09 December 2024
EMA/CHMP/539348/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 09-12 December 2024

Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

09 December 2024, 09:30 – 19:30, virtual meeting/room 2C

10 December 2024, 08:30 – 19:30, virtual meeting/room 2C

11 December 2024, 08:30 – 19:30, virtual meeting/room 2C

12 December 2024, 08:30 – 15:00, virtual meeting/room 2C

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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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 09-12 December 2024. See December 2024 CHMP minutes (to be published post January 2025 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 09-12 December 2024

1.3. Adoption of the minutes

CHMP minutes for September and November 2024.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 02 December 2024.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

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

Scope: Oral explanation

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

List of Outstanding Issues adopted on 19.09.2024. List of Questions adopted on 14.12.2023.

2.1.2. Tiratricol - Orphan - EMEA/H/C/005220

Rare Thyroid Therapeutics International AB; treatment of monocarboxylate transporter 8 (MCT8) deficiency

Scope: Oral explanation

Action: Oral explanation to be held on 11 December 2024 at 09:00

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 22.02.2024.

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 09 December 2024 at 16:00

List of Outstanding Issues adopted on 19.09.2024. List of Questions adopted on 25.05.2023.

2.1.4. Donanemab - EMEA/H/C/006024

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

Scope: Oral explanation

Action: Oral explanation to be held on 11 December 2024 at 14:00

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

2.1.5. Seladelpar lysine dihydrate - PRIME - Orphan - EMEA/H/C/004692

CymaBay Ireland, Ltd; treatment of primary biliary cholangitis (PBC) including pruritus in adults without cirrhosis or with compensated cirrhosis (Child-Pugh A) in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA

Scope: Oral explanation

Action: Oral explanation to be held on 10 December 2024 at 09:00

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 27.06.2024.

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

treatment of neutropenia in paediatric patients

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 30.05.2024.

2.1.7. Methylphenidate hydrochloride - PUMA - EMEA/H/C/005975

treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years of age and over

Scope: Oral explanation

Action: Oral explanation to be held on 10 December 2024 at 11 :00

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 08.06.2023.

2.1.8. 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: Oral explanation

Action: Oral explanation to be held on 10 December 2024 at 16:00

List of Outstanding Issues adopted on 19.09.2024. List of Questions adopted on 25.04.2024.

2.1.9. Clascoterone - EMEA/H/C/006138

indicated for the topical treatment of acne vulgaris in adults and adolescents

Scope: Oral explanation

Action: Oral explanation to be held on 11 December 2024 at 16:00

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 22.02.2024.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Arexvy - Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E - EMEA/H/C/PSUSA/00000031/202405

GlaxoSmithkline Biologicals S.A.

Rapporteur: Patrick Vrijlandt PRAC Rapporteur: Maria del Pilar Rayon

Scope: Oral explanation

Action: Oral explanation to be held on 09 December 2024 at 14:00

See 9.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024, 19.09.2024. List of Questions adopted on 21.03.2024.

3.1.2. Tocilizumab - EMEA/H/C/006196

treatment of rheumatoid arthritis (RA)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024. List of Questions adopted on 27.06.2024.

3.1.3. Acoramidis - Orphan - EMEA/H/C/006333

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 30.05.2024.

3.1.4. Aflibercept - EMEA/H/C/005899

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.09.2024. List of Questions adopted on 25.04.2024.

3.1.5. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 12.11.2024. List of Questions adopted on 17.09.2024.

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

active immunisation to prevent COVID-19

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.09.2024, 30.05.2024. List of Questions adopted on 14.12.2023.

3.1.7. Nemolizumab - EMEA/H/C/006149

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 30.05.2024.

3.1.8. Denosumab - EMEA/H/C/006157

prevention of skeletal related events with advanced malignancies

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024. List of Questions adopted on 25.07.2024.

3.1.9. Guanfacine - EMEA/H/C/006312

treatment of ADHD

Scope: Opinion

Action: List of outstanding issues

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 22.02.2024.

3.1.10. Denosumab - EMEA/H/C/006156

treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024. List of Questions adopted on 25.07.2024.

3.1.11. Imetelstat - Orphan - EMEA/H/C/006105

Geron Netherlands B.V.; for the treatment of transfusion-dependent anaemia in adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS), for the treatment of transfusion-dependent anaemia in adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 25.01.2024.

3.1.12. Ustekinumab - EMEA/H/C/006444

for the treatment of Crohn’s disease and ulcerative colitis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024. List of Questions adopted on 27.06.2024.

3.1.13. Filgrastim - EMEA/H/C/006400

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.09.2024. List of Questions adopted on 25.04.2024.

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

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

3.2.3. Eltrombopag - EMEA/H/C/006459

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

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

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

Scope: List of outstanding issues; Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues to be adopted in December 2024.

Action: For adoption

List of Questions adopted on 25.04.2024.

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

Springworks Therapeutics Ireland Limited; treatment of desmoid tumours

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.06.2024.

3.2.6. Atropine - EMEA/H/C/006324

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

3.2.7. Sargramostim - EMEA/H/C/006411

treatment for exposure to myelosuppressive doses of radiation

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.07.2024.

3.2.8. 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 Outstanding Issues adopted on 19.09.2024. List of Questions adopted on 30.05.2024.

3.2.9. Chikungunya virus virus-like particle - PRIME - Article 28 - EMEA/H/C/005470

Accelerated assessment

prevention of disease caused by chikungunya (CHIKV) virus

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 15.10.2024.

3.2.10. Beremagene geperpavec - PRIME - Orphan - ATMP - EMEA/H/C/006330

Krystal Biotech Netherlands B.V.; treatment of patients from birth with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 11.10.2024. List of Questions adopted on 15.03.2024.

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

3.3.1. Aflibercept - EMEA/H/C/006438

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

Scope: List of questions

Action: For adoption

3.3.2. Lifileucel - ATMP - EMEA/H/C/004741

treatment of unresectable or metastatic melanoma

Scope: List of questions

Action: For information

3.3.3. Denosumab - EMEA/H/C/006526

treatment of osteoporosis and bone loss

Scope: List of questions

Action: For adoption

3.3.4. Sebetralstat - Orphan - EMEA/H/C/006211

KALVISTA PHARMACEUTICALS (IRELAND) Limited; treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older

Scope: List of questions

Action: For adoption

3.3.5. Hydrocortisone - PUMA - EMEA/H/C/005201

prevention of bronchopulmonary dysplasia in preterm infants born less than 28 weeks of gestation.

