose BNT162b2 (60 µg), and a high-dose combination of BNT162b2 OMI and BNT162b2 (30 µg of each), compared to BNT162b2 OMI 30 µg, BNT162b2 30 µg, and a combination of BNT162b2 OMI and BNT162b2 (15 µg of each), given as a fourth dose."

COMIRNATY - COVID-19 mRNA vaccine -

EMEA/H/C/005735/II/0219/G

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "Grouped application comprised of two Type II variations as follows:
C.I.13: To submit the final report for bivalent Omicron-modified vaccine data from study C4591014 (KPSC), a non-interventional (Retrospective database analysis) COVID-19 BNT162b2 vaccine effectiveness study – conducted at Kaiser Permanente Southern California (KPSC), listed as a category 3 study in the RMP.
C.I.13: To submit the final report for bivalent Omicron-modified vaccine from study WI255886 (Bristol), an Avon Community Acquired Pneumonia Surveillance Study (pan-pandemic acute lower respiratory tract disease surveillance study), listed as a category 3 study in the RMP."

COMIRNATY - COVID-19 mRNA vaccine - EMEA/H/C/005735/II/0220/G

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "A grouped application comprised of 2 Type II Variations as follows:
C.I.4: Update of sections 4.8 and 5.1 of the SmPC in order to update safety and immunogenicity information based on interim results from interventional study C4591048 SSB (G1+G2+G3) and SSD (G1+G2+G3) listed as a category 3 study in the RMP. Study C4591048 is a master phase 1/2/3 protocol to investigate the safety, tolerability, and immunogenicity of bivalent BNT162b2 RNA - based vaccine candidate(s) in healthy children.
C.I.4: Update of section 4.9 of the SmPC in order to update safety information based on post-marketing data related to overdose.
In addition, the MAH took the opportunity to implement minor editorial and administrative changes to the PI."

Cosentyx - Secukinumab - EMEA/H/C/003729/II/0120

Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola, "Submission of the interim report for study CAIN457M2301E1. This is an ongoing four-year, multicentre, double-blind, randomized withdrawal extension study of two Phase III studies, CAIN457M2301 and CAIN457M2302, conducted to assess long-term efficacy and safety of two secukinumab 300 mg

dose regimens (Q2W or Q4W), in adult subjects with moderate to severe hidradenitis suppurativa."

Darzalex - Daratumumab - EMEA/H/C/004077/II/0074, Orphan

Janssen-Cilag International N.V., Rapporteur: Aaron Sosa Mejia, "Update of section 5.1 of the SmPC in order to include the results from the final (overall survival) analysis from study 54767414MMY3008 (MAIA). This is a Phase 3 randomized, open-label, parallel-group, active controlled, multicentre study comparing daratumumab, lenalidomide, and dexamethasone (DRd) vs lenalidomide and dexamethasone (Rd) in subjects with previously untreated multiple myeloma who are ineligible for high dose therapy. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Evrysdi - Risdiplam - EMEA/H/C/005145/II/0027

Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Submission of the final report from study BP39056 (FIREFISH) listed as a category 3 study in the RMP; this is a two-part seamless, open-label, multi-centre study to investigate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of risdiplam in infants with type 1 spinal muscular atrophy."

PRAC Led

Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan - Efavirenz/Emtricitabine/Tenofovir disoproxil - EMA/VR/0000179367

Mylan Pharmaceuticals Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP Liaison: Janet Koenig**, "**Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on Bone effects and to add 'bone mineral density decreased' to the list of adverse drug reactions (ADRs) with frequency common, based on the PRAC conclusions from the PSUSA for Emtricitabine/Tenofovir disoproxil (PSUSA/1210/202304). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Fintepla - Fenfluramine - EMEA/H/C/003933/II/0024, Orphan

UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.2 of the SmPC in order to include a table correlating volumes and doses for both Dravet syndrome and Lennox-Gastaut syndrome following the outcome of PSUSA/00010907/202306. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
JCOVDEN - COVID-19 Vaccine Janssen (Ad26.COV2.S) - EMEA/H/C/005737/II/0079/G Janssen-Cilag International N.V., Rapporteur: Christophe Focke, "A grouped application consisting of two Type II variations, as follows: C.I.13: Submission of the final report from study COV4004 listed as a category 3 study in the RMP. This is a non-interventional study to estimate the effectiveness of Ad26.COV2.S in preventing laboratory confirmed SARS-CoV-2 hospitalizations. C.I.13: Submission of the final report from study COV4019. This is a non-interventional study titled 'Comparative effectiveness of heterologous and homologous vaccine boosting to prevent COVID-19 in individuals with a completed primary vaccination series in the United States'."	
LIBTAYO - Cemiplimab - EMEA/H/C/004844/II/0047 Regeneron Ireland Designated Activity Company, Rapporteur: Aaron Sosa Mejia, "Update of sections 4.2, 5.1 and 5.2 of the SmPC to update paediatric population information from Study R2810-ONC-1690 (Study 1690) following the outcome of Article 46 procedure (EMA/H/C/004844/P46/011)."	
LYFNUA - Gefapixant - EMEA/H/C/005476/II/0003/G Merck Sharp & Dohme B.V., Rapporteur: Peter Mol, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information and add 'headache' to the list of adverse drug reactions (ADRs) with frequency common, based on final results from studies MK-7264-042 and MK-7264-043; these are multicentre, randomized, double-blind, placebo controlled Phase 3b studies conducted in patients with refractory or unexplained chronic	

