16 September 2024
EMA/CHMP/392298/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 16-19 September 2024
Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

16 September 2024, 09:00 – 19:30, virtual meeting/room 1C

17 September 2024, 08:30 – 19:30, virtual meeting/room 1C

18 September 2024, 08:30 – 19:30, virtual meeting/room 1C

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

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 16-19 September 2024. See September 2024 CHMP minutes (to be published post October 2024 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 16-19 September 2024

1.3. Adoption of the minutes

CHMP minutes for 22-25 July 2024 Plenary including the minutes for the extraordinary meeting held on 29 July 2024, and 19-22 August 2024 Written Procedure minutes.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 09 September 2024.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Apremilast - EMEA/H/C/006193

Treatment of psoriatic arthritis, psoriasis, Behçet's disease

Scope: Oral explanation

Action: Oral explanation to be held on 17 September 2024 at 14:00

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

2.1.2. Levetiracetam - EMEA/H/C/006186

Treatment of partial onset seizures

Scope: Oral explanation

Action: Oral explanation to be held on 17 September 2024 at 11:00

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

2.1.3. Catumaxomab - EMEA/H/C/005697

Indicated for the treatment of malignant ascites

Scope: Oral explanation

Action: Oral explanation to be held on 18 September 2024 at 11:00

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

2.1.4. Meningococcal group A, B, C, W and Y vaccine - EMEA/H/C/006165

Indicated for active immunisation to prevent invasive disease caused by Neisseria meningitidis groups A, B, C, W, and Y

Scope: Oral explanation

Action: Oral explanation to be held on 17 September 2024 at 09:00

List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 12.10.2023.

2.1.5. 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: Oral explanation

Action: Oral explanation to be held on 18 September 2024 at 14:30

List of Outstanding Issues adopted on 25.07.2024. List of Questions adopted on 23.04.2024.

2.1.6. 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: Oral explanation

Action: Oral explanation to be held on 18 September 2024 at 09:00

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

2.2. Re-examination procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 18 September 2024 at 16:00

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.

See 3.5

2.3. Post-authorisation procedure oral explanations

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

Boehringer Ingelheim International GmbH; treatment of Idiopathic Pulmonary Fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) and systemic sclerosis associated interstitial lung disease (SSc-ILD)

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

Scope: Oral explanation

Action: Oral explanation to be held on 18 September 2024 at 14:00

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

See 4.1

2.3.2. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0145

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Oral explanation

Action: Oral explanation to be held on 17 September 2024 at 16:00

Request for Supplementary Information adopted on 27.06.2024, 25.01.2024.

See 5.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Aflibercept - EMEA/H/C/006150

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 25.01.2024.

3.1.2. Mirvetuximab soravtansine - Orphan - EMEA/H/C/005036

Immunogen Biopharma (Ireland) Limited; treatment of ovarian, fallopian tube, or primary peritoneal cancer

Scope: Opinion

Action: For adoption

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

3.1.3. 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: Opinion

Action: For adoption

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

3.1.4. Serplulimab - Orphan - EMEA/H/C/006170

Henlius Europe GmbH; first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.12.2023. List of Questions adopted on 20.07.2023.

3.1.5. Aflibercept - EMEA/H/C/006056

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 21.03.2024.

3.1.6. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.07.2024. List of Questions adopted on 25.01.2024.

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

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

Scope: Opinion

Action: For adoption

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

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

3.2.1. Aflibercept - EMEA/H/C/006607

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

Scope: List of outstanding issues

Action: For adoption

3.2.2. Repotrectinib - EMEA/H/C/006005

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2024.

3.2.3. Aflibercept - EMEA/H/C/005980

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2024.

3.2.4. Givinostat - Orphan - EMEA/H/C/006079

Italfarmaco S.p.A.; treatment of Duchenne muscular dystrophy (DMD)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.12.2023.

3.2.5. Eltrombopag - EMEA/H/C/006417

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2024.

3.2.6. Aflibercept - EMEA/H/C/005899

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2024.

3.2.7. Garadacimab - Orphan - EMEA/H/C/006116

CSL Behring GmbH; routine prevention of attacks of hereditary angioedema (HAE)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.03.2024.

3.2.8. Insulin human - EMEA/H/C/006011

Treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.05.2023.

3.2.9. Zapomeran – OPEN – EMEA/H/C/006207

Active immunisation to prevent COVID-19

Scope: List of outstanding issues

Action: For adoption

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

3.2.10. Lazertinib - EMEA/H/C/006074

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.05.2024.

3.2.11. rdESAT-6 / rCFP-10 - EMEA/H/C/006177

Diagnosis of infection with *Mycobacterium tuberculosis*

Scope: List of outstanding issues

Action: For adoption

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

3.2.12. Trabectedin - EMEA/H/C/006433

Treatment of soft tissue sarcoma and combination with PLD treatment of relapsed platinum-sensitive ovarian cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 30.05.2024.

3.2.13. Belzutifan - EMEA/H/C/005636

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2024.

3.2.14. Filgrastim - EMEA/H/C/006400

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2024.

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

3.3.1. Atropine - PUMA - EMEA/H/C/006385

Treatment of myopia in children aged 3 years and older

Scope: List of questions

Action: For adoption

3.3.2. Denosumab - EMEA/H/C/006434

Treatment of osteoporosis and bone loss

Scope: List of questions

Action: For adoption

3.3.3. Denosumab - EMEA/H/C/006435

Prevention of skeletal related events with advanced malignancies

Scope: List of questions

Action: For adoption

3.3.4. Denosumab - EMEA/H/C/006199

Prevention of skeletal related events with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone

Scope: List of questions

Action: For adoption

3.3.5. Denosumab - EMEA/H/C/006376

Prevention of skeletal related events with advanced malignancies, treatment of adults and skeletally mature adolescents with giant cell tumour of bone

Scope: List of questions

Action: For adoption

3.3.6. Deutivacaftor / Tezacaftor / Vanzacaftor - Orphan - EMEA/H/C/006382

Vertex Pharmaceuticals (Ireland) Limited; indicated for the treatment of cystic fibrosis

Scope: List of questions

Action: For adoption

3.3.7. Inavolisib - EMEA/H/C/006353

Treatment of adult patients with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer

Scope: List of questions

Action: For adoption

3.3.8. Denosumab - EMEA/H/C/006152

For the treatment of osteoporosis and bone loss.

Scope: List of questions

Action: For adoption

3.3.9. Sipavibart – OPEN – EMEA/H/C/006291

Accelerated assessment

Indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older

Scope: List of questions

Action: For adoption

3.3.10. Macitentan - EMEA/H/C/006524

Treatment of pulmonary arterial hypertension (PAH)

Scope: List of questions

Action: For adoption

3.3.11. Macitentan - EMEA/H/C/006523

Treatment of pulmonary arterial hypertension (PAH)

Scope: List of questions

Action: For adoption

3.3.12. Octreotide - Orphan - EMEA/H/C/006322

Camurus AB; treatment of acromegaly

Scope: List of questions

Action: For adoption

3.3.13. Sepiapterin - Orphan - EMEA/H/C/006331

PTC Therapeutics International Limited; treatment of hyperphenylalaninemia (HPA) in adult and paediatric patients with phenylketonuria (PKU)

Scope: List of questions

Action: For adoption

3.3.14. Teprotumumab - EMEA/H/C/006396

Treatment of moderate to severe Thyroid Eye Disease (TED).

Scope: List of questions

Action: For adoption

3.3.15. Denosumab - EMEA/H/C/006377

For the treatment of osteoporosis and bone loss

Scope: List of questions

Action: For adoption

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

3.4.1. 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: Clockstop extension requested to respond to LoQ, responses expected 20.01.2025.

Action: For information

List of Questions adopted on 19.07.2024.

3.4.2. Deutetrabenazine - EMEA/H/C/006371

Treatment of tardive dyskinesia

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

Action: For information

List of Questions adopted on 25.07.2024.

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

Action: For adoption

List of Questions adopted on 25.07.2024.

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

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

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

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

Action: For information

List of Questions adopted on 19.07.2024.

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

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

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

Scope: Opinion

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.

See 2.2

3.5.2. 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: Questions to the SAG-N

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.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. 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: Withdrawal of initial marketing authorization application

Action: For information

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

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

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

4.1.1. BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/X/0014/G

Hipra Human Health S.L.;

Rapporteur: Beata Maria Jakline Ullrich

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

Action: For adoption

List of Questions adopted on 27.06.2024.

4.1.2. 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 Outstanding Issues adopted on 25.07.2024. List of Questions adopted on 12.10.2023.

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

Boehringer Ingelheim International GmbH; treatment of Idiopathic Pulmonary Fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) and systemic sclerosis associated interstitial lung disease (SSc-ILD)

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

See 2.3

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. Kevzara - Sarilumab - EMEA/H/C/004254/X/0043/G

Sanofi Winthrop Industrie;

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

Scope: "Extension application to add a new strength of 175 mg/ml solution for injection in vial, grouped with an Extension of indication to include treatment of active polyarticular-course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older for KEVZARA, based on results from study DRI13925; this is a multinational, multi-center, open-label, 2 phase, 3 portions study to describe the PK profile as well as safety and efficacy of sarilumab. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

List of Questions adopted on 25.04.2024.

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. Evrysdi - Risdiplam - EMEA/H/C/005145/X/0024/G

Roche Registration GmbH;

Rapporteur: Bruno Sepodes

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

Action: For adoption

4.3.2. Omvoh - Mirikizumab - EMEA/H/C/005122/X/0006/G

Eli Lilly Nederland B.V.;

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Sonja Hrabcik

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

Action: For adoption

4.3.3. Tremfya - Guselkumab - EMEA/H/C/004271/X/0043/G

Janssen-Cilag International N.V.;

Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension application to:

- introduce a new pharmaceutical form (concentrate for solution for infusion), a new strength (200 mg) and a new route of administration (intravenous use)
- add a new strength of 200 mg for solution for injection (in pre-filled syringe / pre-filled pen) for subcutaneous use

This application is grouped with a type II variation (C.I.6.a) to include the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor for Tremfya, based on results of a Phase 2b/3 clinical development programme (CNTO1959UCO3001) consisting of 3 separate studies, an Induction dose finding Study 1 Phase 2b, an Induction Study 2 Phase 3 and a Phase 3 Maintenance Study. These studies were randomized, double-blind, placebo-controlled, parallel-group, multicenter studies that evaluated the efficacy and safety of guselkumab in participants with moderately to severely active UC. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC of the already approved form 100 mg solution for injection are updated. The Package Leaflet and Labelling are updated in accordance. Version 10.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI."

Action: For adoption

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

No items

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

No items

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

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

5.1.1. Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0007

Pfizer Europe Ma EEIG;

Rapporteur: Jayne Crowe, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include active immunization of individuals 18 through 59

years of age for ABRYSVO, based on final results from C3671023 Sub study A; this is a Phase 3 double-blinded, randomised, placebo-controlled study of safety, tolerability and immunogenicity of Abrysvo in participants ≥18 to <60 years of age at high risk of severe RSV disease due to certain chronic medical conditions. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, as part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.2. 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, Multicentre Study to Evaluate the Immunogenicity and Safety of Several Doses of Antigen and MF59 Adjuvant Content in a Monovalent H5N1 Pandemic Influenza Vaccine in Healthy Paediatric Subjects 6 Months to < 9 Years of Age.
As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 5.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024.

5.1.3. BUCCOLAM - Midazolam - EMEA/H/C/002267/II/0061

Neuraxpharm Pharmaceuticals S.L.;

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

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

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024.

5.1.4. Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0072

Janssen-Cilag International N.V.;

Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include, in combination with bortezomib, lenalidomide and dexamethasone, the treatment of adult patients with newly diagnosed multiple myeloma, who are eligible for autologous stem cell transplant for Darzalex, based on the primary analysis results from the pivotal study 54767414MMY3014 (PERSEUS) and the results from study 54767414MMY2004 (GRIFFIN) and the D-VRd cohort of study 54767414MMY2040 (PLEIADES).
MMY3014 (PERSEUS) is a randomised, open-label, active-controlled, multicentre phase 3 study in adult subjects with newly diagnosed multiple myeloma, who are eligible for high dose therapy (as required for autologous stem cell transplant). The primary objective is to compare the efficacy of (subcutaneous) daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) versus bortezomib, lenalidomide and dexamethasone (VRd) in terms of progression free survival (PFS).
MMY2004 (GRIFFIN) is a randomised, open-label, active controlled, multicentre phase 2 study in adult subjects with newly diagnosed multiple myeloma, who are eligible for high dose therapy and autologous stem cell transplant. The primary objective is to compare the efficacy of daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) versus bortezomib, lenalidomide and dexamethasone (VRd), in terms of stringent complete response (sCR) rate.
MMY2040 (PLEIADES) is a randomised, open-label, multicentre phase 2 study to evaluate subcutaneous daratumumab in combination with standard multiple myeloma treatment regimens. The D-VRd cohort included adult subjects with newly diagnosed multiple myeloma, who were evaluated for clinical benefit in terms of very good partial response or better (VGPR) rate.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 27.06.2024.