Scope: List of questions

Action: For adoption

3.3.6. Mirdametinib - Orphan - EMEA/H/C/006460

Springworks Therapeutics Ireland Limited; treatment of neurofibromatosis type 1

Scope: List of questions

Action: For adoption

3.3.7. Pridopidine - Orphan - EMEA/H/C/006261

Prilenia Therapeutics B.V.; treatment of Huntington's disease

Scope: List of questions

Action: For adoption

3.3.8. Olezarsen - EMEA/H/C/006477

treatment of familial chylomicronemia syndrome

Scope: List of questions

Action: For adoption

3.3.9. Denosumab - EMEA/H/C/006534

prevention of skeletal related events with advanced malignancies

Scope: List of questions

Action: For adoption

3.3.10. Zuranolone - EMEA/H/C/006488

the treatment of postpartum depression (PPD) in adults

Scope: List of questions

Action: For adoption

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

3.4.1. Delandistrogene moxeparvovec - Orphan - ATMP - EMEA/H/C/005293

Roche Registration GmbH; treatment of ambulatory patients aged 3 to 7 years old with Duchenne muscular dystrophy

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in October 2024.

The CAT agreed to the request for an extension to the clock-stop to respond to the list of questions adopted in October 2024

Action: For information

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

No items

3.5.1. CINAINU - Liquid ethanolic extract 30 per cent (W/W) of *Allium cepa* fresh bulb and *Citrus limon* fresh fruit / Dry aqueous extract of *paullinia cupana* seed / Dry hydroethanolic extract of *theobroma cacao* seed - EMEA/H/C/004155

Legacy Healthcare (France) S.A.S.; treatment of alopecia areata in children and adolescents

Scope: Request for re-examination, appointment of re-examination rapporteurs

Action: For adoption

Opinion adopted on 14.11.2024. List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 12.10.2023.

3.5.2. Kizfizo - Temozolomide - Orphan - EMEA/H/C/006169

Orphelia Pharma; treatment of neuroblastoma

Scope: Request for re-examination, appointment of re-examination rapporteurs

Action: For adoption

Opinion adopted on 14.11.2024. List of Outstanding Issues adopted on 27.06.2024. List of Questions adopted on 14.12.2023.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Bimatoprost implant - 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: Updated WPAR tabled

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

Pfizer Europe MA EEIG;

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

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

Action: For adoption

List of Questions adopted on 25.07.2024.

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

Upjohn EESV;

Rapporteur: Peter Mol, PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

List of Questions adopted on 30.05.2024.

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

Boehringer Ingelheim International GmbH;

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

Scope: "Extension application to add a new strength of 25 mg hard capsules, grouped with an extension of indication (C.I.6.a) to include treatment of fibrosing Interstitial Lung Diseases (ILDs) in children and adolescents from 6 to 17 years of age for Ofev, following the assessment of procedure X/0052/G, based on final results from study 1199-0337 (A Double

Blind, Randomised, Placebo-controlled Trial to Evaluate the Dose-exposure and Safety of Nintedanib Per os on Top of Standard of Care for 24 Weeks, Followed by Open Label Treatment With Nintedanib of Variable Duration, in Children and Adolescents (6 to 17 Year-old) With Clinically Significant Fibrosing Interstitial Lung Disease), which is supplemented by the currently ongoing prospective Phase III extension trial 1199-0378 (An Open-label Trial of the Long-term Safety and Tolerability of Nintedanib Per os, on Top of Standard of Care, Over at Least 2 Years, in Children and Adolescents With Clinically Significant Fibrosing Interstitial Lung Disease). The main objective of the study 1199-0337 was to evaluate dose-exposure and safety of nintedanib in children and adolescents with fibrosing Interstitial Lung Disease (ILD). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 12.0 of the RMP has also been submitted."

Action: For adoption

List of Outstanding Issues adopted on 14.11.2024, 19.09.2024, 25.07.2024. List of Questions adopted on 22.02.2024.

4.1.4. 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, multicentre, randomized, double-blind, placebo- and active-controlled, treat-through study to evaluate the efficacy and safety of mirikizumab in patients with moderately to severely active Crohn's disease. As a consequence, sections 1, 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.1, 6.5, 6.6 and 8 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. Version 1.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and to update the list of local representatives in the Package Leaflet. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Quality variations are also included as part of this application

Action: For adoption

List of Questions adopted on 19.09.2024.

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

Merck Sharp & Dohme B.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Terhi Lehtinen

Scope: "Extension applications to introduce a new pharmaceutical form (granules in sachet) associated with new strengths (20 and 120 mg) grouped with a type II variation (C.I.6.a) to include treatment of paediatric patients from birth up to 18 years old based on the final

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

Action: For adoption

List of Questions adopted on 25.07.2024.

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

Eli Lilly Nederland B.V.;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to introduce a new pharmaceutical form (film-coated tablets) associated with new strengths (40 mg, 80 mg, 120 mg and 160 mg).
The RMP (version 7.1) is updated in accordance."

Action: For adoption

List of Questions adopted on 25.07.2024.

4.1.7. Uzpruvo - Ustekinumab - EMEA/H/C/006101/X/0001

STADA Arzneimittel AG;

Rapporteur: Christian Gartner, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (130 mg concentrate for solution for infusion) and a new route of administration (intravenous use). The RMP version 1.1 is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 27.06.2024.

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

4.2.1. 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, multicentre studies that evaluated the efficacy and safety of guselkumab in participants with moderately to severely active UC. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC 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

List of Questions adopted on 19.09.2024.

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. Azacitidine Accord - Azacitidine - EMEA/H/C/005147/X/0021

Accord Healthcare S.L.U.;

Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to introduce a new pharmaceutical form (film-coated tablet) associated with new strengths (200 and 300 mg) and new route of administration (oral use).
The RMP (version 2.0) is updated in accordance."

Action: For adoption

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

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

Request for Supplementary Information adopted on 19.09.2024.

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

Takeda Pharma A/S;

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

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

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024.

5.1.3. BLINCYTO - Blinatumomab - Orphan - EMEA/H/C/003731/II/0056

Amgen Europe B.V.;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jana Lukacisinova

Scope: "Extension of indication to include treatment as part of consolidation therapy for the treatment of patients with Philadelphia chromosome negative CD19 positive B-cell precursor ALL for BLINCYTO. The proposed indication is supported by efficacy data from Studies E1910, 20120215, and AALL1331, safety data for Studies E1910, 20120215, AALL1331, MT103-202, and MT103-203, and Pharmacokinetic data for Studies 20120215, AALL1331, MT103-202, MT103-203, and 20190360. As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 18.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024, 30.05.2024.