cough. 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 introduce minor editorial changes to the PI."	
NexoBrid - Concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0071 MediWound Germany GmbH, Rapporteur: Janet Koenig, "Submission of the final report from study MW2012-01-01 listed as a category 3 study in the RMP. This is a phase 3, randomised, controlled, open label study, performed in children with thermal burns, to evaluate the efficacy and safety of NexoBrid as compared to SOC treatment."	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0080 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-501 listed as a category 3 study in the RMP. This is a Phase 2a/b, randomized, observer-blinded, placebo-controlled study to evaluate the efficacy, immunogenicity, and safety of a SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M adjuvant in South African adult subjects living without HIV; and safety and immunogenicity in people living with HIV."	
Ozempic - Semaglutide - EMEA/H/C/004174/II/0046 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Update of sections 4.1, 4.2 and 5.1 of the SmPC to change recommendations and to update efficacy and safety information in the elderly and renal impaired patients based on final results from study NN9535-4321 (FLOW). This is a multi-centre, international, randomised, double-blind, parallel-group, placebo-controlled dedicated kidney outcomes trial conducted to demonstrate the superiority of semaglutide 1 mg vs placebo in delaying the progression of renal impairment and lowering the risk of renal and cardiovascular mortality compared to placebo in subjects with type 2 diabetes (T2D) and chronic kidney disease (CKD). The Package Leaflet is updated	

accordingly.”

Padcev - Enfortumab vedotin - EMEA/H/C/005392/II/0016

Astellas Pharma Europe B.V., Rapporteur: Aaron Sosa Mejia, “Update of sections 4.4 and 4.6 of the SmPC in order to update information on contraception for males and females in line with the SWP/NcWP (EMA/CHMP/SW P/74077/2020 rev. 1) recommendations on the duration of contraception following the end of treatment with a genotoxic drug. The Package Leaflet is updated accordingly.”

Reblozyl - Luspatercept - EMEA/H/C/004444/II/0028, Orphan

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Daniela Philadelphy, “Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on results from Study ACE-536-MDS-002 following procedure EMEA/H/C/004444/II/0021. This is a phase 3, open-label, randomized study to compare the efficacy and safety of luspatercept versus epoetin alfa for the treatment of anaemia due to IPSS-R very low, low, or intermediate risk myelodysplastic syndromes (MDS) in ESA naive subjects who require red blood cell transfusions.”

Reyataz - Atazanavir - EMEA/H/C/000494/II/0141/G

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Jean-Michel Race, “A grouped application consisting of:
Type II (C.I.4): Update of sections 4.3 and 4.4 of the SmPC in order to update information on the contraindication for the coadministration of atazanavir (ATV) (a cytochrome P450 3A4 [CYP3A4] substrate) based on final results from study Study AI424082. This is an open-label, multiple-dose, randomized, drug-interaction study to assess the PK of ATV resulting from 3 regimens of ATV/RTV/RIF relative to those of ATV, with or without RTV.”

RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0055

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, “Update of sections 4.8 and 5.1 of the SmPC in order to include long term efficacy and safety data for ulcerative colitis based on results from study

M14-533. This is a phase 3, multicentre, long-term extension study to evaluate the safety and efficacy of upadacitinib in subjects with ulcerative colitis."

Saphnelo - Anifrolumab - EMEA/H/C/004975/II/0020

AstraZeneca AB, Rapporteur: Outi Mäki-Ikola, "Submission of the final report from study D3461C00023 listed as a category 3 study in the RMP. This is a phase I, non-randomised, multi-centre, open-label, parallel group study to evaluate the potential impact of anifrolumab administered intravenously (IV) on the effectiveness of immune responses to seasonal influenza vaccination in women or men of any race between the ages of 18 and 70 years with active moderate to severe manifestations of SLE."

Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0008, Orphan

Reata Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC to include final results from study 408-C-2201; this is a phase 1, randomized, double-blind, placebo- and active-controlled, 3-way crossover study in healthy participants to determine the effect of omaveloxolone on QTc interval."

Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0009, Orphan

Reata Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.5 of the SmPC in order to update drug-drug interaction information based on final results from study 408-C-2202; this is a Phase 1, single sequence, 2-period, open-label crossover study in healthy participants to determine the effect of a moderate CYP3A4 inducer on the PK of omaveloxolone."

Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0137

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, "To submit the final report from study mRNA-1273-P304 (Phase 3b, Open-Label, Safety and Immunogenicity Study of SARS-CoV-2 mRNA-1273 Vaccine in Adult Solid Organ Transplant Recipients and Healthy Controls) listed as a category 3 study in the RMP. This was a Phase 3b, open-label study to

evaluate the safety, reactogenicity, and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in SOT recipients."

Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0139/G

Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, "A grouped application comprised of two Type II Variations as follows: (2 x C.I.13): Submission of the final reports from the biodistribution studies of mRNA-1273: Study 20456513 and Study 2308-582. Study 20456513 is a single or repeat dose biodistribution study of mRNA-1273 by intramuscular administration in Sprague Dawley rats, while Study 2308-582 is a non-GLP biodistribution study of NPI-Luc mRNA in SM-102/PEG2000-DMG by following a single intramuscular injection in Sprague Dawley rats."

Stelara - Ustekinumab - EMEA/H/C/000958/II/0107

Janssen-Cilag International N.V., Rapporteur: Jayne Crowe, "Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information based on results from study CNTO1275CRD1003. This is a phase 1, open-label, drug interaction study to evaluate the effect of ustekinumab on cytochrome P450 enzyme activities following induction and maintenance dosing in participants with active Crohn's disease or ulcerative colitis. In addition, the MAH took the opportunity to update sections 4.8 and 5.1 to include patient exposure numbers based on results from study CNTO1275UCO3001. This is a phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicenter protocol to evaluate the safety and efficacy of ustekinumab induction and maintenance therapy in subjects with moderately to severely active ulcerative colitis."

Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0019

Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, "Update of section 4.5 of the SmPC in order to include information on co-administration of lenacapavir with systemic dexamethasone based on post-marketing data and literature. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Tecentriq - Atezolizumab - EMEA/H/C/004143/II/0088

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, "Update of Sections 4.8 and 5.1 of the SmPC in order to add "Xerosis" and "blood creatine phosphokinase increased" to the list of adverse drug reactions (ADRs) with frequency "common" and "uncommon" respectively and update the efficacy information based on the final disease-free survival (DFS) results and second interim overall survival (OS) results from study GO29527 (IMpower010); this is a phase III, open-label, randomized study to investigate the efficacy and safety of atezolizumab (Anti-PD-L1 Antibody) compared with best supportive care following adjuvant cisplatin-based chemotherapy in patients with completely resected stage IB-IIIA Non-Small Cell Lung Cancer (NSCLC); the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the SmPC. The MAH also took the opportunity to align the wording in the Package Leaflet with the statement in Section 4.4 of the SmPC related to patient card and to bring the Package leaflet in line with the EMA guidance on polysorbates used as excipients."

Tysabri - Natalizumab - EMEA/H/C/000603/II/0145

Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, "Update of section 4.6 of the SmPC in order to include recommendation on haematocrit monitoring, based on a safety review. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4, and to introduce minor editorial changes to the PI."

Veklury - Remdesivir - EMEA/H/C/005622/II/0059/G

Gilead Sciences Ireland UC, Rapporteur: Janet Koenig, "Update of sections 4.5 and 5.2 of the SmPC in order to update drug-drug interaction information based on data from the two studies GS-US-540-6587 and GS-US-611-6409. GS-US-540-6587 is a Phase 1, open-label, single-centre, fixed-sequence study to evaluate the effect of multiple-dose administration of RDV on the PK of single-dose MDZ in healthy

participants, while study GS-US-611-6409 is a Phase 1, open-label, multicentre, single-sequence (Cohorts 1, 3, 5, and 7) or randomized-sequence (Cohorts 4 and 6), multiple-cohort study to evaluate DDIs of ODV or RDV and probe substrates or strong inhibitors in healthy participants."	
Vyepti - Eptinezumab - EMEA/H/C/005287/II/0021/G H. Lundbeck A/S, Rapporteur: Jan Mueller-Berghaus, "A grouped application consisting of: C.I.4: Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study 18898A (DELIVER). This is an interventional, randomized, double-blind, parallel-group, placebo-controlled study with an extension period to evaluate the efficacy and safety of eptinezumab for the prevention of migraine in patients with unsuccessful prior preventive treatments. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI. C.I.4: Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study 18903A (RELIEF). This is a parallel-group, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of eptinezumab administered intravenously in patients experiencing an acute attack of migraine."	
Xevudy - Sotrovimab - EMEA/H/C/005676/II/0029/G Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "A grouped application comprised of 5 Type II Variations, as follows: C.I.4: Update of section 5.1 of the SmPC based on final results from study 218407 (LUNAR); this is a Phase 4 single-arm prospective cohort genomic surveillance study to describe changes in the SARS-CoV-2 spike protein observed in immunocompromised non-hospitalized patients receiving sotrovimab in Great Britain to monitor the emergence of viral variants. 4 x (C.I.13): To submit the final reports from the following studies:	