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 Paediatric 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 25.07.2024, 21.03.2024.

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

Sanofi Winthrop Industrie;

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

Scope: "Extension of indication to include treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents 12 years and older, who are symptomatic despite treatment with H1 antihistamines and who are intolerant to or inadequately controlled by anti-IgE therapy for Dupixent, based on the results from studies EFC16461 (CUPID) study B (pivotal) and study A (supportive); EFC16461 Study B was a 24-week, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of dupilumab in adult and adolescent participants with CSU who remained symptomatic despite the use of H1-antihistamine and who were intolerant or incomplete responders to omalizumab and EFC16461 Study A was a 24-week, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of dupilumab in participants with CSU who remained symptomatic despite the use of H1-antihistamine and who were naïve to omalizumab. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024.

5.1.7. Esperoct - Turoctocog alfa pegol - EMEA/H/C/004883/II/0023

Novo Nordisk A/S;

Rapporteur: Daniela Philadelphy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Gabriele Maurer

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

Action: For adoption

Request for Supplementary Information adopted on 27.06.2024.

5.1.8. Fasenra - Benralizumab - EMEA/H/C/004433/II/0052

AstraZeneca AB;

Rapporteur: Fátima Ventura (PT) (MNAT with EL for Clinical Safety, EL for Clinical Pharmacology, EL for Clinical Efficacy), PRAC Rapporteur: David Olsen

Scope: "Extension of indication to include treatment of eosinophilic granulomatosis with

polyangiitis for Fasenra, based results from study D3253C00001 (Mandara); this was a randomised, double-blind, multicentre, parallel group, active-controlled, non-inferiority study that evaluated the efficacy and safety of benralizumab compared with mepolizumab in treatment of patients with EGPA on corticosteroid therapy with or without stable immunosuppressive therapy. 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 6.1 of the RMP has also been submitted. In addition, the MAH took this opportunity to introduce editorial changes. 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, 21.03.2024.

5.1.9. IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0108

Bavarian Nordic A/S;

Rapporteur: Jan Mueller-Berghaus

Scope: "Extension of indication to include treatment of adolescents from 12 to 17 years of age for IMVANEX based on interim results from study DMID 22-0020. This is a Phase 2 randomized open label multisite trial to inform Public Health strategies involving the use of MVA-BN vaccine for mpox. 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. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

5.1.10. JEMPERLI - Dostarlimab - EMEA/H/C/005204/II/0032

GlaxoSmithKline (Ireland) Limited;

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication for JEMPERLI to include, in combination with carboplatin and paclitaxel, the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy based on Interim Analysis 1 and 2 from study RUBY Part 1 (213361). This is a phase 3, randomized, double-blind, controlled study evaluating the efficacy and safety of dostarlimab plus carboplatin and paclitaxel in primary advanced or recurrent EC versus placebo plus carboplatin and paclitaxel.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC and to align the PI with the latest QRD template version 10.4."

Action: For adoption

5.1.11. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0145

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy) the treatment of high-risk locally advanced cervical cancer in adults who have not received prior definitive therapy [Stage IB2-IIB (with node-positive disease) or Stage III-IVA based on FIGO 2014] for Keytruda, based on KEYNOTE-A18: A Randomized, Phase 3, Double-Blind Study of Chemoradiotherapy With or Without Pembrolizumab for the Treatment of High-risk, Locally Advanced Cervical Cancer. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 44.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 27.06.2024, 25.01.2024.

See 2.3

5.1.12. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0153

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

Request for Supplementary Information adopted on 27.06.2024.

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

Advanced Accelerator Applications;

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of newly diagnosed, unresectable or metastatic, well-differentiated (G2 and G3), somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) adult patients for LUTATHERA, based on primary analysis results from study CAAA601A22301 (NETTER-2); NETTER-2 study is a Phase III, multicentre, stratified, open-label, randomized, comparator-controlled study comparing treatment with Lutathera plus octreotide LAR 30 mg (Lutathera arm) to treatment with high-dose octreotide LAR 60 mg (control arm). The main purpose of the

NETTER-2 study was to determine if treatment in the Lutathera arm prolongs PFS in subjects with newly diagnosed SSTR-positive, G2 and G3 advanced GEP-NET when compared with treatment in the control arm.
As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes in the SmPC. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.14. Ngenla - Somatrogon - Orphan - EMEA/H/C/005633/II/0016

Pfizer Europe MA EEIG;

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include the long-term replacement of endogenous growth hormone of adults with growth hormone deficiency for Ngenla, based on supplemental results from study CP-4-005 and the Phase 2 supportive study CP-4-003. CP-4-005 is a Phase 3, multicentre study designed to evaluate the efficacy and safety of a Long Acting hGH Product (MOD-4023) in adult subjects with Growth Hormone Deficiency. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9 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."

Action: For adoption

5.1.15. 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 25.07.2024, 21.03.2024.

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

Aimmune Therapeutics Ireland Limited;

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Terhi Lehtinen

Scope: "Grouped variation consisting of:
C.I.6.a (Extension of indication): Extension of indication to include treatment of patients 1 to 3 years old for PALFORZIA, based on final results from study ARC005; this is a Phase 3 randomized, double-blind, placebo-controlled Peanut Oral Immunotherapy Study of Early Intervention for Desensitization (POSEIDON) to evaluate the safety and efficacy of peanut powder in terms of superiority of placebo in children of 1 year to less than 4 years of age with peanut allergy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 6.5 and 8 of the SmPC are updated. The Package Leaflet and Labelling were updated accordingly. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC and to update the list of local representatives in the Package Leaflet. As part of the application the MAH is requesting a 1-year extension of the market protection.
B.II.e.5.a: Introduction of a new pack-size.
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024, 14.12.2023.

5.1.17. Pravafenix - Fenofibrate / Pravastatin sodium - EMEA/H/C/001243/II/0037

Laboratoires SMB s.a.;

Rapporteur: Jean-Michel Race, PRAC Rapporteur: Nathalie Gault

Scope: "Extension of indication to include treatment of mixed hyperlipidaemia in adult patients while on a treatment with pravastatin 40 mg monotherapy or on another moderate-intensity statin regimen for PRAVAFENIX, based on final results from the non-interventional PASS: POSE (Pravafenix Observational Study in Europe); this is a European, observational, three-year cohort comparative study on the safety of the fixed dose combination pravastatin 40 mg/fenofibrate 160 mg (Pravafenix) versus statin alone in real clinical practice. As a consequence, sections 4.1 and 4.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 27.06.2024, 21.03.2024.

5.1.18. REKAMBYS - Rilpivirine - EMEA/H/C/005060/II/0022

Janssen-Cilag International N.V.;

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Bruno Sepodes, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include in combination with cabotegravir injection, the treatment of adolescents (at least 12 years of age and weighing at least 35 kg) for Rekambys, based on interim results from study 208580 (Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents). This is an ongoing Phase 1/Phase 2 multicentre, open-label, non-comparative study evaluating the safety, acceptability, tolerability, and PK of oral and LA injectable CAB and LA injectable RPV in virologically suppressed HIV-infected adolescents 12 to <18 years of age and weighing at least 35 kg who are receiving stable cART consisting of 2 or more drugs from 2 or more classes of ARV drugs. Consequently, 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 5.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update a local representative in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4"

Action: For adoption

5.1.19. Rybrevant - Amivantamab - EMEA/H/C/005454/II/0013

Janssen-Cilag International N.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include amivantamab in combination with lazertinib for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 L858R substitution mutations (EGFRm NSCLC), based on results from study 73841937NSC3003 (MARIPOSA). This is a randomized, open-label, Phase 3 study that compares the efficacy and safety of the combination of amivantamab and lazertinib (Arm A) versus osimertinib monotherapy (Arm B) and lazertinib monotherapy (Arm C) in participants with EGFRm NSCLC. The primary objective of the MARIPOSA study was to assess the efficacy of the combination of amivantamab and lazertinib (Arm A), compared with osimertinib (Arm B), as measured by PFS assessed by BICR in adult participants with EGFRm NSCLC.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1, 5.2, 6.6 and 9 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.3 of the EU RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024.

5.1.20. Slenyto - Melatonin - EMEA/H/C/004425/II/0028

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 insomnia in children and adolescents aged 2-18 with Attention-Deficit Hyperactivity Disorder (ADHD), where sleep hygiene measures have been insufficient, based on results from phase III study NEU_CH_7911 and literature. As a consequence, sections 4.1 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."

Action: For adoption

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

Boehringer Ingelheim International GmbH;

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

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

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024.

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

Beigene Ireland Limited;

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

Scope: "Extension of indication to include in combination with platinum-based chemotherapy the first-line treatment of adult patients with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma (OSCC) for TEVIMBRA, based on results from study BGB-A317-306; this is a multi-regional, randomized, placebo-controlled, double-blind phase 3 study evaluating the efficacy and safety of tislelizumab in combination with chemotherapy compared to placebo in combination with chemotherapy as first-line treatment in patients with unresectable or locally advanced recurrent or metastatic OSCC. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024.

5.1.23. Tremfya - Guselkumab - EMEA/H/C/004271/II/0044

Janssen-Cilag International N.V.;

Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication for TREMFYA to include treatment of adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic treatment, based on results from GALAXI Phase 2/3 program and the GRAVITI Phase 3 study. GALAXI is a Phase 2/3, randomized, double-blind, placebo- and active-controlled, parallel-group, multicentre protocol to evaluate the efficacy and safety of guselkumab in participants with moderately to severely active CD who have demonstrated an inadequate response or failure to tolerate previous conventional or biologic therapy. GRAVITI is a Phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicentre study to evaluate the efficacy and safety of guselkumab SC induction therapy in participants with moderately to severely active CD.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2, and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.24. Vocabria - Cabotegravir - EMEA/H/C/004976/II/0022

ViiV Healthcare B.V.;

Rapporteur: Jean-Michel Race, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include in combination with rilpivirine injection, the treatment of adolescents (at least 12 years of age and weighing at least 35 kg) for Vocabria, based on interim results from study 208580 (Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents). This is an ongoing Phase 1/Phase 2 multicentre, open-label, non-comparative study evaluating the safety, acceptability, tolerability, and PK of oral and LA injectable CAB and LA injectable RPV in virologically suppressed HIV-infected adolescents 12 to <18 years of age and weighing at least 35 kg who are receiving stable cART consisting of 2 or more drugs from 2 or more classes of ARV drugs. 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 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

5.1.25. Vyvgart - Efgartigimod alfa - Orphan - EMEA/H/C/005849/II/0020

Argenx;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension of indication to include the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) with active disease despite treatment

with corticosteroids or immunoglobulins for VYVGART, based on final results from study ARGX-113-1802; this is a pivotal study to investigate the efficacy, safety and tolerability of efgartigimod PH20 SC in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP); and based on interim results from study ARGX-113-1902; this is an open-label extension study of the ARGX-113-1802 trial to investigate the long-term safety, tolerability and efficacy of efgartigimod PH20 SC in patients with (CIDP).
As a consequence, sections 4.1, 4.2. 4.4, 4.8, 5.1 and 5.2 of the SmPC has been updated. The Package Leaflet has been updated in accordance with the SmPC. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Action: For adoption

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

Theramex Ireland Limited;

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

Scope: "Extension of indication to include treatment of endometriosis-associated pain in adult women of reproductive age for YSELTY, based on final results from studies Edelweiss 3 (18-OBE2109-003) and Edelweiss 6 (19-OBE2109-006) as well as additional supporting studies. Edelweiss 3 is a pivotal phase 3, randomised, double-blind, placebo-controlled, safety and efficacy study to evaluate linzagolix with add-back therapy as a therapy for pain associated with endometriosis, while Edelweiss 6 is an open-label extension study including patients who completed Edelweiss 3 pivotal study regardless of their previous treatment assignment and met the eligibility criteria. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024.