5.1.4. Bridion - Sugammadex - EMEA/H/C/000885/II/0047

Merck Sharp & Dohme B.V.;

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Terhi Lehtinen

Scope: "Extension of indication to include treatment of paediatric patients from birth to less than 2 years of age for Bridion based on final results from paediatric study PN169 (MK-8616-P169); this is a Phase 4 double-blinded, randomized, active comparator-controlled clinical trial to study the efficacy, safety, and pharmacokinetics of sugammadex (MK-8616) for reversal of neuromuscular blockade in paediatric participants aged birth to <2 years. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, to implement minor editorial corrections and to update the information intended for healthcare professionals (HCPs) at the end of the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

5.1.5. CABOMETYX - Cabozantinib - EMEA/H/C/004163/II/0040

Ipsen Pharma;

Rapporteur: Ingrid Wang, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Bianca Mulder

Scope: "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."

Action: For adoption

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

AstraZeneca AB;

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "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, Multicenter 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)

Action: For adoption

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

AstraZeneca AB;

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "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."

Action: For adoption

5.1.8. Flucelvax Tetra - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/II/0047

Seqirus Netherlands B.V.;

Rapporteur: Sol Ruiz, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include treatment of adults and children from 6 months of age and older for FLUCELVAX TETRA based on final results from study V130_14. This is a phase 3, randomized, observer-blind, multicentre study to evaluate the efficacy,

immunogenicity, and safety of Seqirus' Cell-Based Quadrivalent Subunit Influenza Virus Vaccine (QIVc) compared to a non-influenza vaccine when administrated in healthy subjects aged 6 months through 47 months. 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 3.3 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024.

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

Valneva Austria GmbH;

Rapporteur: Christophe Focke, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Gabriele Maurer

Scope: "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."

Action: For adoption

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

GlaxoSmithKline (Ireland) Limited;

Rapporteur: Antonio Gomez-Outes, Co-Rapporteur: Boje Kvorning Pires Ehmsen, 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

Request for Supplementary Information adopted on 19.09.2024.

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

Eli Lilly Nederland B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024, 17.10.2024.

5.1.12. Neuraceq - Florbetaben (18F) - EMA/VR/0000227744

Life Molecular Imaging GmbH

Rapporteur: Antonio Gomez-Outes

Scope: "Extension of indication to include monitoring of the biological treatment response to pharmacological and non-pharmacological interventions for NEURACEQ, based on supporting literature. As a consequence, sections 4.1, 4.4 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.91 of the RMP has also been submitted. In addition, the MAH took the opportunity to include the proposal to discontinue the inclusion of a paper copy of the SmPC with the product package."

Action: For adoption

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

Incyte Biosciences Distribution B.V.;

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

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

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024, 25.04.2024.

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

Janssen-Cilag International N.V.;

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Fátima Ventura, 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

Request for Supplementary Information adopted on 19.09.2024.

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

Novartis Europharm Limited;

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Monica Martinez Redondo

Scope: "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."

Action: For adoption

5.1.16. 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."

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024.

5.1.17. Veklury - Remdesivir - EMEA/H/C/005622/II/0053/G

Gilead Sciences Ireland UC;

Rapporteur: Janet Koenig (DE) (MNAT with AT for Quality), PRAC Rapporteur: Eva Jirsová

Scope: "Grouped application comprising two extensions of indication to include treatment of paediatric patients weighing at least 1.5 kg for VEKLURY, based on final results from study GS-US-540-5823; this is a Phase 2/3 single-arm, open-label study to evaluate the safety, tolerability, pharmacokinetics, and efficacy of remdesivir in participants from birth to < 18 years of age with COVID-19; As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

5.1.18. 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

Request for Supplementary Information adopted on 19.09.2024.

5.1.19. Xydalba - Dalbavancin - EMEA/H/C/002840/II/0050

AbbVie Deutschland GmbH & Co. KG;

Rapporteur: Filip Josephson, PRAC Rapporteur: Rugile Pilviniene

Scope: "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."

Action: For adoption

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

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

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Martin Huber

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

Request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in July 2024.

Action: For adoption

Request for Supplementary Information adopted on 25.07.2027, 25.04.2024.

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

Vertex Pharmaceuticals (Ireland) Limited; treatment of cystic fibrosis.

Rapporteur: Peter Mol, Co-Rapporteur: Finbarr Leacy

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

Update on the procedure, Third party intervention

Action: For discussion

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

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

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

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

Action: re-examination request, appointment of re-examination rapporteur

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

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/006590

detection of HLA-B*5701 allele, which is a predictor of hypersensitivity to abacavir, a drug used for treating HIV-1 infection

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. Nogapendekin alfa/Inbakicept - H0006622

an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours.

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

Pfizer Europe MA EEIG

Rapporteur: Jean-Michel Race, PRAC Rapporteur: Martin Huber

Scope: "Grouped application consisting of:
C.I.4: Update of sections 4.2, 4.4, 4.8 and 5.2 of the SmPC in order to provide a new dosing recommendation in patients with severe renal impairment based on final results from study C4671028; this is a Phase 1, Open-Label, Non-Randomized Study to Investigate the Safety and PK Following Multiple Oral Doses of PF-07321332 (Nirmatrelvir)/Ritonavir in Adult Participants With COVID-19 and Severe Renal Impairment Either on Hemodialysis or Not on Hemodialysis. The Package Leaflet and Labelling are updated accordingly. The updated RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.
B.II.e.5.a.2: To introduce a new pack size."

DHPC communication

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024.

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

Novartis Europharm Limited

Rapporteur: Antonio Gomez-Outes

Scope: "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."

Action: For adoption

Request for Supplementary Information adopted on 05.09.2024.

9.1.3. Zejula - Niraparib - EMEA/H/C/004249/II/0056, Orphan

GlaxoSmithKline (Ireland) Limited

Rapporteur: Ingrid Wang, PRAC Rapporteur: Jan Neuhauser

Scope: "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from PRIMA study (PR-30-5017-C) listed as a PAES in the Annex II; this is a Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicentre Study of Niraparib Maintenance Treatment in Patients with Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy. The RMP version 9.0 has also been submitted. In addition, the MAH took the opportunity to update section D of Annex II, and to implement editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 28.11.2024.

9.1.4. Arexvy - Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E - EMEA/H/C/PSUSA/00000031/202405

GlaxoSmithkline Biologicals S.A.

PRAC Rapporteur: Maria del Pilar Rayon, PRAC-CHMP Liaison: Antonio Gomez-Outes

Scope: "Update of section(s) 4.8 of the SmPC to add the adverse reaction injection site necrosis with frequency not known. The Package leaflet is updated accordingly".