COMET-TAIL Safety Substudy (217114); this is a Phase 3 randomized, multi-centre, open label study to assess the efficacy, safety, and tolerability of monoclonal antibody VIR-7831 (sotrovimab) given intramuscularly versus intravenously for the treatment of mild/moderate coronavirus disease 2019 (COVID-19) in high- risk non-hospitalized patients; Safety Substudy assessing the safety and tolerability of single ascending dose monoclonal antibody VIR-7831.
AGILE (215337); this is a randomized, multicentre, seamless, adaptive, Phase 1/2 platform study to determine the Phase 2a dose of VIR-7832, and evaluate the safety and efficacy of VIR-7831 and VIR-7832 for the treatment of COVID-19.
COSMIC (218128); this is a Phase 1, open-label, randomized, parallel group, single-dose clinical pharmacology study to investigate the relative bioavailability, safety, and tolerability of two different concentrations of sotrovimab administered at different injection sites, in male or female healthy participants aged 18 to 65 years.
And from a clinical pharmacology study evaluating SARS-CoV-2 specific T cells responses in participants receiving 500 mg IV sotrovimab in COMET-ICE (PC-22-0123)."

WS2706
Delstrigo-EMEA/H/C/004746/WS2706/0039
Pifeltro-EMEA/H/C/004747/WS2706/0030
Merck Sharp & Dohme B.V., Lead Rapporteur: Filip Josephson, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on Severe Skin Reaction and to add "toxic epidermal necrolysis (TEN)" to the list of adverse drug reactions (ADRs) with frequency "not known", based on post-marketing experience; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to 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 implement editorial changes to the SmPC."

WS2722
Keppra-EMEA/H/C/000277/WS2722/0202
UCB Pharma S.A., Lead Rapporteur: Karin

Janssen van Doorn, "Update of section 4.8 of the SmPC in order to include additional information on signs and symptoms of Drug Reactions with Eosinophilia and Systemic Symptoms (DRESS), based on a safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to introduce minor editorial changes to the PI and to align the PI with the latest QRD template version 10.4."

WS2724
Blitzima-
EMEA/H/C/004723/WS2724/0074
Truxima-
EMEA/H/C/004112/WS2724/0077
Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz, "Update of section 4.2 of the SmPC in order to include rapid infusion for adult non-Hodgkin's lymphoma (NHL) and chronic lymphocytic leukaemia (CLL) patients based on literature and post-approval studies. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

WS2729
Segluromet-
EMEA/H/C/004314/WS2729/0024
Steglatro-
EMEA/H/C/004315/WS2729/0024
Steglujan-
EMEA/H/C/004313/WS2729/0028
Merck Sharp & Dohme B.V., Lead Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC for Steglatro, Steglujan and Segluromet in order to add 'rash' to the list of adverse drug reactions (ADRs) related to ertugliflozin with frequency not known, based on a cumulative safety review. The Package Leaflet is updated accordingly. 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."

B.6.10. CHMP-PRAC assessed procedures

Apretude - Cabotegravir -
EMEA/H/C/005756/II/0004
ViiV Healthcare B.V., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Martin Huber,

"Update of sections 4.8, 5.1 and 5.2 of the SmPC to include data from clinical studies in HIV-1 uninfected adolescents (HPTN 083-01 and HPTN 084-01), updated data from the MOCHA study and updated PK data based on a population PK analysis of cabotegravir in adolescents in MOCHA, HPTN 083-01 and HPTN 084-01. In addition, the MAH took the opportunity to update section 4.2 of the SmPC to clarify the wording related to missed doses of oral PrEP and renal impairment, and to implement editorial changes in the SmPC. Furthermore, the MAH took the opportunity to align the PI with the latest QRD template version 10.4. The RMP version 1.1 has also been submitted."

BESPONSA - Inotuzumab ozogamicin - EMEA/H/C/004119/II/0029, Orphan

Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer, "Submission of the final report from study B1931030 listed as a category 3 study in the RMP. Phase 4, open-label, randomized study of two Inotuzumab Ozogamicin dose levels in adult patients with relapsed or refractory B-cell acute lymphoblastic leukaemia eligible for hematopoietic stem cell transplantation and who have risk factor(s) for veno-occlusive disease. The RMP version 3.1 has also been submitted."