5.1.27. Zavicefta - Ceftazidime / Avibactam - EMEA/H/C/004027/II/0035

Pfizer Ireland Pharmaceuticals;

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

Scope: "Extension of indication to include treatment of paediatric patients from birth to less than 3-months of age in the following infections: complicated intra-abdominal infection (cIAI), complicated urinary tract infection (cUTI), including pyelonephritis, hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) and in the treatment of infections due to aerobic Gram-negative organisms in patients with limited treatment options, for ZAVICEFTA, based on final results from study C3591024 and the population PK modelling/simulation analyses. Study C3591024 is a Phase 2a, 2-part, open-label, non-randomized, multicentre, single and multiple dose trial to evaluate pharmacokinetics, safety and tolerability of ceftazidime and avibactam in neonates and infants from birth to less than 3 months of age with suspected or confirmed infections due to gram-negative pathogens

requiring intravenous antibiotic treatment. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.3 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 27.06.2024, 25.04.2024.

5.1.28. 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."

Third party intervention.

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024, 22.02.2024.

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

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

Incyte Biosciences Distribution B.V.;

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

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

(EC) 726/2004),

Clock-stop extension requested to respond to RSI

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024, 25.04.2024.

5.2.2. Kisqali - Ribociclib - EMEA/H/C/004213/0045 and EMEA/H/C/004213/0054/G

Novartis Europharm Limited;

Lead Rapporteur: Filip Josephson

Scope (0045): "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."

Scope (0054/G): Group of 17 variations including introduction of a limit for mutagenic nitrosamine impurity DMP433, reduction of shelf life of the finished product as packaged for sale, from 36 months to 12 months and change in the storage conditions of the product from "this medicinal product does not require any special storage conditions" to "store in a refrigerator (2 °C – 8 °C)."

Action: For information

Request for Supplementary Information (0045) adopted on 14.12.2023, 21.03.2024, 25.07.2024.

Request for Supplementary Information (0054/G): 19.09.2024.

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/006587

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

Scope: List of Questions

Action: For adoption

6.3.2. 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

8.1.1. deoxythymidine,doxecitine - H0005119

Treatment of adult and paediatric patients with thymidine kinase 2 (TK2) deficiency
Scope: Briefing note and the Rapporteurs' recommendation on the request for accelerated assessment.

Action: For adoption

8.2. Priority Medicines (PRIME)

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. PHEBURANE - Sodium phenylbutyrate - EMEA/H/C/002500/X/0037

Eurocept International B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu

Scope: Withdrawal of extension of application

Action: For information

9.1.2. Exviera – Dasabuvir – EMEA/H/C/003837

AbbVie Deutschland GmbH & Co. KG; treatment of chronic hepatitis C

Rapporteur: Filip Josephson, Co-Rapporteur: Patrick Vrijlandt

Scope: Withdrawal of marketing authorization

Action: For information

9.1.3. Viekirax - Ombitasvir/Paritaprevir/Ritonavir – EMEA/H/C/003839

AbbVie Deutschland GmbH & Co. KG; treatment of chronic hepatitis C

Rapporteur: Filip Josephson, Co-Rapporteur: Patrick Vrijlandt

Scope: Withdrawal of marketing authorization

Action: For information

9.1.4. Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0044

AstraZeneca AB

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

Scope: "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP

version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

9.1.5. 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: Daniela PhiladelphyScope:

Action: For adoption
Request for Supplementary Information adopted on 25.07.2024.

9.1.6. COMIRNATY - COVID-19 mRNA vaccine – EMA/VR/0000225514

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson

Scope:

Action: For adoption

9.1.7. Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0078

Novavax CZ a.s.

Rapporteur: Patrick Vrijlandt

Action: For adoption

9.1.8. Alecensa - Alectinib - EMEA/H/C/004164/II/0048

Roche Registration GmbH

Rapporteur: Filip Josephson

Scope: "To update sections 4.4 and 4.6 of the SmPC to update the safety information to amend the duration of the period for which female patients of child-bearing potential must use highly effective contraceptive methods following the last dose of Alecensa, and must be informed of potential harm to the foetus in the event of pregnancy, from 3 months to 5 weeks based on the latest guidelines on contraception requirements for drugs with aneugenic potential. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

CHMP request to PRAC for advice on DHPC.

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024.

9.1.9. 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 25.07.2024, 11.04.2024.

9.1.10. Eurartesim - Piperaquine tetraphosphate / Artenimol - EMEA/H/C/001199/X/0041

Alfasigma S.p.A.

Rapporteur: Janet Koenig

Scope: Withdrawal of extension of application

Action: For information

9.1.11. Sialanar – Glycopyrronium – EMEA/H/C/003883/II/29

Proveca Pharma Limited

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Thomas Radimersky

Scope: Withdrawal of extention of indication application

Action: For information

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

September 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

14.1.1. Election of new CHMP chairperson

Harald Enzmann has served as Chair of the CHMP since 21 September 2018 and his second 3-year mandate will shortly come to an end.

The election of a new Chairperson will take place at the September 2024 CHMP plenary meeting as previously communicated to the Committee.

Candidates for the position of CHMP Chair are now invited to indicate their interest in standing for this position. Although candidates can express their interest until the start of the September 2024 CHMP meeting, we would appreciate receiving nominations **by Wednesday, 11 September 2024** EOB to facilitate preparation of the meeting.

Candidates should declare their interest by circulating a letter, indicating their intention to stand, together with a motivation for so doing, as well as a brief résumé to the EMA

Any questions regarding the election can be addressed

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 September 2024

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at September 2024 PDCO

Action: For information

Report from the PDCO meeting held on 03-06 September 2024

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 BarbuReports from the BWP meeting for CHMP adoption

Action: For adoption

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Paolo FoggiReport from the SAWP meeting held on 02-05 September 2024. Table of conclusions

Action: For information

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

14.3.3. Election of new Vice-Chair – Haematology Working Party (HaemWP)

Following the call for nominations launched in July 2024, CHMP to elect the Vice-Chair from the candidates who submitted nominations.

Action: For election

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

14.8.1. Update of the Business Pipeline report for the human scientific committees

Forecast for Q3-2024 – update of the Business Pipeline report

Action: For information

14.9. Others

No items

15. Any other business

15.1. AOB topic

No items

Explanatory notes

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

Oral explanations *(section 2)*

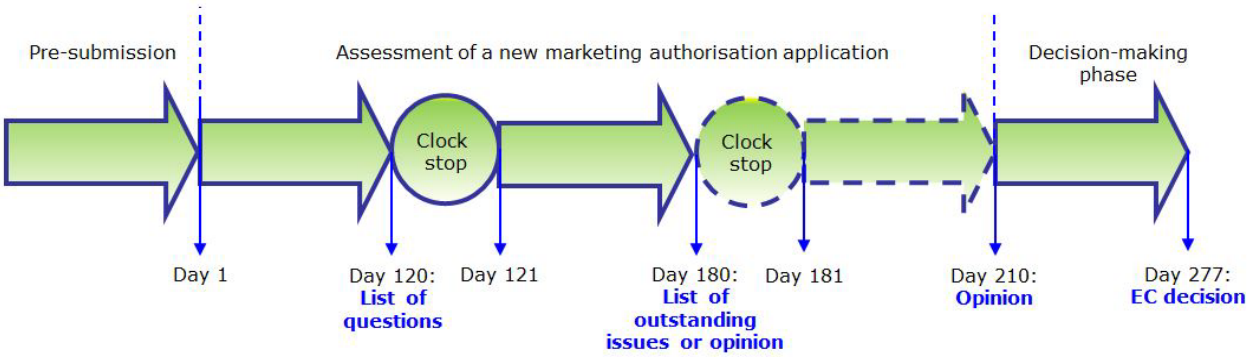
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 September 2024
EMA/CHMP/392969/2024

Annex to 16-19 September 2024 CHMP Agenda

Pre-submission and post-authorisations issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for September 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

EVKEEZA - Evinacumab - EMEA/H/C/005449/S/0018
Ultragenyx Germany GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Mari Thorn

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

GIVLAARI - Givosiran - EMEA/H/C/004775/R/0020, Orphan
Alnylam Netherlands B.V., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Martin Huber

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Azacitidine Accord - Azacitidine - EMEA/H/C/005147/R/0019
Accord Healthcare S.L.U., Generic of Vidaza, Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Bianca Mulder

Azacitidine Mylan - Azacitidine - EMEA/H/C/004984/R/0019

Mylan Ireland Limited, Generic of Vidaza,
Rapporteur: Hrefna Gudmundsdottir, PRAC
Rapporteur: Bianca Mulder

Deferasirox Accord - Deferasirox -
EMEA/H/C/005156/R/0011
Accord Healthcare S.L.U., Generic of EXJADE,
Rapporteur: Daniela Philadelphy, PRAC
Rapporteur: Tiphaine Vaillant
Request for Supplementary Information adopted
on 25.07.2024.

Dexmedetomidine Accord -
Dexmedetomidine -
EMEA/H/C/005152/R/0013
Accord Healthcare S.L.U., Generic of Dexdor,
Rapporteur: John Joseph Borg, PRAC
Rapporteur: Mari Thorn

Lyumjev - Insulin lispro -
EMEA/H/C/005037/R/0019
Eli Lilly Nederland B.V., Rapporteur: Outi Mäki-
Ikola, Co-Rapporteur: Karin Janssen van Doorn,
PRAC Rapporteur: Mari Thorn

Nilemdo - Bempedoic acid -
EMEA/H/C/004958/R/0042
Daiichi Sankyo Europe GmbH, Rapporteur:
Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC
Rapporteur: Kimmo Jaakkola

NUBEQA - Darolutamide -
EMEA/H/C/004790/R/0021
Bayer AG, Rapporteur: Alexandre Moreau, Co-
Rapporteur: Carolina Prieto Fernandez, PRAC
Rapporteur: Jan Neuhauser

Nustendi - Bempedoic acid / Ezetimibe -
EMEA/H/C/004959/R/0047
Daiichi Sankyo Europe GmbH, Rapporteur:
Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC
Rapporteur: Kimmo Jaakkola

Ruxience - Rituximab -
EMEA/H/C/004696/R/0017
Pfizer Europe MA EEIG, Rapporteur: Peter Mol,
PRAC Rapporteur: Karin Erneholm

Rybelsus - Semaglutide -
EMEA/H/C/004953/R/0042
Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt,
Co-Rapporteur: Thalia Marie Estrup Blicher,
PRAC Rapporteur: Mari Thorn

Tavlesse - Fostamatinib -
EMEA/H/C/005012/R/0018
Instituto Grifols, S.A., Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Bianca Mulder
Request for Supplementary Information adopted on 25.07.2024.

Trepulmix - Treprostinil sodium -
EMEA/H/C/005207/R/0020, Orphan
SciPharm Sarl, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Zane Neikena

B.2.3. Renewals of Conditional Marketing Authorisations

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

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

Zynlonta - Loncastuximab tesirine - EMEA/H/C/005685/R/0018
Swedish Orphan Biovitrum AB (publ), Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Eva Jirsová

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 02-05 September 2024 PRAC:

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

EMEA/H/C/PSUSA/00000225/202402
(elranatamab)
CAPS:
ELREXFIO (EMEA/H/C/005908) (Elranatamab), Pfizer Europe Ma EEIG, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Barbara Kovacic Bytyqi, "14/08/2023 To: 13/02/2024"

EMEA/H/C/PSUSA/00000385/202401
(besilesomab)
CAPS:
Scintimun (EMEA/H/C/001045) (Besilesomab), CIS BIO International, Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Monica Martinez Redondo, "10/01/2019 To: 10/01/2024"

EMEA/H/C/PSUSA/00001892/202312
(liraglutide)
CAPS:
Saxenda (EMEA/H/C/003780) (Liraglutide), Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt
Victoza (EMEA/H/C/001026) (Liraglutide), Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Bianca Mulder, "31/12/2020 To: 31/12/2023"

EMEA/H/C/PSUSA/00002182/202401
(estradiol / nomegestrol acetate)
CAPS:
Zoely (EMEA/H/C/001213) (Nomegestrol acetate / Estradiol), Theramex Ireland Limited, Rapporteur: Jean-Michel Race
NAPS:
NAPs - EUROPA
, PRAC Rapporteur: Nathalie Gault, "27/01/2021 To: 26/01/2024"

EMEA/H/C/PSUSA/00010294/202401
(dapagliflozin / metformin)
CAPS:
Ebymect (EMEA/H/C/004162) (Dapagliflozin / Metformin), AstraZeneca AB, Rapporteur: Kristina Dunder
Xigduo (EMEA/H/C/002672) (Dapagliflozin / Metformin), AstraZeneca AB, Rapporteur: Kristina Dunder, PRAC Rapporteur: Bianca Mulder, "16/01/2021 To: 15/01/2024"