Action: For adoption

See 2.3

9.1.5. Krazati - Adagrasib - EMEA/H/C/006013/II/0010/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Kimmo Jaakkola

Scope: "A grouped application consisting of: C.I.4: Update of section 5.1 of the SmPC based on final results from study 849-012 (KRYSTAL-12) listed as a specific obligation in the Annex II. This is a Randomized Phase 3 Study of MRTX849 versus Docetaxel in Patients with Previously Treated Non-Small Cell Lung Cancer with KRAS 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 IIE of the PI.

C.I.4: Update of section 4.8 of the SmPC in order to update safety information based on an integrated analysis of data from interventional studies 849-012 (KRYSTAL-12), 849-007 (KRYSTAL-7) and 849-001 (KRYSTAL-1)."

Action: For adoption

9.1.6. Alofisel – Darvadstrocel – ATMP - EMEA/H/C/004258, EMEA/H/C/004258/II/0051/G

Takeda Pharma A/S; Alofisel is indicated for the treatment of complex perianal fistulas in

adult patients with non-active/mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy. Alofisel should be used after conditioning of fistula.

CAT Rapporteur: Maria Luttgen, CHMP Coordinator: Kristina Dunder

Scope: Update on the procedure

Action: For information

10. Referral procedures

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

10.1.1. Oxbryta - Voxelotor - EMEA/H/A-20/1538/C/004869/0014

Pfizer Europé Ma EEIG

Referral Rapporteur: Patrick Vrijlandt, Referral Co- Rapporteur: Alexandre Moreau

Scope: List of Outstanding Issues, Revised Timetable

Action: For adoption

The EC initiated a procedure under Article 20 of Regulation (EC) No 726/2004 to assess the benefit-risk balance of Oxbryta in its authorised indication. The initiation of the review follows an imbalance of deaths between voxelotor and placebo observed in clinical trials. The findings from these emerging safety data need to be further reviewed, taking into account all available data, to determine whether there is an impact on the benefit-risk balance of Oxbryta in its authorised indication.

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

Orexigen Therapeutics Ireland Limited

Rapporteur: Kristina Dunder, Co-Rapporteur: Daniela Philadelphy

Scope: List of Outstanding issues, Revised Timetable

Action: For adoption

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

List of Questions adopted on 30.05.2024

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

December 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

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by Proxy

No items

14.1.2. CHMP membership

No items

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

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

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at December 2024 PDCO

Action: For information

Agenda of the PDCO meeting held on 10-13 December 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 Barbu

Action: For adoption

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 19-20 November 2024.

Action: For adoption

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 25-28 November 2024. Table of conclusions

Action: For information

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

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

14.9.1. CHMP Learnings

CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

Action: For information

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

Clock-stop extensions and feedback from GIREX

Action: For discussion

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)*

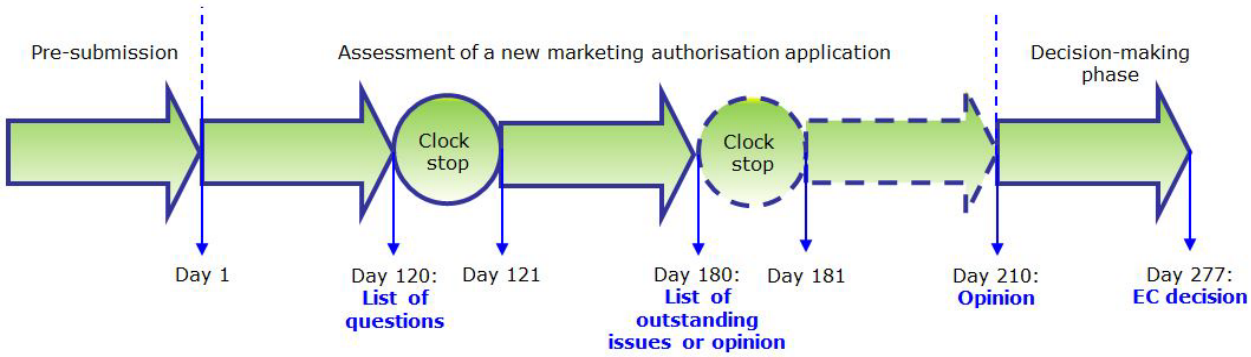
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

09 December 2024
EMA/CHMP/539457/2024

Annex to 09-12 December 2024 CHMP Agenda

Pre-submission and post-authorisations issues

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for December 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

Brineura - Cerliponase alfa - EMEA/H/C/004065/S/0047, Orphan
BioMarin International Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Mari Thorn
Request for Supplementary Information adopted on 14.11.2024.

Increlex - Mecasermin - EMEA/H/C/000704/S/0083
Ipsen Pharma, Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Terhi Lehtinen

Lojuxta - Lomitapide - EMEA/H/C/002578/S/0061
Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder
Request for Supplementary Information adopted on 14.11.2024.

Strensiq - Asfotase alfa - EMEA/H/C/003794/S/0069, Orphan
Alexion Europe SAS, Rapporteur: Paolo

Gasparini, PRAC Rapporteur: Eamon O Murchu

Upstaza - Eladocagene exuparvovec - EMEA/H/C/005352/S/0025, Orphan, ATMP
PTC Therapeutics International Limited, Rapporteur: Joseph DeCourcey, Co-Rapporteur: Maria Luttgen, CHMP Coordinator: Finbarr Leacy, PRAC Rapporteur: Gabriele Maurer

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

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Atectura Breezhaler - Indacaterol / Mometasone - EMEA/H/C/005067/R/0031
Novartis Europharm Limited, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser
Request for Supplementary Information adopted on 14.11.2024.

Bemrist Breezhaler - Indacaterol / Mometasone - EMEA/H/C/005516/R/0026
Novartis Europharm Limited, Duplicate of Atectura Breezhaler, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser
Request for Supplementary Information adopted on 14.11.2024.

Daurismo - Glasdegib - EMEA/H/C/004878/R/0015, Orphan
Pfizer Europe MA EEIG, Rapporteur: Alexandre Moreau, Co-Rapporteur: Boje Kvorning Pires Ehmsen, 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

GoResp Digihaler - Budesonide /

Formoterol fumarate dihydrate - EMEA/H/C/004882/R/0016
Teva Pharma B.V., Duplicate of DuoResp Spiromax, Rapporteur: John Joseph Borg, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Marie Louise Schougaard Christiansen
Request for Supplementary Information adopted on 17.10.2024.