Bimzelx - Bimekizumab - EMEA/H/C/005316/II/0028

UCB Pharma S.A., Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan, "Update of section 5.1 of the SmPC in order to update efficacy information based on the final results from study PS0015 (BE RADIANT) listed as a category 3 study in the RMP; this is a multicentre, randomized, double-blind, secukinumab-controlled, parallel-group study to evaluate the efficacy and safety of bimekizumab in adult subjects with moderate to severe chronic plaque psoriasis. In addition, the MAH has taken the opportunity to update the list of local representatives in the Package leaflet and align the PI with the latest QRD template version 10.4 as well as to update wording on polysorbates in the SmPC and the Package leaflet to align with the annex of the guideline related to excipients. The RMP version 2.1 has

also been submitted."

CAMZYOS - Mavacamten - EMEA/H/C/005457/II/0011/G

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprised of 2 Type II Variations as follows:
C.I.4: Update of section 4.2 of the SmPC to change the echocardiography monitoring frequency once a patient is on a stable dose of mavacamten. The proposed update is supported by the clinical data from interim Clinical study report of MAVA-LTE (CV027-003) study: "A Long-term Safety Extension Study of Mavacamten in Adults with Hypertrophic Cardiomyopathy who have completed the MAVERICK-HCM (MYK-461-006) or EXPLORER-HCM (MYK-461-005) trials", modelling & simulation results and safety data from post-approval safety database. The Package Leaflet is updated accordingly.
C.I.4: Update of section 4.2 of the SmPC to introduce the optional use of the Left ventricular outflow track (LVOT) gradient by post-exercise testing to guide dose titration for patient with specific characteristics. The proposed update is supported by the exposure-response modeling and simulation report with LVOT post-exercise gradient, based on the previously developed model with the data from the following studies: MYK-461-004 (PIONEER), MYK-461-005 (EXPLORER), MYK-461-007, MYK-461-008 (MAVA-LTE) and MYK-461-017 (VALOR).
The RMP version 4.0 has also been submitted."

Hepcludex - Bulevirtide - EMEA/H/C/004854/II/0034, Orphan

Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski, "Update of section 4.8 of the SmPC in order to update safety information based on final results from study MYR204 listed as a category 3 study in the RMP; this is a multicentre, open-label, randomized Phase 2b clinical study to assess efficacy and safety of bulevirtide in combination with pegylated interferon alfa-2a in patients with chronic hepatitis delta. The RMP version 4.2 has also been submitted."

Sapropterin Dipharma - Sapropterin -

EMEA/H/C/005646/II/0014
DIPHARMA Arzneimittel GmbH, Generic of Kuvan, Rapporteur: Frantisek Drafi, PRAC Rapporteur: Eamon O Murchu, "Update of sections 4.2 and 6.6 of the SmPC in order to modify administration instructions based on results from studies RE135VAR0900 and RE137VAR0938. The Package Leaflet and Labelling are updated accordingly."

Shingrix - Herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0076
GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik, "Update of sections 4.8 and 5.1 of the SmPC to include the final results of study ZOSTER-049, listed as a category 3 study in the RMP. This is a Phase 3b, open label, multi-country, long-term follow-up study that assessed the prophylactic efficacy, safety, and immunogenicity persistence of Shingrix in adults ≥50 years of age at the time of primary vaccination in studies ZOSTER 006 and ZOSTER-022. The study also assessed 1 or 2 additional doses of Shingrix on a 0 or 0, 2-month schedule in two subgroups of older adults. The updated RMP version 8.0 is also included. In addition, the MAH took the opportunity to implement editorial changes to the SmPC, Labelling and Package Leaflet; and to bring the PI in line with the latest QRD template version 10.4."

Spinraza - Nusinersen - EMEA/H/C/004312/II/0034/G, Orphan
Biogen Netherlands B.V., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Ulla Wändel Liminga, "A grouped application consisting of:
C.I.4: Update of sections 5.1 and 5.2 of the SmPC based on final results from study CS11 (SHINE) listed as a PAES in the Annex II. The Annex II and the RMP v12.1 are updated accordingly. SHINE is a phase III, open-label extension study for patients with Spinal Muscular Atrophy (SMA) who previously participated in investigational studies of ISIS 396443.
C.I.4: Update of section 5.1 of the SmPC based on interim results from study CS5 (NURTURE, 232SM201). NURTURE is a Phase II, open-label study to assess the efficacy, safety, tolerability,