EMEA/H/C/PSUSA/00010341/202312
(secukinumab)
CAPS:
Cosentyx (EMEA/H/C/003729) (Secukinumab), Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Monica Martinez Redondo, "26/12/2020 To: 25/12/2023"

EMEA/H/C/PSUSA/00010447/202401
(brivaracetam)
CAPS:
Briviact (EMEA/H/C/003898) (Brivaracetam), UCB Pharma S.A., Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski, "15/01/2021 To: 14/01/2024"

EMEA/H/C/PSUSA/00010503/202312
(selexipag)
CAPS:
Uptravi (EMEA/H/C/003774) (Selexipag), Janssen-Cilag International N.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Nathalie Gault, "20/12/2020 To: 20/12/2023"

EMEA/H/C/PSUSA/00010745/202402
(apalutamide)
CAPS:
Erleada (EMEA/H/C/004452) (Apalutamide), Janssen-Cilag International N.V., Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Tiphaine Vaillant, "14/02/2023 To: 13/02/2024"

EMEA/H/C/PSUSA/00010949/202401
(odevixibat)
CAPS:
Bylvay (EMEA/H/C/004691) (Odevixibat), Ipsen Pharma, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski, "14/07/2023 To: 14/01/2024"

EMEA/H/C/PSUSA/00010971/202401
(tecovirimat)
CAPS:
Tecovirimat SIGA (EMEA/H/C/005248) (Tecovirimat), SIGA Technologies Netherlands B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber, "13/07/2023 To: 12/01/2024"

EMEA/H/C/PSUSA/00010991/202401
(tebentafusp)
CAPS:
KIMMTRAK (EMEA/H/C/004929) (Tebentafusp), Immunocore Ireland Limited, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Bianca Mulder, "24/07/2023 To: 24/01/2024"

EMEA/H/C/PSUSA/00010993/202401
(daridorexant)
CAPS:
QUVIVIQ (EMEA/H/C/005634) (Daridorexant), Idorsia Pharmaceuticals Deutschland GmbH, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ana Sofia Diniz Martins, "07/07/2023 To: 06/01/2024"

EMEA/H/C/PSUSA/00010994/202401
(relugolix)
CAPS:
Orgovyx (EMEA/H/C/005353) (Relugolix), Accord Healthcare S.L.U., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Karin Erneholm, "08/07/2023 To: 07/01/2024"

EMEA/H/C/PSUSA/00011020/202401 (voclosporin) CAPS: **Lupkynis** (EMEA/H/C/005256) (Voclosporin), Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Adam Przybylkowski, "21/07/2023 To: 21/01/2024"

B.4. EPARs / WPARs

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

Aranesp - Darbepoetin alfa - EMEA/H/C/000332/II/0166/G Amgen Europe B.V., Rapporteur: Janet Koenig	
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 Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Azopt - Brinzolamide - EMEA/H/C/000267/II/0078/G Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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: Daniela Philadelphy Request for Supplementary Information adopted on 25.07.2024.	See 9.1
COMIRNATY - COVID-19 mRNA vaccine –	See 9.1

EMA/VR/0000225514 BioNTech Manufacturing GmbH; Rapporteur: Filip Josephson	
Dynastat - Parecoxib - EMEA/H/C/000381/II/0093 Pfizer Europe MA EEIG, Duplicate of Xapit (SRD), Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 12.09.2024.	Request for supplementary information adopted with a specific timetable.
Empliciti - Elotuzumab - EMEA/H/C/003967/II/0040/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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 Request for Supplementary Information adopted on 12.09.2024.	Request for supplementary information adopted with a specific timetable.
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 Request for Supplementary Information adopted on 18.07.2024.	
GONAL-f - Follitropin alfa - EMEA/H/C/000071/II/0172/G Merck Europe B.V., Rapporteur: Patrick Vrijlandt	
Hemangiol - Propranolol - EMEA/H/C/002621/II/0025 Pierre Fabre Medicament, Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 05.10.2023.	
Herzuma - Trastuzumab - EMEA/H/C/002575/II/0061/G Celltrion Healthcare Hungary Kft., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.

Request for Supplementary Information adopted on 18.07.2024, 11.04.2024.	
Idefirix - Imlifidase - EMEA/H/C/004849/II/0024/G, Orphan Hansa Biopharma AB, Rapporteur: Janet Koenig	
Inhixa - Enoxaparin sodium - EMEA/H/C/004264/II/0109 Techdow Pharma Netherlands B.V., Duplicate of Thorinane (EXP), Rapporteur: Christian Gartner Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 25.07.2024, 20.06.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Insuman - Insulin human - EMEA/H/C/000201/II/0150 Sanofi-Aventis Deutschland GmbH, Rapporteur: Karin Janssen van Doorn Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Kisqali - Ribociclib - EMEA/H/C/004213/II/0054/G Novartis Europharm Limited, Rapporteur: Filip Josephson	
Kovaltry - Octocog alfa - EMEA/H/C/003825/II/0044/G Bayer AG, Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 27.06.2024, 21.03.2024.	
LIVOGIVA - Teriparatide - EMEA/H/C/005087/II/0012 Theramex Ireland Limited, Rapporteur: Christian Gartner Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 04.07.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Lutetium (177Lu) chloride Billev - Lutetium (177Lu) chloride - EMEA/H/C/005859/II/0005/G Billev Pharma ApS, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 05.09.2024.	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	

Request for Supplementary Information adopted on 25.07.2024.	
NexoBrid - Concentrate of proteolytic enzymes enriched in bromelain - EMEA/H/C/002246/II/0069 MediWound Germany GmbH, Rapporteur: Janet Koenig Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0136/G Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0063/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 04.07.2024, 25.04.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0070/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 25.07.2024, 20.06.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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 05.09.2024, 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0078 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt	See 9.1
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	Positive Opinion adopted by consensus on 05.09.2024.

Samsung Bioepis NL B.V., Rapporteur: Karin Janssen van Doorn Opinion adopted on 05.09.2024.	
Opdualag - Nivolumab / Relatlimab - EMEA/H/C/005481/II/0009/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Orencia - Abatacept - EMEA/H/C/000701/II/0166/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 16.05.2024.	
Phesgo - Pertuzumab / Trastuzumab - EMEA/H/C/005386/II/0025/G Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Puregon - Follitropin beta - EMEA/H/C/000086/II/0130 Organon N.V., Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 25.07.2024.	
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	
Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0035/G Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson	
Retacrit - Epoetin zeta - EMEA/H/C/000872/II/0119 Pfizer Europe MA EEIG, Rapporteur: Janet Koenig	
Rezzayo - Rezafungin - EMEA/H/C/005900/II/0002, Orphan Mundipharma GmbH, Rapporteur: Bruno Sepodes Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 11.07.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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 Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Semglee - Insulin glargine - EMEA/H/C/004280/II/0050 Biosimilar Collaborations Ireland Limited, Rapporteur: Janet Koenig Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Silapo - Epoetin zeta - EMEA/H/C/000760/II/0074 STADA Arzneimittel AG, Rapporteur: Janet Koenig Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0049/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
SomaKit TOC - Edotreotide -	Request for supplementary information adopted

EMEA/H/C/004140/II/0028, Orphan Advanced Accelerator Applications, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 05.09.2024, 16.05.2024.	with a specific timetable.
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0123/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 05.09.2024, 27.06.2024, 25.04.2024.	Request for supplementary information adopted with a specific timetable.
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0132/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 20.06.2024.	
Steen Solution - Human albumin solution - EMEA/H/D/000002/II/0005 XVIVO Perfusion AB, Rapporteur: Filip Josephson, "To reconfirm the Scientific opinion granted under MDD (93/42/EEC) for the purpose of certification under MDR (MDR/2017/745)." Request for Supplementary Information adopted on 20.06.2024.	
Stimufend - Pegfilgrastim - EMEA/H/C/004780/II/0007 Fresenius Kabi Deutschland GmbH, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 05.09.2024, 20.06.2024, 16.05.2024.	Request for supplementary information adopted with a specific timetable.
Stimufend - Pegfilgrastim - EMEA/H/C/004780/II/0008 Fresenius Kabi Deutschland GmbH, Rapporteur: Christian Gartner	
Surgiflo Haemostatic Matrix Kit - Human thrombin - EMEA/H/D/002301/II/0039/G Ferrosan Medical Devices A/S, Rapporteur: Jan Mueller-Berghaus	
Synflorix - Pneumococcal polysaccharide conjugate vaccine (adsorbed) - EMEA/H/C/000973/II/0185/G GlaxoSmithkline Biologicals SA, Rapporteur: Kristina Dunder	
Tyenne - Tocilizumab -	Positive Opinion adopted by consensus on

EMEA/H/C/005781/II/0003 Fresenius Kabi Deutschland GmbH, Rapporteur: Kristina Dunder Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 27.06.2024.	05.09.2024.
Tyruko - Natalizumab - EMEA/H/C/005752/II/0004 Sandoz GmbH, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Vabysmo - Faricimab - EMEA/H/C/005642/II/0011/G Roche Registration GmbH, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 27.06.2024.	
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	
Vazkepa - Icosapent ethyl - EMEA/H/C/005398/II/0023/G Amarin Pharmaceuticals Ireland Limited, Rapporteur: Janet Koenig Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 25.04.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Voxzogo - Vosoritide - EMEA/H/C/005475/II/0015, Orphan BioMarin International Limited, Rapporteur: Janet Koenig Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 25.07.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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 Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.

Wakix - Pitolisant - EMEA/H/C/002616/II/0040/G, Orphan Bioprojet Pharma, Rapporteur: Jean-Michel Race Opinion adopted on 12.09.2024.	Positive Opinion adopted by consensus on 12.09.2024.
Yargesa - Miglustat - EMEA/H/C/004016/II/0014 Piramal Critical Care B.V., Generic of Zavesca, Rapporteur: Daniela Philadelphy Request for Supplementary Information adopted on 05.09.2024, 21.03.2024.	Request for supplementary information adopted with a specific timetable.
Yellox - Bromfenac - EMEA/H/C/001198/II/0036/G Bausch + Lomb Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 30.05.2024, 25.01.2024.	
Zerbaxa - Ceftolozane / Tazobactam - EMEA/H/C/003772/II/0046/G Merck Sharp & Dohme B.V., Rapporteur: Ingrid Wang	
Zometa - Zoledronic acid - EMEA/H/C/000336/II/0103/G Phoenix Labs Unlimited Company, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 06.06.2024, 21.03.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Zynlonta - Loncastuximab tesirine - EMEA/H/C/005685/II/0015/G Swedish Orphan Biovitrum AB (publ), Rapporteur: Aaron Sosa Mejia Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
WS2659/G **Riarify- EMEA/H/C/004836/WS2659/0032/G** **Trimbow- EMEA/H/C/004257/WS2659/0039/G** **Trydonis- EMEA/H/C/004702/WS2659/0036/G** Chiesi Farmaceutici S.p.A., Informed Consent of Trimbow, Lead Rapporteur: Janet Koenig Request for Supplementary Information adopted on 25.04.2024.	
WS2710 **Infanrix hexa- EMEA/H/C/000296/WS2710/0346**	Positive Opinion adopted by consensus on 12.09.2024.

GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 12.09.2024.	
WS2714/G **Infanrix hexa-** **EMEA/H/C/000296/WS2714/0347/G** 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 Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

AGAMREE - Vamorolone - **EMEA/H/C/005679/II/0005, Orphan** Santhera Pharmaceuticals (Deutschland) GmbH, Rapporteur: Janet Koenig, "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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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."	Positive Opinion adopted by consensus on 05.09.2024.

Opinion adopted on 05.09.2024.	
Alecensa - Alectinib - EMEA/H/C/004164/II/0048 Roche Registration GmbH, Rapporteur: Filip Josephson, "To update sections 4.4 and 4.6 of the SmPC to update the safety information to amend the duration of the period for which female patients of child-bearing potential must use highly effective contraceptive methods following the last dose of Alecensa, and must be informed of potential harm to the foetus in the event of pregnancy, from 3 months to 5 weeks based on the latest guidelines on contraception requirements for drugs with aneugenic potential. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 25.07.2024.	See 9.1
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 4.2, 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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.