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: Boje Kvorning Pires Ehmsen, 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

SARCLISA - Isatuximab - EMEA/H/C/004977/R/0033
Sanofi Winthrop Industrie, Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Monica Martinez Redondo
Request for Supplementary Information adopted on 14.11.2024.

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.2.3. Renewals of Conditional Marketing Authorisations

Casgevy - Exagamglogene autotemcel - EMEA/H/C/005763/R/0006, Orphan, ATMP
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Heli Suila, CHMP Coordinator: Jan

Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder
Request for Supplementary Information adopted on 11.10.2024.

FILSPARI - Sparsentan - EMEA/H/C/005783/R/0004, Orphan
Vifor France, Rapporteur: Vilma Petrikaite, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber

Natpar - Parathyroid hormone - EMEA/H/C/003861/R/0058, Orphan
Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Rhea Fitzgerald

Pemazyre - Pemigatinib - EMEA/H/C/005266/R/0019, Orphan
Incyte Biosciences Distribution B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

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
Request for Supplementary Information adopted on 14.11.2024, 13.09.2024.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 26-28 November 2024 PRAC:

Signal of non-cirrhotic portal hypertension/Portosinusoidal vascular
Azathioprine – JAYEMPI (CAP & NAP)
Rapporteur: John Joseph Borg, PRAC Rapporteur: Karin Erneholm
PRAC recommendation on a variation
Action: For adoption

Signal of pulmonary oedema in patients with veno-occlusive disease
Nitric oxide – INOMAX (CAP & NAP)
Rapporteur: Christophe Focke, Co-Rapporteur: John Joseph Borg, PRAC Rapporteur: Jo Robays
PRAC recommendation on a variation
Action: For adoption

PRAC recommendations on PASS results adopted at the PRAC meeting held on 26-28 November 2024 PRAC:

BRETARIS GENUAIR (CAP), EKLIRA GENUAIR (CAP); BRIMICA GENUAIR (CAP), DUAKLIR GENUAIR - (CAP) - EMEA/H/C/PSR/S/0047
(Aclidinium; aclidinium, formoterol fumarate dihydrate)
PRAC rapporteur: Adam Przybylkowski,
Scope: Final study report for a post-authorisation safety study to evaluate the potential cardiovascular safety concerns and all-cause mortality described in the risk management plan for aclidinium bromide as monotherapy and fixed-dose combination of aclidinium/formoterol.
PRAC recommendation to CHMP
Action: For adoption

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

EMEA/H/C/PSUSA/00000231/202405
(fezolinetant)
CAPS:
Veoza (EMEA/H/C/005851) (Fezolinetant), Astellas Pharma Europe B.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "11/11/2023 To: 11/05/2024"

EMEA/H/C/PSUSA/00002839/202403
(tacrolimus (systemic formulations))
CAPS:
Advagraf (EMEA/H/C/000712) (Tacrolimus), Astellas Pharma Europe B.V., Rapporteur: Jayne Crowe
Envarsus (EMEA/H/C/002655) (Tacrolimus), Chiesi Farmaceutici S.p.A., Rapporteur: John Joseph Borg
Modigraf (EMEA/H/C/000954) (Tacrolimus), Astellas Pharma Europe B.V., Rapporteur: Kristina Dunder
NAPS:
NAPs - EU
PRAC Rapporteur: Eamon O Murchu, "31/03/2021 To: 31/03/2024"

EMEA/H/C/PSUSA/00009154/202404
(fluticasone furoate)
CAPS:
Avamys (EMEA/H/C/000770) (Fluticasone furoate), GlaxoSmithKline (Ireland) Limited, Rapporteur: Ewa Balkowiec Iskra
NAPS:
NAPs - EU
PRAC Rapporteur: Adam Przybylkowski, "27/04/2021 To: 26/04/2024"

EMEA/H/C/PSUSA/00010388/202404
(empagliflozin, empagliflozin / metformin)
CAPS:
Jardiance (EMEA/H/C/002677) (Empagliflozin), Boehringer Ingelheim International GmbH, Rapporteur: Patrick Vrijlandt
Synjardy (EMEA/H/C/003770) (Empagliflozin / Metformin), Boehringer Ingelheim International GmbH, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon, "17/04/2022 To: 17/04/2024"

EMEA/H/C/PSUSA/00011019/202405
(tirzepatide)
CAPS:
Mounjaro (EMEA/H/C/005620) (Tirzepatide), Eli Lilly Nederland B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder, "14/11/2023 To: 13/05/2024"

EMEA/H/C/PSUSA/00011038/202404 (tremelimumab) CAPS: **IMJUDO** (EMEA/H/C/006016) (Tremelimumab), AstraZeneca AB, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: David Olsen, "21/10/2023 To: 20/04/2024"	

B.4. EPARs / WPARs

Afqlir – Aflibercept - EMEA/H/C/006150 Sandoz GmbH, treatment of age-related macular degeneration (AMD) or visual impairment, Biosimilar to Eylea, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Ahzantive - Aflibercept - EMEA/H/C/006607 Klinge Biopharma GmbH, treatment of age-related macular degeneration (AMD) and visual impairment, Duplicate, Duplicate of Baiama, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
AUGTYRO - Repotrectinib - EMEA/H/C/006005 Bristol-Myers Squibb Pharma EEIG, treatment of ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) and for solid tumours, New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Baiama - Aflibercept - EMEA/H/C/005980 Formycon AG, treatment of age-related macular degeneration (AMD) and visual impairment, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Gohibic - Vilobelimab - EMEA/H/C/006123 InflaRx GmbH, treatment of adult patients with SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO)., New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Kizfizo - Temozolomide - EMEA/H/C/006169, Orphan Orphelia Pharma, treatment of neuroblastoma, Hybrid application (Article 10(3) of Directive No	For information only. Comments can be sent to the PL in case necessary.