and pharmacokinetics of multiple doses of nusinersen delivered intrathecally to patients with genetically diagnosed and presymptomatic SMA. C.I.4: Update of section 5.1 of the SmPC in order to relocate the updated information regarding immunogenicity from SmPC section 4.8 to section 5.1 as per applicable CHMP guidance. The data has been revised based on an updated integrated analysis across several studies. C.I.4: Update of section 5.1 of the SmPC based on the outcome of a systematic literature review (SLR) and Natural History data from an International SMA registry (ISMAR)."	
TAVNEOS - Avacopan - EMEA/H/C/005523/II/0015, Orphan Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder, PRAC Rapporteur: Liana Martirosyan, "Update of sections 4.5 and 5.2 of the SmPC based on final results from study CL020_168; this is an open-label, phase 1 study to evaluate the effect of repeated oral doses of avacopan on the pharmacokinetics of a single dose of simvastatin in healthy volunteers; the Package Leaflet is updated accordingly. The updated RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."	
Tecentriq - Atezolizumab - EMEA/H/C/004143/II/0087 Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre, "Update of sections 4.2, 4.8 and 5.1 in order to include information regarding switching treatment between Tecentriq intravenous and subcutaneous (and vice versa) and to update safety information, based on primary results from study MO43576 (IMscin002); this is a phase II, randomised, multicentre, open-label cross-over study to evaluate participants and healthcare professional reported reference for subcutaneous atezolizumab compared with intravenous atezolizumab formulation in participants with non-small cell lung cancer. The RMP version 31.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI."	

Trumenba - Meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0053

Pfizer Europe MA EEIG, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.4 and 5.1 of the SmPC in order to amend an existing warning on immunocompromised individuals and to add immunogenicity data in individuals 10 years of age and above with complement deficiencies or splenic dysfunction based on final results from study B1971060 (A Phase 4, Open-Label, Single-Arm Trial to Describe the Safety, Tolerability, and Immunogenicity of Trumenba When Administered to Immunocompromised Participants ≥10 Years of Age) listed as a category 3 study in the RMP. This was an open-label, single-arm, multicentre trial in which up to 50 immunocompromised participants ≥10 years of age with asplenia (anatomic or functional) or complement deficiency have been enrolled and received bivalent rLP2086 on a 2-dose, 0- and 6-month schedule. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.4."

Votubia - Everolimus - EMEA/H/C/002311/II/0089

Novartis Europharm Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Submission of the final report from study CRAD001M2305 listed as a category 3 study in the RMP. This is an interventional PASS study to monitor the growth and development of pediatric patients previously treated with everolimus in study CRAD001M2301 (EXIST-LT). The RMP version 15.0 has also been submitted."

Zykadia - Ceritinib - EMEA/H/C/003819/II/0055

Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of the final report from PAES study LDK378A2303; this is a Phase III, multicentre, randomized, open-label study of oral LDK378 versus standard chemotherapy in adult patients with ALK rearranged (ALK-positive) advanced non-small

cell lung cancer who have been treated previously with chemotherapy (platinum doublet) and crizotinib. The RMP (version 18.0) is updated accordingly."

WS2733
Edistride-
EMEA/H/C/004161/WS2733/0068
Forxiga-
EMEA/H/C/002322/WS2733/0089
AstraZeneca AB, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Mari Thorn, "Submission of the post-treatment week 104 safety results from study D1680C00019 (T2NOW) listed as a category 3 study in the RMP. This is a randomised, placebo-controlled, double-blind, parallel-group, phase 3 trial with a 26-week safety extension period evaluating the safety and efficacy of dapagliflozin 5 and 10 mg, and saxagliptin 2.5 and 5 mg in paediatric patients with type 2 diabetes mellitus who are between 10 and below 18 years of age. The RMP version 31,s1 has also been submitted."

B.6.11. PRAC assessed procedures

PRAC Led
DECTOVA - Zanamivir -
EMEA/H/C/004102/II/0020
GlaxoSmithKline Trading Services Limited, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study 208140 listed as a category 3 PASS in the RMP. This is an observational study of the safety of zanamivir 10 mg/ml solution for infusion exposure in pregnant women with complicated influenza and their offspring. The RMP version 8.0 has also been submitted."

PRAC Led
Dengvaxia - Dengue tetravalent vaccine (live, attenuated) -
EMEA/H/C/004171/II/0031
Sanofi Pasteur, PRAC Rapporteur: Sonja Hrabcik, PRAC-CHMP liaison: Daniela Philadelphy, "Submission of final study report of DNG15, listed in the RMP as category 3. DNG15 was a prospective, multinational, non-interventional, observational study aiming to assess the risk of AEs associated with CYD dengue vaccine in the real-world immunization

setting."

PRAC Led
Fintepla - Fenfluramine -
EMEA/H/C/003933/II/0025, Orphan
UCB Pharma SA, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of section 4.8 of the SmPC in order to propose a combined Adverse Drug Reaction table for Dravet Syndrome and Lennox-Gastaut syndrome following PSUSA procedure EMEA/H/C/PSUSA/00010907/202306. The package leaflet is updated accordingly."

PRAC Led
Grepid - Clopidogrel -
EMEA/H/C/001059/II/0058
Pharmathen S.A., Generic of Plavix, PRAC Rapporteur: Carla Torre, PRAC-CHMP liaison: Bruno Sepodes, "Submission of an RMP version 0.1 following procedure EMEA/H/C/001059/IB/0057/G."