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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Cetrotide - Cetrorelix - EMEA/H/C/000233/II/0091 Merck Europe B.V., Rapporteur: Janet Koenig, "Type II C.I.4 To update section 6.6 of the SmPC to amend the administered dose of cetrorelix from 'dose of at least 0.23 mg' to 'dose of 0.21 mg' based on the representative dose study conducted to evaluate the administered dose after reconstitution." Request for Supplementary Information adopted on 05.09.2024, 25.04.2024.	Request for supplementary information adopted with a specific timetable.
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 Sub study E, listed as a category 3 study in the RMP. This was an interventional, randomised, observer-blinded sub study 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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.

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."	
Constella - Linaclotide - EMEA/H/C/002490/II/0063 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Janet Koenig, "Update of section	Positive Opinion adopted by consensus on 05.09.2024.

4.4 of the SmPC in order to remove the statement relating to guanylate cyclase-C (GCC) receptor expression in the paediatric population based on final results from study MCP-103-311; this is a non-interventional clinical research study to characterize GCC mRNA expression in duodenal and colonic mucosal biopsies in children aged 0 to 17 years. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information and to bring it in line with the latest QRD template." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 13.06.2024.	
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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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."	
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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Gazyvaro - Obinutuzumab - EMEA/H/C/002799/II/0054/G, Orphan Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, "Grouped application comprising two variations as follows: C.I.4 - Update of section 4.4 of the SmPC in order to amend the cytokine release syndrome (CRS) statement based on the cumulative review of the MAH safety database, clinical trials and literature. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.3. A.6 - To change the ATC Code of Obinutuzumab	Positive Opinion adopted by consensus on 05.09.2024.

from L01XC15 to L01FA03." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 02.05.2024, 11.01.2024.	
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)." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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."	
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, 4.8 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." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 25.07.2024, 04.04.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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.”	
Onivyde pegylated liposomal - Irinotecan hydrochloride trihydrate - EMEA/H/C/004125/II/0035, Orphan Les Laboratoires Servier, Rapporteur: Filip Josephson, “Update of section 4.8 of the SmPC in order to add “Interstitial lung disease (including pneumonitis)” to the list of adverse drug reactions (ADRs) with frequency “Not known” based on post-marketing data and literature. The Package Leaflet is updated accordingly.” Request for Supplementary Information adopted on 16.05.2024.	
Opfolda - Miglustat - EMEA/H/C/005695/II/0010/G Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, “A grouped application comprised of two Type II Variations, as follows: C.I.4: Update of section 5.2 of the SmPC in order to update drug metabolism information based on the final report of the in vitro transporter study 8496647 as well as the population PK study AMC0206. Study 8496647 was for the evaluation of miglustat as a substrate and inhibitor of a panel of human drug transporters. C.I.4: Update of sections 4.6 and 5.3 of the SmPC in order to update reproductive and developmental toxicology information based on reassessment of non-clinical data. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information.” Request for Supplementary Information adopted on 05.09.2024, 02.05.2024.	Request for supplementary information adopted with a specific timetable.
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.

OZAWADE - Pitolisant - EMEA/H/C/005117/II/0010

Bioprojet Pharma, Rapporteur: Peter Mol, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a new posology regimen, change posology recommendations for patients with renal and hepatic impairment and to update the list of adverse drug reactions (ADRs) as well as efficacy information, based on the final results from study P15-13 (HAROSA III); this is a prospective, multicentre, randomized, double blind, placebo-controlled phase 3 study of the efficacy and safety of pitolisant in the treatment of excessive daytime sleepiness in patients with obstructive sleep apnoea (OSA). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information, to bring it in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet."
Request for Supplementary Information adopted on 30.05.2024.

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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0051/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "Grouped application comprising of the following variations: Type II (C.I.4): Update of section 4.2 of the SmPC in order to add clarifying language to the posology section to distinguish between symptom severity and baseline disease severity. Type II (C.I.4): Update of section 4.4 of the SmPC in order to add information on severe, life-threatening, and fatal drug reactions associated with DDIs. Type II (C.I.4): Update of section 4.6 of the SmPC in order to clarify that there is limited human data on the use of Paxlovid during pregnancy. Type II (C.I.4): Update of section 5.1 of the SmPC in order to update information on antiviral activity." Request for Supplementary Information adopted on 30.05.2024, 25.01.2024.	
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0052/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, "A grouped application comprised of 2 Type II Variations, as follows: C.I.4: Update of section 4.5 of the SmPC in order to include more detailed dosing information within the clinical comments for the drug-drug interactions (DDIs) related to venetoclax, apixaban, saxagliptin and cariprazine and to remove the reference to the dabigatran SmPC in the dabigatran DDI clinical comments.	Positive Opinion adopted by consensus on 12.09.2024.

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." Opinion adopted on 12.09.2024. Request for Supplementary Information adopted on 11.07.2024, 02.05.2024.	
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.	
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 clarify the contraindication for the co-administration of atazanavir with strong inducers of CYP3A4,	Positive Opinion adopted by consensus on 05.09.2024.

based on the results from study AI424082. This was 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." Opinion adopted on 05.09.2024.	
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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0008, Orphan Biogen Netherlands B.V., 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 Biogen Netherlands B.V., 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 clinical study 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 Solid Organ Transplant patients." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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, multicentre 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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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."	
Uptravi - Selexipag - EMEA/H/C/003774/II/0042/G Janssen-Cilag International N.V., Rapporteur: Janet Koenig, "A grouped application comprised of 3 Type II Variations as follows: C.I.4: Update of sections 4.2 and 5.2 of the SmPC in order to update pharmacokinetic information based on results from the paediatric PK study AC-065A203; this is a phase 2 multicentre, open-label, single-arm study to evaluate the safety, tolerability and pharmacokinetics of selexipag in children from 2 years to less than 18 years of age with pulmonary arterial hypertension (PAH). C.I.4: Update of sections 4.2 and 5.1 of the SmPC in order to update efficacy and safety information based on results from study AC-065A310 (SALTO); this is a phase 3 multicentre, double-blind, randomized, placebo-controlled, parallel group study with open-label extension period to assess the efficacy and safety of selexipag as add-on to standard of care in children from 2 years to less than 18 years of age with pulmonary arterial hypertension (PAH). C.I.4: Update of sections 4.2 and 5.1 of the SmPC in order to update efficacy information based on results from the pharmacodynamic (PD) similarity/comparison study to compare the PD and clinical responses for efficacy based on study AC-065A203, study AC-065A310 and study AC-065A302 in paediatric participants from 2 years to less than 18 years of age and adult participants with PAH. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."	

Request for Supplementary Information adopted on 16.05.2024.	
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 or randomized-sequence , multiple-cohort study to evaluate DDIs of ODV or RDV and probe substrates or strong inhibitors in healthy participants." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Venclyxto - Venetoclax - EMEA/H/C/004106/II/0048 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update safety and efficacy information on paediatric population following the assessment of procedure P46/018 based on final results from study M13-833 - A Phase 1 Study of the Safety and Pharmacokinetics of Venetoclax in Paediatric and Young Adult Patients With Relapsed or Refractory Malignancies. The Package Leaflet is updated accordingly." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 16.05.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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."	
Wegovy - Semaglutide - EMEA/H/C/005422/II/0019 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Update of sections 4.1, 4.4, 4.8 and 5.1 in order to include information in patients with obesity-related HFpEF, with and without type 2 diabetes based on the final reports from studies EX9536-4665 STEP-HFpEF, EX9536-4773 STEP HFpEF-DM and EX9536-4388 SELECT. In addition, the MAH took this opportunity to introduce editorial changes to the PI." Request for Supplementary Information adopted on 25.07.2024, 11.04.2024.	See 9.1
Wegovy - Semaglutide - EMEA/H/C/005422/II/0021 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt, "Update of section 5.1 of the SmPC in order to include new data generated in patients with knee osteoarthritis (OA), based on final results from study NN9536-4578 (STEP 9); this is a phase 3b randomised, two-arm, double-blinded, multi-centre clinical trial comparing semaglutide s.c. 2.4 mg once-weekly with semaglutide placebo in subjects with moderate OA of one or both knees, pain due to knee OA, and obesity." Request for Supplementary Information adopted on 05.09.2024, 23.05.2024.	Request for supplementary information adopted with a specific timetable.
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"	Positive Opinion adopted by consensus on 05.09.2024.

based on post marketing data and literature. The Package Leaflet is updated accordingly." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 18.07.2024.	
Xevudy - Sotrovimab - EMEA/H/C/005676/II/0029/G Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "A grouped application comprised of 5 Type II Variations, as follows: C.I.4: Update of section 5.1 of the SmPC based on final results from study 218407 (LUNAR); this is a Phase 4 single-arm prospective cohort genomic surveillance study to describe changes in the SARS-CoV-2 spike protein observed in immunocompromised non-hospitalized patients receiving sotrovimab in Great Britain to monitor the emergence of viral variants. 4 x (C.I.13): To submit the final reports from the following studies: COMET-TAIL Safety Sub study (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 Sub study 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	Request for supplementary information adopted with a specific timetable.

years. And from a clinical pharmacology study evaluating SARS-CoV-2 specific T cells responses in participants receiving 500 mg IV sotrovimab in COMET-ICE (PC-22-0123).” Request for Supplementary Information adopted on 12.09.2024.	
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.” Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 04.07.2024, 04.04.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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 cutaneous adverse reactions (SCARs) and to add "toxic epidermal necrolysis (TEN)" to the list of adverse drug reactions (ADRs) with frequency not known, based on clinical trials, literature and post-marketing safety data. 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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.

B.5.3. CHMP-PRAC assessed procedures

Apretude - Cabotegravir - **EMEA/H/C/005756/II/0004** ViiV Healthcare B.V., Duplicate of Vocabria, 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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 05.09.2024.	
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 modelling 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	Request for supplementary information adopted with a specific timetable.

been submitted." Request for Supplementary Information adopted on 05.09.2024.	
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 05.09.2024, 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Loargys - Pegzilarginase - EMEA/H/C/005484/II/0002/G, Orphan Immedica Pharma AB, Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, "Grouped application comprising two type II variations as follows: C.I.4 – Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study CAEB1102-300A (SOB 003), listed as a specific obligation in Annex II. Study 300A was a Phase 3, randomized, double blind, placebo-controlled study of the efficacy and safety of pegzilarginase in adults, adolescents and children with arginase 1 deficiency (ARG1 D). C.I.4 – Update of section 4.8 of the SmPC in order to update efficacy and safety information based on final results from study CAEB1102-102A (SOB 004), listed as a specific obligation in Annex II. Study 102A was an open label extension study to evaluate the long-term safety, tolerability, and efficacy of pegzilarginase in adults, adolescents and children with arginase 1 deficiency (ARG1 D). The Package Leaflet and Annex II are updated accordingly. The RMP version 1.2 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." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 13.06.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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 25.07.2024, 25.04.2024, 14.12.2023, 25.05.2023.	
Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0044 AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3."	See 9.1

Request for Supplementary Information adopted on 21.03.2024.	
RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0052 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to change posology recommendations in adolescents with atopic dermatitis to include the 30mg dose option based on results from studies M16-045, M16-047 and M18-891 (pivotal phase 3 studies with adolescent sub studies). The Package Leaflet is updated accordingly. The RMP version 14.0 has also been submitted." Request for Supplementary Information adopted on 30.05.2024.	
Sapropterin Dipharma - Sapropterin - EMEA/H/C/005646/II/0014 DIPHARMA Arzneimittel GmbH, Generic of Kuvan, Rapporteur: Frantisek Drafi, "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."	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 05.09.2024.	
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 Opinion adopted on 09.09.2024. Request for Supplementary Information adopted on 25.07.2024, 27.06.2024.	Positive Opinion adopted by consensus on 09.09.2024. See PROM agenda
Spinraza - Nusinersen - EMEA/H/C/004312/II/0034/G, Orphan Biogen Netherlands B.V., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Mari Thorn, "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)." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
TAVNEOS - Avacopan - EMEA/H/C/005523/II/0015, Orphan Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder, PRAC	Request for supplementary information adopted with a specific timetable.

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." Request for Supplementary Information adopted on 05.09.2024.	
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	Request for supplementary information adopted with a specific timetable.