2001/83/EC)	
Lazcluze - Lazertinib - EMEA/H/C/006074 Janssen Cilag International, treatment of adult patients mwith advanced non-small cell lung cancer (NSCLC), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
LEQEMBI - Lecanemab - EMEA/H/C/005966 Eisai GmbH, a disease modifying treatment in adult patients with Mild Cognitive Impairment due to Alzheimer's disease and Mild Alzheimer's disease (Early Alzheimer's disease), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Masitinib AB Science - Masitinib - EMEA/H/C/005897, Orphan AB Science, in combination with riluzole for the treatment of adult patients with amyotrophic lateral sclerosis (ALS), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Obodence - Denosumab - EMEA/H/C/006424 Samsung Bioepis NL B.V., treatment of osteoporosis and bone loss, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Opuviz - Aflibercept - EMEA/H/C/006056 Samsung Bioepis NL B.V.; treatment of age-related macular degeneration (AMD) and visual impairment, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	
Xbryk - Denosumab - EMEA/H/C/006468 Samsung Bioepis NL B.V., prevention of skeletal related events with advanced malignancies and treatment of giant cell tumour of bone Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) -	

EMEA/H/C/006027/II/0010/G Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 14.11.2024.	
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.	
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.	
Busulfan Fresenius Kabi – Busulfan - EMA/VR/0000228648 Fresenius Kabi Deutschland GmbH, Rapporteur: John Joseph Borg	
COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000228506 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson	
Dupixent - Dupilumab - EMEA/H/C/004390/II/0090/G Sanofi Winthrop Industrie, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 21.11.2024.	Positive Opinion adopted by consensus on 21.11.2024.
Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan - Efavirenz / Emtricitabine / Tenofovir disoproxil - EMA/VR/0000177462 Mylan Pharmaceuticals Limited, Rapporteur: Fátima Ventura	
Emtricitabine/Tenofovir disoproxil Mylan - Emtricitabine / Tenofovir disoproxil - EMA/VR/0000177324 Mylan Pharmaceuticals Limited, Rapporteur: Vilma Petrikaite	
Emtricitabine/Tenofovir disoproxil Mylan - Emtricitabine / Tenofovir disoproxil - EMA/VR/0000223057 Mylan Pharmaceuticals Limited, Rapporteur: Vilma Petrikaite, Quality	

Enhertu - Trastuzumab - EMEA/H/C/005124/II/0051 Daiichi Sankyo Europe GmbH, Rapporteur: Boje Kvorning Pires Ehmsen	
Entecavir Viatris - Entecavir - EMEA/H/C/004377/II/0013 Viatris Limited, Generic of Baraclude, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 07.11.2024.	
Fluad Tetra - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/004993/II/0056/G Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Request for Supplementary Information adopted on 05.12.2024.	Request for supplementary information adopted with a specific timetable.
GONAL-f - Follitropin alfa - EMEA/H/C/000071/II/0172/G Merck Europe B.V., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 12.09.2024.	
Hemangiol - Propranolol - EMEA/H/C/002621/II/0025 Pierre Fabre Medicament, Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 05.09.2024, 05.10.2023.	
IDELVION - Albutrepenonacog alfa - EMEA/H/C/003955/II/0074, Orphan CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus	
JEMPERLI - Dostarlimab - EMEA/H/C/005204/II/0038/G GlaxoSmithKline (Ireland) Limited, Rapporteur: Antonio Gomez-Outes Opinion adopted on 21.11.2024.	Positive Opinion adopted by consensus on 21.11.2024.
Kanuma - Sebelipase alfa - EMEA/H/C/004004/II/0050/G, Orphan Alexion Europe SAS, Rapporteur: Karin Janssen van Doorn Opinion adopted on 28.11.2024.	Positive Opinion adopted by consensus on 28.11.2024.
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0162 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini	
Lonquex - Lipegfilgrastim -	Positive Opinion adopted by consensus on

EMEA/H/C/002556/II/0096/G Teva B.V., Rapporteur: Outi Mäki-Ikola Opinion adopted on 21.11.2024.	21.11.2024.
Menveo - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/001095/II/0122/G GSK Vaccines S.r.l, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 28.11.2024, 03.10.2024.	Request for supplementary information adopted with a specific timetable.
Orgovyx - Relugolix - EMEA/H/C/005353/II/0023 Accord Healthcare S.L.U., Rapporteur: Patrick Vrijlandt Opinion adopted on 28.11.2024.	Positive Opinion adopted by consensus on 28.11.2024.
OZAWADE - Pitolisant - EMEA/H/C/005117/II/0011/G Bioprojet Pharma, Rapporteur: Peter Mol Opinion adopted on 05.12.2024.	Positive Opinion adopted by consensus on 05.12.2024.
Padcev - Enfortumab vedotin - EMEA/H/C/005392/II/0021/G Astellas Pharma Europe B.V., Rapporteur: Boje Kvorning Pires Ehmsen Opinion adopted on 05.12.2024.	Positive Opinion adopted by consensus on 05.12.2024.
Pifeltro - Doravirine - EMEA/H/C/004747/II/0031/G Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson Opinion adopted on 21.11.2024.	Positive Opinion adopted by consensus on 21.11.2024.
Qarziba - Dinutuximab beta - EMEA/H/C/003918/II/0062/G, Orphan Recordati Netherlands B.V., Rapporteur: Peter Mol Request for Supplementary Information adopted on 21.11.2024, 12.09.2024.	Request for supplementary information adopted with a specific timetable.
Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0032/G Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson Opinion adopted on 21.11.2024. Request for Supplementary Information adopted on 19.09.2024.	Positive Opinion adopted by consensus on 21.11.2024.
Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0033/G Merck Sharp & Dohme B.V., Rapporteur: Filip	Positive Opinion adopted by consensus on 21.11.2024.

Josephson Opinion adopted on 21.11.2024. Request for Supplementary Information adopted on 19.09.2024.	
Revolade - Eltrombopag - EMEA/H/C/001110/II/0078/G Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes Opinion adopted on 21.11.2024.	Positive Opinion adopted by consensus on 21.11.2024.
Rybrevant - Amivantamab - EMEA/H/C/005454/II/0018/G Janssen-Cilag International N.V., Rapporteur: Filip Josephson	
Semglee - Insulin glargine - EMEA/H/C/004280/II/0050 Biosimilar Collaborations Ireland Limited, Rapporteur: Janet Koenig Opinion adopted on 21.11.2024. Request for Supplementary Information adopted on 10.10.2024, 05.09.2024.	Positive Opinion adopted by consensus on 21.11.2024.
Soliris - Eculizumab - EMEA/H/C/000791/II/0134/G, Orphan Alexion Europe SAS, Rapporteur: Antonio Gomez-Outes	
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0123/G Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 05.12.2024. Request for Supplementary Information adopted on 05.09.2024, 27.06.2024, 25.04.2024.	Positive Opinion adopted by consensus on 05.12.2024.
Tyruko - Natalizumab - EMEA/H/C/005752/II/0004 Sandoz GmbH, Rapporteur: Christian Gartner Opinion adopted on 05.12.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 05.12.2024.
Vabysmo - Faricimab - EMEA/H/C/005642/II/0011/G Roche Registration GmbH, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 19.09.2024, 27.06.2024.	
VEYVONDI - Vonicog alfa - EMEA/H/C/004454/II/0036/G Baxalta Innovations GmbH, Rapporteur: Jan	