PRAC Led
Kaftrio - Ivacaftor / Tezacaftor /
Elexacaftor -
EMEA/H/C/005269/II/0052/G, Orphan
Vertex Pharmaceuticals (Ireland) Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Grouped application comprising of two type II variations as follows:
Type II (C.I.3.b) – Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on rash and to add hypersensitivity to the list of adverse drug reactions (ADRs) with frequency "not known" following the outcome of procedure PSUSA/00010868/202310. The Package Leaflet is updated accordingly.
Type II (C.I.z) – Submission of post-marketing breast-feeding case reports."

PRAC Led
Kineret - Anakinra -
EMEA/H/C/000363/II/0093
Swedish Orphan Biovitrum AB (publ), PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Update of section 4.4 of the SmPC in order to add a new warning on 'Amyloidosis (systemic)' based on an updated safety review, following the PRAC recommendation on a signal. In addition, the MAH took the opportunity to correct a numerical

error in the SmPC."

PRAC Led

Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0137

Pfizer Europe MA EEIG, PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, "Update of section 4.8 of the SmPC in order to add 'hypersensitivity' to the list of adverse drug reactions (ADRs) with frequency uncommon, following PRAC's recommendation for procedure EMEA/H/002226/PAM/LEG/058. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

PRAC Led

Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0020

Sanofi Pasteur, PRAC Rapporteur: Nathalie Gault, PRAC-CHMP liaison: Alexandre Moreau, "Update of section 4.6 of the SmPC in order to update pregnancy information based on final results from study VAP00007 (non-interventional PASS); this is a Phase IV, observational retrospective post-authorization, descriptive, safety surveillance study to evaluate the safety of RIV4 in pregnant women and their offspring exposed during pregnancy or up to 28 days preceding the estimated date of conception with regards to pregnancy, birth, and neonatal/infant outcomes."

PRAC Led

TEZSPIRE - Tezepelumab - EMEA/H/C/005588/II/0013/G

AstraZeneca AB, PRAC Rapporteur: Eva Jirsová, PRAC-CHMP liaison: Petr Vrbata, "A grouped application consisting of:
Type II (C.I.11.b): Submission of an updated RMP version V 3, S 1 in order to remove the SUNRISE study (D5180C00024) from the RMP due to discontinuation of the study. This is a Phase 3, randomised, double-blind, parallel-group, placebo-controlled, multicentre study to evaluate the efficacy and safety of tezepelumab 210 mg Q4W administered SC for 28 weeks using an accessorised pre-filled syringe, compared with placebo in reducing OCS use in OCS-dependent adult asthma participants. In addition, the MAH took the opportunity to

implement updates to the Targeted Safety Questionnaires (TSQs) and to the Module SI of the RMP to bring it up to date. Type IB (C.I.11.z): Submission of an updated RMP version V 3, S 1 in order to remove the DESTINATION study (D5180C00018) following procedure EMEA/H/C/005588/11/0004. Type IB (C.I.11.z): Submission of an updated RMP version V 3, S 1 in order to propose changes to the study design and objectives for the Pregnancy PASS (D5180R00010), following procedure EMEA/H/C/005588/MEA/001.2. Type IB (C.I.11.z): Submission of an updated RMP version V 3, S 1 in order to propose changes to the study design and objectives for the Cardiac PASS (D5180R00024), following procedure EMEA/H/C/005588/MEA/005."	
PRAC Led **Trulicity - Dulaglutide - EMEA/H/C/002825/II/0071** Eli Lilly Nederland B.V., PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, "Submission of an updated RMP version 8.1 in order to add a medullary thyroid cancer (MTC) database linkage study (Study I8F-MC-B014) as an additional pharmacovigilance activity to evaluate the important potential risk of MTC in patients exposed to long-acting glucagon-like peptide-1 receptor agonist (GLP-1 RA) therapies. In addition, the MAH took the opportunity to include an amendment to Study H9X-MC-B013 due to the removal of the United States data source."	
PRAC Led **WS2696 Adrovance- EMEA/H/C/000759/WS2696/0055 FOSAVANCE- EMEA/H/C/000619/WS2696/0058 VANTAVO- EMEA/H/C/001180/WS2696/0045** Organon N.V., Lead PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Christian Gartner, "Submission of an updated RMP version 8.0 following the assessment outcome from procedure WS/2467 to reclassify the risk of atypical femoral fracture from "important potential risk" to "important identified risk" and to extend the risk of "atypical femoral fracture"	