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." Request for Supplementary Information adopted on 05.09.2024.	
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 paediatric patients previously treated with everolimus in study CRAD001M2301 (EXIST-LT). The RMP version 16.0 has also been submitted." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Zykadia - Ceritinib - EMEA/H/C/003819/II/0055 Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Mari Thorn, "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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
WS2619/G **Invokana- EMEA/H/C/002649/WS2619/0066/G** **Vokanamet- EMEA/H/C/002656/WS2619/0073/G** Janssen-Cilag International N.V., Lead Rapporteur: Janet Koenig, Lead PRAC Rapporteur: Martin Huber, "A grouped application consisting of two Type II variations,	Positive Opinion adopted by consensus on 05.09.2024.

as follows: C.I.4: Update of section 4.4 of the SmPC in order to amend an existing warning on Diabetic Ketoacidosis based on literature. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.6 and 5.3 of the SmPC in order to update information on pregnancy based on literature. The RMP version 11.1 has also been submitted." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 13.06.2024, 11.04.2024.	
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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda- **EMEA/H/W/005362/WS2593/0012** **Qdenga-** **EMEA/H/C/005155/WS2593/0013** Takeda GmbH, Lead Rapporteur: Sol Ruiz, Lead PRAC Rapporteur: Liana Martirosyan, "Update of section 4.5 of the SmPC in order to add co-administration information with HPV vaccine based on final results from study DEN-308 listed as a category 3 study in the RMP (MEA003/MEA004); this is a Phase 3, open-label, randomized trial to investigate the immunogenicity and safety of the co-administration of a subcutaneous dengue tetravalent vaccine (live, attenuated) (TDV) and an intramuscular recombinant 9-valent human papillomavirus (9vHPV) vaccine in subjects aged ≥9 to <15 years in an endemic country for	Positive Opinion adopted by consensus on 05.09.2024.

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." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 11.07.2024, 16.05.2024, 07.03.2024.	

B.5.4. PRAC assessed procedures

PRAC Led **Amlodipine-Valsartan Mylan - Amlodipine / Valsartan - EMEA/H/C/004037/II/0021** Mylan Pharmaceuticals Limited, Generic of Exforge, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of an updated RMP version 4.0 in order to align the safety concerns with the latest version of RMP for Amlodipine/Valsartan available in the public domain and to bring the RMP in line with the latest RMP template." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 16.05.2024.	Positive Opinion adopted by consensus on 05.09.2024.
PRAC Led **ASPAVELI - Pegcetacoplan - EMEA/H/C/005553/II/0018, Orphan** Swedish Orphan Biovitrum AB (publ), PRAC Rapporteur: Kimmo Jaakkola, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of an updated RMP version 2.2 in order to revise the category 3 PASS Sobi.PEGCET-301 and Sobi.PEGCET-302." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 16.05.2024.	Positive Opinion adopted by consensus on 05.09.2024.
PRAC Led **BESPONSA - Inotuzumab ozogamicin - EMEA/H/C/004119/II/0028, Orphan** Pfizer Europe MA EEIG, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report from study B1931028; this is a non-interventional post-authorization safety study (PASS) of inotuzumab ozogamicin to characterize complications post-hematopoietic stem cell transplantation (HSCT) following	Positive Opinion adopted by consensus on 05.09.2024.

inotuzumab ozogamicin treatment in adult and paediatric patients with B-cell precursor acute lymphoblastic leukaemia (ALL). The RMP version 3.0 has also been submitted." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 13.06.2024.	
PRAC Led **DECTOVA - Zanamivir - EMEA/H/C/004102/II/0020** GlaxoSmithKline Trading Services Limited, PRAC Rapporteur: Mari Thorn, 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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan - Efavirenz / Emtricitabine / Tenofovir disoproxil – EMA/VR/0000179367 Mylan Pharmaceuticals Limited; 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	Positive Opinion adopted by consensus on 05.09.2024.

updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
PRAC Led **Eurartesim - Piperaquine tetraphosphate / Artenimol - EMEA/H/C/001199/II/0040/G** Alfasigma S.p.A., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "C.I.13: Submission of the final report from the effectiveness evaluation survey for Eurartesim (protocol no. 3366) listed as a category 3 study in the RMP. This is a European multi-centre online survey to assess physician understanding of the revised edition of the educational material. Consequential changes to RMP version 16.1 have been implemented. C.I.11.b: Submission of an updated RMP version 16.1 in order to delete "Severe Malaria" from the Missing Information." Request for Supplementary Information adopted on 05.09.2024, 16.05.2024, 11.01.2024, 28.09.2023, 08.06.2023.	Request for supplementary information adopted with a specific timetable.
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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor -**	Request for supplementary information adopted with a specific timetable.

EMEA/H/C/005269/II/0052/G, Orphan Vertex Pharmaceuticals (Ireland) Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Grouped application comprising 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." Request for Supplementary Information adopted on 05.09.2024.	
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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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' and 'Anaphylaxis' to the list of adverse drug reactions (ADRs) with frequency 'uncommon' and 'not known' respectively, 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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
PRAC Led **Olumiant - Baricitinib - EMEA/H/C/004085/II/0047**	Positive Opinion adopted by consensus on 05.09.2024.

Eli Lilly Nederland B.V., PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Submission of the final report from non-interventional Study I4V-MC-B012 listed as a category 3 study in the RMP. This is a post-marketing safety surveillance of baricitinib in three European registries. The RMP version 23.2 is agreed." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 13.06.2024.	
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)." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 11.07.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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)." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 11.07.2024.	Positive Opinion adopted by consensus on 05.09.2024.
PRAC Led **Stelara - Ustekinumab - EMEA/H/C/000958/II/0104** Janssen-Cilag International N.V., PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Submission of the final report from study RRA-20745 listed as a category 3 study in the RMP. This is an observational post-authorization safety study (PASS) to describe the safety of ustekinumab and other Crohn's disease treatments in a cohort of patients with Crohn's disease. The RMP version 27.2 has also been submitted."	Positive Opinion adopted by consensus on 05.09.2024.

Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 13.06.2024, 11.01.2024.	
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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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	Request for supplementary information adopted with a specific timetable.

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." Request for Supplementary Information adopted on 05.09.2024.	
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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2519/G** **Advagraf-** **EMEA/H/C/000712/WS2519/0071/G** **Modigraf-** **EMEA/H/C/000954/WS2519/0046/G** Astellas Pharma Europe B.V., Lead PRAC Rapporteur: Eamon O Murchu, PRAC-CHMP liaison: Jayne Crowe, "A grouped application consisting of: Type II (C.I.13): Submission of the final report from study F506-PV-0001 (EUPAS37025) listed as a category 3 study in the RMP for Advagraf and Modigraf. This is a non-interventional post-authorization safety study (NI-PASS) of outcomes associated with the use of tacrolimus around conception, or during pregnancy or lactation using data from Transplant Pregnancy Registry International (TPRI). The RMP version	Positive Opinion adopted by consensus on 05.09.2024.

5.2 has also been approved. In addition, section 4.6 of the SmPC has been updated to reflect the results of the study. The package leaflet is updated accordingly. Type IB (C.I.11.z): To include the feasibility assessment of using alternative secondary-use data sources to replicate the Transplant Pregnancy Registry International (TPRI) study as a category 3 additional pharmacovigilance activity in the RMP, including the milestones for the progress report and the final report of the feasibility assessment, related to EMEA/H/C/000712/MEA/032 and EMEA/H/C/000954/MEA/024." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 11.04.2024, 26.10.2023.	
PRAC Led **WS2587** **TECFIDERA-** **EMEA/H/C/002601/WS2587/0085** **Vumerity-** **EMEA/H/C/005437/WS2587/0015** Biogen Netherlands B.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of the final report from Study 109MS401, a multicentre, global, observational study to collect information on safety and to document the drug utilization of Tecfidera (Dimethyl Fumarate) when used in routine medical practice in the treatment of Multiple Sclerosis (ESTEEM), listed as a category 3 study in the RMP (MEA007.6). Section 4.8 is updated to change the frequency category of DILI from "not known" to "rare". The PL is updated accordingly. The EU-RMP for Tecfidera is updated to version 17.0 and the EU-RMP for Vumerity is updated to version 3.0)." Opinion adopted on 05.09.2024. Request for Supplementary Information adopted on 13.06.2024, 08.02.2024.	Positive Opinion adopted by consensus on 05.09.2024.
PRAC Led **WS2696** **Adrovance-** **EMEA/H/C/000759/WS2696/0055** **FOSAVANCE-** **EMEA/H/C/000619/WS2696/0058** **VANTAVO-** **EMEA/H/C/001180/WS2696/0045**	Request for supplementary information adopted with a specific timetable.

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"." Request for Supplementary Information adopted on 05.09.2024.	
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)." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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." Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
PRAC Led **WS2709** **Rivaroxaban Viatris-EMEA/H/C/005600/WS2709/0012** Viatris Limited, Generic of Xarelto, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "To provide an updated RMP to remove the following safety concerns (classified	Positive Opinion adopted by consensus on 05.09.2024.

as Missing information) in order to align with RMP version 13.4 of the reference product Xarelto: - Patients with severe renal impairment (CrCl < 30 mL/min) - Patients receiving concomitant systemic inhibitors of CYP 3A4 or P-gp other than azole antimycotics (e.g. ketoconazole) and HIV-protease inhibitors (e.g. ritonavir) - Pregnant or breast-feeding women - Long-term therapy with rivaroxaban in treatment of DVT, PE, SPAF and ACS in real-life setting - Patients with significant liver diseases (severe hepatic impairment/Child Pugh C) - Patients < 18 years." Opinion adopted on 05.09.2024.	
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." Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
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: Janet Koenig, "Submission of the final report from study PCSCVM003617, listed as a category 3 study in the RMP. This is a Real-World	Positive Opinion adopted by consensus on 05.09.2024.

Database Study of Canagliflozin Utilization in Type 1 Diabetes Patients Over Time among European Countries. The RMP version 12.1 has also been submitted."
Opinion adopted on 05.09.2024.

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 19.07.2024, 24.05.2024.

CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0027/G, Orphan, ATMP
Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus
Request for Supplementary Information adopted on 24.05.2024.

Casgevy - Exagamglogene autotemcel - EMEA/H/C/005763/II/0003/G, Orphan, ATMP
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus
Request for Supplementary Information adopted on 21.06.2024.

Ebvallo - Tabelecleucel - EMEA/H/C/004577/II/0011/G, Orphan, ATMP
Pierre Fabre Medicament, Rapporteur: Egbert Flory, CHMP Coordinator: Jan Mueller-Berghaus

Hemgenix - Etranacogene dezaparvovec - EMEA/H/C/004827/II/0014/G, Orphan,

ATMP
CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy
Request for Supplementary Information adopted on 19.07.2024.

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

WS2689
Tecartus-
EMEA/H/C/005102/WS2689/0045

Yescarta- **EMEA/H/C/004480/WS2689/0076** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus Request for Supplementary Information adopted on 21.06.2024.	
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.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. 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, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of an updated RMP version 7.0 in order 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.5.8. Unclassified procedures and worksharing procedures of type I variations

WS2656/G **Copalia HCT-** **EMEA/H/C/001159/WS2656/0112/G** **Dafiro HCT-** **EMEA/H/C/001160/WS2656/0114/G** **Exforge HCT-** **EMEA/H/C/001068/WS2656/0111/G** Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher, Quality Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.

Request for Supplementary Information adopted on 27.06.2024, 02.05.2024.	
WS2711 **Ambirix-** **EMEA/H/C/000426/WS2711/0134** **Fendrix-** **EMEA/H/C/000550/WS2711/0087** **Infanrix hexa-** **EMEA/H/C/000296/WS2711/0348** **Twinrix Adult-** **EMEA/H/C/000112/WS2711/0169** **Twinrix Paediatric-** **EMEA/H/C/000129/WS2711/0170** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke, Quality”	
WS2712/G **Bretaris Genuair-** **EMEA/H/C/002706/WS2712/0055/G** **Eklira Genuair-** **EMEA/H/C/002211/WS2712/0055/G** Covis Pharma Europe B.V., Lead Rapporteur: Ewa Balkowiec Iskra, Quality Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
WS2716/G **Hexacima-** **EMEA/H/C/002702/WS2716/0158/G** **Hexyon-** **EMEA/H/C/002796/WS2716/0162/G** **MenQuadfi-** **EMEA/H/C/005084/WS2716/0036/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus, Quality Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
WS2720/G **Brimica Genuair-** **EMEA/H/C/003969/WS2720/0043/G** **Duaklir Genuair-** **EMEA/H/C/003745/WS2720/0042/G** Covis Pharma Europe B.V., Lead Rapporteur: Ewa Balkowiec Iskra, Quality Request for Supplementary Information adopted on 05.09.2024.	Request for supplementary information adopted with a specific timetable.
WS2723/G **Abseamed-** **EMEA/H/C/000727/WS2723/0110/G** **Binocrit-** **EMEA/H/C/000725/WS2723/0110/G**	Positive Opinion adopted by consensus on 05.09.2024.