Mueller-Berghaus	
Xofigo - Radium-223 - EMEA/H/C/002653/II/0053 Bayer AG, Rapporteur: Janet Koenig Request for Supplementary Information adopted on 30.11.2023.	
Yuflyma - Adalimumab - EMEA/H/C/005188/II/0042/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola	
Zirabev - Bevacizumab - EMEA/H/C/004697/II/0032 Pfizer Europe MA EEIG, Rapporteur: Eva Skovlund Opinion adopted on 05.12.2024. Request for Supplementary Information adopted on 01.02.2024.	Positive Opinion adopted by consensus on 05.12.2024.
WS2752 **Infanrix hexa- EMEA/H/C/000296/WS2752/0349** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 05.12.2024.	Positive Opinion adopted by consensus on 05.12.2024.
WS2756 **Hexacima- EMEA/H/C/002702/WS2756/0160** **Hexyon- EMEA/H/C/002796/WS2756/0164** Sanofi Pasteur Europe, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 05.12.2024.	Request for supplementary information adopted with a specific timetable.

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

Abraxane - Paclitaxel - EMEA/H/C/000778/II/0115 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update section 4.6 of the SmPC based on the Reproductive Toxicity Testing and Labeling recommendations, Food and Drug Administration Guidance (May 2019) and the Non-clinical Working Party/Non-clinical Working Party (S/Nc), European Medicines Agency recommendations (March 2023) on the duration of contraception following the end of treatment with a genotoxic drug. The Package Leaflet is updated accordingly.	

In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.”	
Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0012 Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe, “Update of section 5.1 of the SmPC in order to update information based on end-of-season 2 data from clinical study C3671013. This is an ongoing Phase 3, randomized, double-blind, placebo controlled to evaluate safety immunogenicity, and efficacy of Abrysvo in prevention of lower respiratory tract disease in adults 60 years of age and older during the first respiratory syncytial virus (RSV) season and the long-term immunogenicity and efficacy of Abrysvo in the second RSV season and across 2 RSV seasons. In addition, the MAH took the opportunity to introduce minor changes to the PI based on the already submitted clinical study report C3671008.” Request for Supplementary Information adopted on 21.11.2024.	Request for supplementary information adopted with a specific timetable.
Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0014 Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe, “Update of section 4.5 of the SmPC in order to add information regarding coadministration of Abrysvo and COVID-19 mRNA vaccines, with or without a high dose influenza vaccine following Phase 1/2 study C5481001 Substudy A - a Study to Evaluate the Safety, Tolerability, and Immunogenicity of Combined Vaccine Candidate(s) Against Infectious Respiratory Illnesses, Including COVID 19 and RSV, in healthy participants ≥65 years of age; the Package Leaflet is updated accordingly.”	See 9.1
AGAMREE - Vamorolone - EMEA/H/C/005679/II/0005, Orphan Santhera Pharmaceuticals (Deutschland) GmbH, Rapporteur: Janet Koenig, “Submission of updated information on biotransformation based on results from clinical and non-clinical studies.” Opinion adopted on 28.11.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 28.11.2024.

Amvuttra - Vutrisiran - EMEA/H/C/005852/II/0013/G, Orphan Alnylam Netherlands B.V., Rapporteur: Janet Koenig, "Update of section 5.3 of the SmPC in order to update non-clinical information on the carcinogenicity of vutrisiran, based on final results from studies NCS-21-00440 and TTRSC02-GLP18-003; these are 2-year carcinogenicity studies in CD-1 mice and Sprague Dawley rats, respectively. In addition, the MAH took the opportunity to submit Amended Report 1 of study TTRSC02-GLP18-013." Opinion adopted on 28.11.2024.	Positive Opinion adopted by consensus on 28.11.2024.
Amvuttra - Vutrisiran - EMEA/H/C/005852/II/0014, Orphan Alnylam Netherlands B.V., Rapporteur: Janet Koenig, "Update of section 4.2 of the SmPC in order to add the option for administration by patient and/or caregiver, based on an updated Notified Body Opinion report. 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 make editorial changes in the PI."	
Balversa - Erdafitinib - EMEA/H/C/006050/II/0001 Janssen-Cilag International N.V., Rapporteur: Janet Koenig, "Update of section 4.8 of the SmPC in order to add cataract as a new ADR with frequency common based on a review of new information observed in clinical studies and in the post marketing setting. In addition, the MAH took the opportunity to correct the list of the most common ADRs in the SmPC section 4.8 and to make editorial corrections in the SmPC and Package Leaflet." Opinion adopted on 28.11.2024.	Positive Opinion adopted by consensus on 28.11.2024.
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." Opinion adopted on 21.11.2024.	Positive Opinion adopted by consensus on 21.11.2024.

Request for Supplementary Information adopted on 05.09.2024.

Braftovi - Encorafenib - EMEA/H/C/004580/II/0041

Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4 and 5.2 of the SmPC to include a dose recommendation for patients with moderate hepatic impairment based on the results of a modelling and simulation study and post-marketing data The Package Leaflet is updated accordingly."

COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000224683

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, "A grouped application comprised of 3 Type II Variations as follows:

C.I.4: Update of sections 4.6, 4.8 and 5.1 of the SmPC in order to update pregnancy related information based on final results from interventional study C4591015, listed as a category 3 study in the RMP. Study C4591015 is a phase 2/3, placebo controlled, randomized, observer-blinded study to evaluate the safety, tolerability, and immunogenicity of a SARS-CoV-2 RNA vaccine candidate (BNT162b2) against COVID-19 in healthy pregnant women 18 years of age and older. The Package Leaflet is updated accordingly.

C.I.4: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update information for immunocompromised individuals based on final results from interventional study C4591024, listed as a category 3 study in the RMP. Study C4591024 is a phase 2b, open-label study to evaluate the safety, tolerability, and immunogenicity of vaccine candidate BNT162b2 in immunocompromised participants $\geqslant$2 years of age. The Package Leaflet is updated accordingly.

C.I.13: Submission of the C4591030 (secondary BNT162b2 immunogenicity endpoint analysis) supplementary (post-final) clinical study report. This is a phase 3, randomized, observer-blind trial to evaluate the safety and immunogenicity of BNT162b2 when co-administered with seasonal inactivated influenza vaccine (SIIV) in adults 18 through 64 years of age.