to "atypical fractures of long bones"."
PRAC Led **WS2697** **Cialis-EMEA/H/C/000436/WS2697/0098** **Tadalafil Lilly-** **EMEA/H/C/004666/WS2697/0012** Eli Lilly Nederland B.V., Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Antonio Gomez-Outes, "To provide an updated RMP version for Cialis and Tadalafil Lilly to align with the currently approved RMP version of Adcirca. There is only one RMP for all 3 tadalafil products (Adcirca, Cialis and Tadalafil Lilly), however different versions of the same RMP are officially approved in the EMA database (for Adcirca v9.2; for Cialis and Tadalafil Lilly v8.2)."
PRAC Led **WS2708** **Lyrica-EMEA/H/C/000546/WS2708/0136** **Pregabalin Pfizer-** **EMEA/H/C/003880/WS2708/0057** Upjohn EESV, Lead PRAC Rapporteur: Liana Martirosyan, PRAC-CHMP liaison: Peter Mol, "Submission of the final report from study A0081096 listed as a category 3 study in the RMP. This is a prospective randomized 12-week controlled study of visual field change in subjects with partial seizures receiving pregabalin or placebo."
PRAC Led **WS2713** **Glyxambi-** **EMEA/H/C/003833/WS2713/0062** **Jardiance-** **EMEA/H/C/002677/WS2713/0089** **Synjardy-** **EMEA/H/C/003770/WS2713/0080** Boehringer Ingelheim International GmbH, Lead PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP liaison: Carolina Prieto Fernandez, "Submission of the final report from study 1245-0097. This is a post-authorisation safety study (PASS) to assess the risk of urinary tract malignancies in relation to empagliflozin exposure in patients with type 2 diabetes: a multi-database European study. The RMP versions 23.0, 17.0 and 11.0 are also submitted for Jardiance, Synjardy and Glyxambi, respectively."

PRAC Led
WS2719
Invokana-
EMEA/H/C/002649/WS2719/0068
Vokanamet-
EMEA/H/C/002656/WS2719/0075
Janssen-Cilag International N.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final report from study PCSCVM003617, listed as a category 3 study in the RMP. This is a Real-World Database Study of Canagliflozin Utilization in Type 1 Diabetes Patients Over Time among European Countries. The RMP version 12.1 has also been submitted."

B.6.12. CHMP-CAT assessed procedures

Hemgenix - Etranacogene dezaparvovec - EMEA/H/C/004827/II/0015, Orphan, ATMP
CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy, "Submission of the final report from study AMT-061-01/CSL222_2001 listed as a Specific Obligation in the Annex II of the Product Information. This is a Phase IIb, open-label, single-dose, single-arm, multi-centre trial to confirm the factor IX activity level of the serotype 5 adeno-associated viral vector containing the Padua variant of a codon-optimized human factor IX gene (AAV5-hFIXco-Padua, AMT-061) administered to adult subjects with severe or moderately severe haemophilia B. The Annex II is updated accordingly."

Hemgenix - Etranacogene dezaparvovec - EMEA/H/C/004827/II/0016/G, Orphan, ATMP
CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy

Libmeldy - Atidarsagene autotemcel - EMEA/H/C/005321/II/0027, Orphan, ATMP
Orchard Therapeutics (Netherlands) B.V., Rapporteur: Emmely de Vries, CHMP Coordinator: Peter Mol

Libmeldy - Atidarsagene autotemcel - EMEA/H/C/005321/II/0029, Orphan, ATMP

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

Luxturna - Voretigene neparvovec - EMEA/H/C/004451/II/0050/G, Orphan, ATMP
Novartis Europharm Limited, Rapporteur: Sol Ruiz, CHMP Coordinator: Antonio Gomez-Outes

WS2736
Tecartus- EMEA/H/C/005102/WS2736/0048
Yescarta- EMEA/H/C/004480/WS2736/0080
Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

PRAC Led
Strimvelis - Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - EMEA/H/C/003854/II/0040, Orphan, ATMP
Fondazione Telethon ETS, CHMP Coordinator: Antonio Gomez-Outes, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 7.0 in order to to propose amendments to the STRIM-005 and STRIM-003 study protocols, as well as revised timelines for completion of both studies. In addition, the Annex II is updated accordingly."

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

WS2731/G
Biktarvy- EMEA/H/C/004449/WS2731/0061/G
Descovy- EMEA/H/C/004094/WS2731/0067/G
Emtriva- EMEA/H/C/000533/WS2731/0143/G
Eviplera- EMEA/H/C/002312/WS2731/0116/G

Genvoya-
EMEA/H/C/004042/WS2731/0092/G
Odefsey-
EMEA/H/C/004156/WS2731/0064/G
Stribild-
EMEA/H/C/002574/WS2731/0124/G
Truvada-
EMEA/H/C/000594/WS2731/0181/G
Gilead Sciences Ireland UC, Lead Rapporteur:
Bruno Sepodes, Quality

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

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

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

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

G. ANNEX G

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

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

G.2. PRIME

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

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