Epoetin alfa Hexal- **EMEA/H/C/000726/WS2723/0110/G** Sandoz GmbH, Lead Rapporteur: Alexandre Moreau, Quality. Opinion adopted on 05.09.2024.	
WS2726 **Entresto-** **EMEA/H/C/004062/WS2726/0064** **Neparvis-** **EMEA/H/C/004343/WS2726/0061** Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt, Quality Opinion adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.09.2024.
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	
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 Request for Supplementary Information adopted on 25.07.2024.	
WS2745 **Entresto-** **EMEA/H/C/004062/WS2745/0067** **Neparvis-** **EMEA/H/C/004343/WS2745/0064** Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt, 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

WS2550 **Aldara-EMEA/H/C/000179/WS2550/0089** **Zyclara-EMEA/H/C/002387/WS2550/0031** Viatris Healthcare Limited, Lead Rapporteur: Ewa Balkowiec Iskra Request for Supplementary Information adopted on 02.05.2024.	Request by the applicant for an extension to the clock stop to respond to the RSI adopted in May 2024.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

In vitro diagnostic medical device -
EMEA/H/D/006590
detection of HLA-B*5701 allele, which is a predictor of hypersensitivity to abacavir, a drug used for treating HIV-1 infection

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

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

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

Strensiq - Asfotase alfa -
EMEA/H/C/003794/S/0069, Orphan
Alexion Europe SAS, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Eamon O Murchu

Vyndaqel - Tafamidis -
EMEA/H/C/002294/S/0095, Orphan
Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Tiphaine Vaillant

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

Daurismo - Glasdegib -
EMEA/H/C/004878/R/0015, Orphan
Pfizer Europe MA EEIG, Rapporteur: Alexandre Moreau, Co-Rapporteur: Aaron Sosa Mejia,

PRAC Rapporteur: Bianca Mulder

Enerzair Breezhaler - Indacaterol / Glycopyrronium bromide / Mometasone - EMEA/H/C/005061/R/0029
Novartis Europharm Limited, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser

Nepexto - Etanercept - EMEA/H/C/004711/R/0033
Biosimilar Collaborations Ireland Limited, Rapporteur: Janet Koenig, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Monica Martinez Redondo

Piqray - Alpelisib - EMEA/H/C/004804/R/0028
Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Bianca Mulder

Reblozyl - Luspatercept - EMEA/H/C/004444/R/0031, Orphan
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Daniela Philadelphy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jo Robays

Zimbus Breezhaler - Indacaterol / Glycopyrronium bromide / Mometasone - EMEA/H/C/005518/R/0025
Novartis Europharm Limited, Duplicate of Enerzair Breezhaler, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser

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

CABOMETYX - Cabozantinib - EMEA/H/C/004163/II/0040
Ipsen Pharma, Rapporteur: Ingrid Wang, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Bianca Mulder, "Extension of indication to include the treatment of adult patients with progressive extra-pancreatic (epNET) and pancreatic (pNET) neuroendocrine tumours after prior systemic therapy for CABOMETYX based on final results from study CABINET (A021602).

This is a multicentre, two-arm, randomised, double-blind, placebo-controlled phase 3 study investigating cabozantinib versus placebo in patients with advanced Neuroendocrine Tumours (NET). 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 8.0 of the RMP has also been submitted."

Calquence - Acalabrutinib - EMEA/H/C/005299/II/0025

AstraZeneca AB, Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi, "Extension of indication to include CALQUENCE in combination with bendamustine and rituximab (BR) as treatment of adult patients with previously untreated Mantle Cell Lymphoma (MCL) based on interim results from study ACE-LY-308 (ECHO, D8220C00004); this is a Phase III, Randomized, Double-blind, Placebo-controlled, Multicentre Study of Bendamustine and Rituximab (BR) Alone Versus in Combination with Acalabrutinib (ACP-196) in Subjects with Previously Untreated Mantle Cell Lymphoma. 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 6, succession 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)

Calquence - Acalabrutinib - EMEA/H/C/005299/II/0026

AstraZeneca AB, Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi, "Extension of indication to include CALQUENCE as monotherapy for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy based on final results from study ACE-LY-004 (D8225C00002); this is an open-label, phase 2 study of ACP-196 in subjects with Mantle Cell Lymphoma. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7 of

the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI."

IXCHIQ - Chikungunya virus, strain delta5nsP3, live attenuated – OPEN - EMEA/H/C/005797/II/0001

Valneva Austria GmbH, Rapporteur: Christophe Focke, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Gabriele Maurer, "Extension of indication to include active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in adolescents 12 years and older for IXCHIQ, based on interim 6 months results from study VLA1553-321; this is a randomized, double-blinded, multicentre study to evaluate the immunogenicity and safety of the adult dose of VLA1553 6 months following vaccination in adolescents from 12 years to less than 18 years of age after a single immunization. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Revolade - Eltrombopag - EMEA/H/C/001110/II/0077

Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Monica Martinez Redondo, "Extension of indication to include second-line treatment of paediatric patients aged 2 years and above with acquired severe aplastic anaemia (SAA) for REVOLADE based on the ETB115E2201 (E2201) study primary analysis results; this is a paediatric phase II, open-label, uncontrolled, intra-patient dose escalation study to characterise the pharmacokinetics after oral administration of eltrombopag in paediatric patients with refractory, relapsed severe aplastic anaemia or recurrent aplastic anaemia. 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 56.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Xydalba - Dalbavancin -

EMEA/H/C/002840/II/0050
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, PRAC Rapporteur: Rugile Pilviniene, "Extension of indication to include the treatment of acute bacterial skin and skin structure infections (ABSSSI) in paediatric patients from birth, including paediatric patients aged less than 3 months with suspected or confirmed sepsis associated with skin and subcutaneous tissue infections for Xydalba, based on final results from study DUR001-306, together with data from three Phase 1 PK studies (A8841004, DUR001-106, and DUR001-107 (DAL-PK-02); DUR001-306 was a Phase 3, multicentre, open-label, randomized, comparator controlled trial evaluating the safety and efficacy of a single dose of IV dalbavancin and a 2-dose regimen of once weekly IV dalbavancin (for a total of 14 days of coverage) for the treatment of ABSSSI known or suspected to be due to susceptible Gram-positive organisms in children. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet in line with the latest QRD template version 10.4."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0010/G
Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe

Bexsero - meningococcal group b vaccine (rdna, component, adsorbed) - EMA/VR/0000228110
Glaxosmithkline Vaccines S.r.l., Rapporteur: Filip Josephson

Cablivi - Caplacizumab - EMEA/H/C/004426/II/0052, Orphan
Ablynx NV, Rapporteur: Filip Josephson

Camcevi – Leuprorelin – EMA/VR/0000226224

Accord Healthcare S.L.U., Rapporteur: Johanna Lähteenvuo

Camcevi – Leuprorelin – EMA/VR/0000226224
Accord Healthcare S.L.U., Rapporteur: Johanna Lähteenvuo

Ceprotin - Human protein C - EMEA/H/C/000334/II/0141
Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus

Columvi - Glofitamab - EMEA/H/C/005751/II/0006/G, Orphan
Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia

Elaprase - Idursulfase - EMEA/H/C/000700/II/0119/G
Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Patrick Vrijlandt

Entecavir Viatris - Entecavir - EMEA/H/C/004377/II/0013
Viatris Limited, Generic of Baraclude, Rapporteur: Alexandre Moreau

Jubbonti - Denosumab - EMEA/H/C/005964/II/0002/G
Sandoz GmbH, Rapporteur: Christian Gartner

LIVOGIVA - Teriparatide - EMEA/H/C/005087/II/0013/G
Theramex Ireland Limited, Rapporteur: Christian Gartner

Metalyse - Tenecteplase - EMEA/H/C/000306/II/0074/G
Boehringer Ingelheim International GmbH, Rapporteur: Janet Koenig

Polivy - Polatuzumab vedotin - EMEA/H/C/004870/II/0032/G, Orphan
Roche Registration GmbH, Rapporteur: Alexandre Moreau

Remsima - Infliximab - EMEA/H/C/002576/II/0143/G
Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola

Spectrila - Asparaginase - EMEA/H/C/002661/II/0042/G
medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Christian

Gartner

TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0035/G
Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus

Wyost - Denosumab - EMEA/H/C/006378/II/0002/G
Sandoz GmbH, Duplicate of Jubbonti, Rapporteur: Christian Gartner

WS2549/G
Hexacima- EMEA/H/C/002702/WS2549/0159/G
Hexyon- EMEA/H/C/002796/WS2549/0163/G
Sanofi Pasteur Europe, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus

WS2742/G
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda- EMEA/H/W/005362/WS2742/0017/G
Qdenga- EMEA/H/C/005155/WS2742/0018/G
Takeda GmbH, Lead Rapporteur: Sol Ruiz

WS2744/G
GONAL-f- EMEA/H/C/000071/WS2744/0174/G
Pergoveris- EMEA/H/C/000714/WS2744/0096/G
Merck Europe B.V., Lead Rapporteur: Patrick Vrijlandt

WS2747/G
Nuwiq- EMEA/H/C/002813/WS2747/0063/G
Vihuma- EMEA/H/C/004459/WS2747/0045/G
Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus

WS2748
Silodosin Recordati- EMEA/H/C/004964/WS2748/0015
Silodyx-EMEA/H/C/001209/WS2748/0056
Urorec-EMEA/H/C/001092/WS2748/0059
Recordati Ireland Ltd, Lead Rapporteur: Paolo Gasparini

WS2761
Blitzima-

EMEA/H/C/004723/WS2761/0078
Truxima-
EMEA/H/C/004112/WS2761/0081
Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz

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

Dovprela - Pretomanid -
EMEA/H/C/005167/II/0022, Orphan
Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson, "Update of section 4.2 of the SmPC in order to add clarifications on administration instructions based on post marketing data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement an editorial correction to section 5.1 of the SmPC."

Eylea - Aflibercept -
EMEA/H/C/002392/II/0095
Bayer AG, Rapporteur: Jean-Michel Race, "Update of section 4.8 of the SmPC in order to add 'scleritis' to the list of adverse drug reactions (ADRs) with frequency of '0.2 cases per 1 million injections' based on pharmacovigilance data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to add warnings for polysorbate into the SmPC and the Package Leaflet in line with the instructions in the most recent updates to the Appendix of the EC Excipient Guideline."

Galafold - Migalastat -
EMEA/H/C/004059/II/0043, Orphan
Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, "Update of section 4.8 of the SmPC in order to add 'angioedema' to the list of adverse drug reactions (ADRs) with frequency unknown based on a safety review. The Package Leaflet is updated accordingly. In addition, the MAH has taken the opportunity to update the Product Information (PI) to align with the revised QRD template (version 10.4) and to update the list of local representatives in the Package Leaflet."

MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine -
EMEA/H/C/005084/II/0037
Sanofi Pasteur, Rapporteur: Daniela Philadelphy, "Update of section 4.8 of the SmPC

in order to add 'convulsions with or without fever' to the list of adverse drug reactions (ADRs) with frequency not known, based on a safety review. The Package Leaflet is updated accordingly."	
Nplate – Romiplostim – EMA/ VR/0000226893 Amgen Europe B.V., Rapporteur: Antonio Gomez-Outes "Update of sections 4.4 and 4.8 of the SmPC in order to update the warning on thrombotic/thromboembolic complications and update the frequency of 'deep vein thrombosis' in the list of adverse drug reactions (ADRs) from 'uncommon' to 'common', based on a comprehensive safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the wording pertaining to bone marrow aspirate and/or biopsy in patients over 60 years of age to be consistent with current standards and international guidelines for immune thrombocytopenia (ITP) diagnosis and management and to introduce minor editorial changes to the PI and update the list of the local representatives in the Package Leaflet."	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0085/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "A grouped application comprised of 3 Type II Variations as follows: C.I.13: Submission of the final non-clinical study report 702-087 - Antibody and Cell-mediated Immune Responses to SARS-CoV-2 rS Vaccines in Baboons. C.I.13: Submission of the final non-clinical study report 702-134 – Immunogenicity of a Primary Series with SARS-CoV-2 Prototype rS or Omicron BA.1 rS Followed by a Booster Immunization with Omicron BA.5 rS or Bivalent Prototype rS + Omicron BA.5 rS in Baboons. C.I.13: Submission of the final non-clinical study report 702-115 – Long-term Immunogenicity and Protective Efficacy of SARS-CoV-2 rS Nanoparticle Vaccines with Matrix-M Adjuvant in Rhesus Macaques."	
Nuvaxovid - Covid-19 Vaccine	

(recombinant, adjuvanted) - EMEA/H/C/005808/II/0087

Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-311 Part 2 listed as a category 3 study in the RMP. This is a Multi-Part, Phase 3, Randomized, Observer Blinded Study to Evaluate the Safety and Immunogenicity of Omicron Subvariant and Bivalent SARS-CoV-2 rS Vaccines in Adults Previously Vaccinated with other COVID-19 Vaccines."

Oxlumo - Lumasiran - EMEA/H/C/005040/II/0021, Orphan

Alnylam Netherlands B.V., Rapporteur: Janet Koenig, "Update of sections 4.8 and 5.1 of the SmPC in order to include information on the End-of Study safety (patient years of exposure) and efficacy of lumasiran in patients with Primary Hyperoxaluria Type 1 (PH1) based on final results from study ALN-GO1-003 (ILLUMINATE) listed as a category 3 study in the RMP; this is a phase 3 randomized, double-blind placebo-controlled study with an extended dosing period to evaluate the efficacy and safety of lumasiran in children and adults with PH1. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Oxlumo - Lumasiran - EMEA/H/C/005040/II/0022, Orphan

Alnylam Netherlands B.V., Rapporteur: Janet Koenig, "Update of section 4.8 of the SmPC in order to add "hypersensitivity" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on post marketing safety data and literature. In addition, the MAH has taken the opportunity to update the Product Information (PI) to align with the revised QRD template (version 10.4) and to update the list of local representatives in the Package Leaflet."

Skyrizi - Risankizumab - EMEA/H/C/004759/II/0050

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, "Update of sections 4.8 and 5.1 of the SmPC in order to add information based on data of the final study report M15-997 (LIMMITLESS) listed as a category 3 study in the RMP. This is a multicentre, open label study to assess the safety and efficacy of risankizumab for

maintenance in moderate to severe plaque type psoriasis. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	
Vabysmo - Faricimab - EMEA/H/C/005642/II/0014 Roche Registration GmbH, Rapporteur: Jayne Crowe, "Update of section 4.2 of the SmPC to modify the posology for two approved indications, neovascular (wet) Age-related Macular Degeneration (nAMD) and visual impairment due to Diabetic Macular Edema (DME), based on the post-hoc efficacy analysis of Phase III interventional nAMD studies TENAYA (GR40306) and LUCERNE (GR40844), and Phase III interventional DME studies YOSEMITE (GR40349) and RHINE (GR40398).The Package leaflet is updated accordingly."	
Voxzogo - Vosoritide - EMEA/H/C/005475/II/0017, Orphan BioMarin International Limited, Rapporteur: Janet Koenig, "Submission of the BMN-111 PK Modelling report for young children with achondroplasia (ACH). This is a population pharmacokinetic [P(PK)] analysis by body weight group (<10kg) to evaluate the PPK model performance of vosoritide in young children with achondroplasia"	
WS2739 M-M-RvaxPro- EMEA/H/C/000604/WS2739/0128 Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.5 and 5.1 of the SmPC in order to update information regarding the concomitant use of MMRvaxPro and Varivax with Pneumococcal Conjugate Vaccines (PCVs), based on the final results from study V114- 029; this is a phase 3, multicentre, randomized, double-blind, active-comparator-controlled study to evaluate the safety, tolerability, and immunogenicity of a 4-dose regimen of V114 in healthy infants (PNEU-PED). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet."	

WS2754
Iscover-
EMEA/H/C/000175/WS2754/0156
Plavix-EMEA/H/C/000174/WS2754/0157
Sanofi Winthrop Industrie, Lead Rapporteur: Bruno Sepodes, "Update of sections 4.2 and 5.1 of the SmPC in order to include information on posology enhancement and to update pharmacodynamic information based on post marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the SmPC."

B.6.10. CHMP-PRAC assessed procedures

Bavencio - Avelumab -
EMEA/H/C/004338/II/0046/G
Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Karin Erneholm, "A grouped application consisting of:
C.I.4: Update of sections 4.2, 4.4, 4.6 and 4.8 of the SmPC in order to add the immune-mediated adverse reactions sclerosing cholangitis, arthritis, polymyalgia rheumatica, and Sjogren's syndrome based on post-marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 7.3 has also been submitted.

C.I.4: Update of section 4.8 of the SmPC in order to update the immunogenicity information based on results from studies EMR100070-003, B9991003 and 100/B9991001. Study EMR100070-003 is a Phase 2, single-arm, open label, multicentre study to investigate the clinical activity and safety of avelumab in patients with mMCC. T. Study B9991003 is a Phase 3 multinational, multicentre, randomized (1:1), open-label, parallel 2 - arm study of avelumab in combination with axitinib versus sunitinib monotherapy in the 1L treatment of participants with aRCC. Study 100/B9991001 is a Phase 3, multicentre, multinational, randomized, open-label, parallel-arm efficacy and safety study of avelumab plus best supportive care (BSC) versus BSC alone as a maintenance treatment in adult participants with locally advanced or metastatic UC whose disease did not progress after completion of 1L

platinum-containing chemotherapy."

Bimzelx - Bimekizumab - EMEA/H/C/005316/II/0029

UCB Pharma S.A., Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan, "Submission of the final report from study PS0014 (BE BRIGHT) listed as a category 3 study in the RMP. This is a multicentre, open-label extension (OLE) study to assess the long-term safety, tolerability, and efficacy of bimekizumab in adult study participants with moderate to severe plaque PSO who completed 1 of the 3 completed feeder studies. The RMP version 2.2 has also been submitted."

HyQvia - Human normal immunoglobulin - EMEA/H/C/002491/II/0102

Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Submission of the final report from study 161505; this is a Phase 3b, open-label, non-controlled, multicentre study to assess the long-term tolerability and safety of immune globulin infusion 10% (human) with recombinant human hyaluronidase (HYQVIA/HyQvia) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP). The RMP version 16.0 has also been submitted."

Kadcyla - Trastuzumab emtansine - EMEA/H/C/002389/II/0071/G

Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Karin Erneholm, "A grouped application consisting of:
C.I.4 (Type II): Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on interim results from study BO27938 (KATHERINE) listed as a PAES in the Annex II and as a category 3 study in the RMP. This is a Randomized, Multicentre, Open Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients with HER2-Positive Primary Breast Cancer who have Residual Tumour Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy. The Package Leaflet is updated in accordance. The RMP version 16.0 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, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI. Furthermore, the MAH took the opportunity to update Annex II-D and to implement editorial changes to the Labelling section.

Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/II/0056, Orphan

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, "Update of sections 4.8 and 5.1 of the SmPC in order to update safety and efficacy data based on final results from study VX19-445-107 (Study 107); this is a Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of ELX/TEZ/IVA Combination Therapy in Subjects With Cystic Fibrosis Who Are 6 Years of Age and Older. The RMP version 9.2 has also been submitted."

Pyzchiva - Ustekinumab - EMEA/H/C/006183/II/0005/G

Samsung Bioepis NL B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Type IB C.I.2.a To update section 4.6 Fertility, Pregnancy and lactation of the SmPC to update information on pregnancy following assessment of the same change for the reference product Stelara (EMEA/H/C/000958).
An updated RMP (version 4.0) is provided.

Rystiggo - Rozanolixizumab - EMEA/H/C/005824/II/0006, Orphan

UCB Pharma, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Maria del Pilar Rayon, "Update of section 5.1 of the SmPC based on final results from study MG0007 listed as a specific a category 3 study in the RMP; this is a randomized, open-label extension study to evaluate the long-term safety, tolerability, and efficacy of repeated 6-week treatment cycles of rozanolixizumab based on myasthenia gravis worsening in adult study participants with generalized myasthenia gravis. The RMP version 1.1 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 update the PI in accordance with the latest EMA excipients guideline."

SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0053, Orphan

Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Submission of an updated RMP version 9.12 to include changes made to the pharmacokinetic study CUV052 including the inclusion of adolescent patients in the protocol. CUV052 is an interventional study to evaluate the pharmacokinetics of afamelanotide in patients with Erythropoietic Protoporphyria (EPP)."

Truqap - Capivasertib - EMEA/H/C/006017/II/0001

AstraZeneca AB, Rapporteur: Janet Koenig, PRAC Rapporteur: Sonja Hrabcik, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update the posology recommendation and the warning regarding Diabetic Ketoacidosis (DKA) and add it to the list of adverse drug reactions (ADRs) with frequency uncommon based on a safety review. The Package Leaflet is updated accordingly. The RMP version 2 has also been submitted. In addition, the MAH took the opportunity to remove post authorisation measures which were added to Annex II in error, 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."

Vyvgart - Efgartigimod alfa - EMEA/H/C/005849/II/0022/G, Orphan

Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald Quality

WEZENLA - Ustekinumab - EMEA/H/C/006132/II/0003/G

Amgen Technology (Ireland) Unlimited Company, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Rhea Fitzgerald, Quality

Xenpozyme - Olipudase alfa - EMEA/H/C/004850/II/0012/G, Orphan

Sanofi B.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "A grouped application consisting of:
C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study DFI12712

ASCEND, listed as a category 3 study in the RMP; this is a Phase 2/3, multicenter, randomised, double-blinded, placebo-controlled, repeat-dose study to evaluate the efficacy, safety, pharmacodynamics and pharmacokinetics of olipudase alfa in patients with AMSD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the SmPC.

C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study LTS13632 listed as a category 3 study in the RMP; this is a long-term study the ongoing safety and efficacy of olipudase alfa in patients with ASMD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted."

B.6.11. PRAC assessed procedures

PRAC Led
Humira - Adalimumab - EMEA/H/C/000481/II/0219
AbbVie Deutschland GmbH & Co. KG, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study P10-262 listed as a category 3 study in the RMP. This is a long-term, multi-centre, longitudinal, post-marketing observational registry to assess long-term safety and effectiveness of Humira (adalimumab) in children with moderately to severely active polyarticular or polyarticular-course juvenile idiopathic arthritis (JIA). The RMP version 16.1 has also been submitted."

PRAC Led
Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/II/0055, Orphan
Vertex Pharmaceuticals (Ireland) Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of section 4.6 of the SmPC in order to amend the existing wording on exposure during pregnancy following PSUR procedure

(EMEA/H/C/PSUSA/00010868/202310).”

PRAC Led
Signifor - Pasireotide -
EMEA/H/C/002052/II/0070, Orphan
Recordati Rare Diseases, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, “Submission of the final report from study CSOM230B2410 listed as a category 3 PASS in the RMP. This is a non-interventional, multinational, multi-centre post-marketing study to further document the safety and efficacy of pasireotide s.c. administered in routine clinical practice in patients with Cushing's disease. The RMP version 8.0 has also been submitted.”

PRAC Led
Zejula - Niraparib -
EMEA/H/C/004249/II/0055, Orphan
GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Christian Gartner, “Submission of an updated RMP version 8.0 in order to remove the category 3 PASS 3000-04-002/ GSK 214708; this is an integrated meta-analysis of MDS/AML and other SPM incidence in patients with ovarian cancer who have been treated with niraparib.”

B.6.12. CHMP-CAT assessed procedures

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

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

WS2740/G
Alkindi-
EMEA/H/C/004416/WS2740/0023/G
Efmody-
EMEA/H/C/005105/WS2740/0010/G
Diurnal Europe BV, Lead Rapporteur: Karin Janssen van Doorn, Quality.

WS2745
Entresto-
EMEA/H/C/004062/WS2745/0067

Neparvis-
EMEA/H/C/004343/WS2745/0064
Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt, Quality.

WS2750
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-
EMEA/H/W/005362/WS2750/0018
Qdenga-
EMEA/H/C/005155/WS2750/0019
Takeda GmbH, Lead Rapporteur: Sol Ruiz, Quality

WS2757/G
Aerius-
EMEA/H/C/000313/WS2757/0107/G
Azomyr-
EMEA/H/C/000310/WS2757/0111/G
Neoclarityn-
EMEA/H/C/000314/WS2757/0105/G
Organon N.V., Lead Rapporteur: Christophe Focke, Quality.

WS2759/G
Mirapexin-
EMEA/H/C/000134/WS2759/0109/G
Sifrol-
EMEA/H/C/000133/WS2759/0100/G
Boehringer Ingelheim International GmbH, Lead Rapporteur: Thalia Marie Estrup Blicher, Quality.

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

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

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

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

G. ANNEX G

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

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

G.2. PRIME

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

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