In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.”	
Drovelis - Drospirenone / Estetrol - EMEA/H/C/005336/II/0025 Gedeon Richter Plc., Rapporteur: Kristina Dunder, “Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding renal impairment based on final results from study MIT-Do001-C103. This is a Phase 1, open-label, sequential group, single-dose study to evaluate the pharmacokinetics and safety of estetrol monohydrate (E4) in female subjects with varying degrees of renal function. The Package Leaflet is updated accordingly.” Request for Supplementary Information adopted on 25.07.2024.	
Erbitux - Cetuximab - EMEA/H/C/000558/II/0102 Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Mari Thorn, “Update of section 5.1 of the SmPC based on results from study CALGB/SWOG 80405; this is a phase 3 trial of irinotecan/5-fu/leucovorin or oxaliplatin/5-fu/leucovorin with bevacizumab, or cetuximab (C225), or with the combination of bevacizumab and cetuximab for patients with KRAS wild-type untreated metastatic adenocarcinoma of the colon or rectum, with efficacy as primary objective.”	
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 05.12.2024, 05.09.2024.	Request for supplementary information adopted with a specific timetable.
Fluenz - Influenza vaccine (live attenuated, nasal) - EMEA/H/C/006514/II/0002 AstraZeneca AB, Rapporteur: Christophe Focke, “Update of section 4.2 of the SmPC, upon request by the CHMP, to include an adequate age range for children that should be vaccinated with a 2-dose schedule, and section 4.4 of the	

SmPC to include a statement regarding the postponement of vaccinations in individuals with symptoms of an acute infection. In addition, the MAH took the opportunity to implement editorial changes in the SmPC, labelling and Package Leaflet, as well as a rearrangement of existing text for increased clarity.”	
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.” Request for Supplementary Information adopted on 31.10.2024.	
Kesimpta - Ofatumumab - EMEA/H/C/005410/II/0022 Novartis Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, “Update of section 5.1 of the SmPC in order to include information from pre-planned analyses of serum neurofilament light chain (NfL) concentration based on data from phase III studies COMB157G2301 (ASCLEPIOS I) and COMB157G2302 (ASCLEPIOS II), and from the open-label extension study COMB157G2399 (ALITHIOS). The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to make editorial changes.”	
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0160 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, “Update of section 5.1 of the SmPC in order to update information based on the Interim Analysis 7 (IA7) results from the P522V05MK3475 (KEYNOTE-522) study. This is a Phase 3 randomized, double-blind study to evaluate pembrolizumab plus chemotherapy vs placebo plus chemotherapy as neoadjuvant therapy and pembrolizumab vs placebo as adjuvant therapy for triple negative breast cancer (TNBC).”	Positive Opinion adopted by consensus on 21.11.2024.

Opinion adopted on 21.11.2024.	
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0161 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, "Update of sections 4.4 and 4.8 of the SmPC in order to update information on pericarditis and include the risk of pericarditis under the section "Other immune-mediated adverse reactions" based on post-marketing data and literature. The Package Leaflet is updated accordingly."	
Lydisilka - Drospirenone / Estetrol - EMEA/H/C/005382/II/0025 Estetra SRL, Duplicate of Drovelis, Rapporteur: Kristina Dunder, "Update of sections 4.2 and 5.2 of the SmPC in order to update information regarding renal impairment based on final results from study MIT-Do001-C103. This is a Phase 1, open-label, sequential group, single-dose study to evaluate the pharmacokinetics and safety of estetrol monohydrate (E4) in female subjects with varying degrees of renal function. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 25.07.2024.	
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." Request for Supplementary Information adopted on 05.12.2024, 12.09.2024.	Request for supplementary information adopted with a specific timetable.
Mayzent - Siponimod - EMEA/H/C/004712/II/0032 Novartis Europharm Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of	

the SmPC in order to update efficacy and safety information from study CBAF312A2304 (EXPAND) listed as a category 3 study in the RMP. This is a phase III study and is comprised of two parts: a Core Part and an Extension Part. The Core Part was a multicentre, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of siponimod in SPMS patients. This was followed by an open-label Extension Part, collecting long-term efficacy and safety data on siponimod for up to 7 years. In addition, the MAH took the opportunity to add editorial changes to the PI."	
Mektovi - Binimetinib - EMEA/H/C/004579/II/0034 Pierre Fabre Medicament, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4 and 5.2 of the SmPC to include a dose recommendation for patients with moderate hepatic impairment based on the results of a modelling and simulation study and post-marketing data. The Package Leaflet is updated accordingly."	
Mosquirix - Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0086 GlaxoSmithkline Biologicals SA, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2, 4.5, 4.8 and 5.1 of the SmPC in order to update posology, efficacy and safety information based on final results from study MALARIA-094 and literature. This is a Phase 2b, randomized, open-label, controlled, multi-centre study of the efficacy, safety and immunogenicity of RTS,S/AS01E evaluating schedules with or without fractional doses, early dose 4 and yearly doses, in children living in sub-Saharan Africa. The Package Leaflet and Labelling are 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, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI."	
Neuraceq - Florbetaben (18F) - EMA/VR/0000227744 Life Molecular Imaging GmbH; Rapporteur: Antonio Gomez-Outes, "Extension of indication	

to include monitoring of the biological treatment response to pharmacological and non-pharmacological interventions for NEURACEQ, based on supporting literature. As a consequence, sections 4.1, 4.4 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6.91 of the RMP has also been submitted. In addition, the MAH took the opportunity to include the proposal to discontinue the inclusion of a paper copy of the SmPC with the product package."	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0083 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from study 2019nCoV-301 (Adult population) listed as a category 3 study in the RMP. This is A Phase 3, Randomized, Observer-Blinded, Placebo Controlled Study To Evaluate The Efficacy, Safety, And Immunogenicity Of A Sars-Cov-2 Recombinant Spike Protein Nanoparticle Vaccine (Sars-Cov-2 Rs) With Matrix-M1 Adjuvant In Adult Participants ≥ 18 Years With A Paediatric Expansion In Adolescents (12 To < 18 Years)." Opinion adopted on 28.11.2024. Request for Supplementary Information adopted on 03.10.2024.	Positive Opinion adopted by consensus on 28.11.2024.
Olumiant - Baricitinib - EMEA/H/C/004085/II/0050/G Eli Lilly Nederland B.V., Rapporteur: Peter Mol, "C.I.4: Update of section 5.1 of the SmPC in order to update information based on final long-term efficacy data from study I4V-MC-JAHN (BREEZE-AD3); this is a phase 3, double-blind study to evaluate the long-term safety and efficacy of baricitinib in adult patients with atopic dermatitis. C.I.13: Submission of the final long-term data from study I4V-MC-JAIN (BREEZE-AD4); this is a phase 3, double-blind, randomized, placebo-controlled study to evaluate the safety and efficacy of baricitinib in combination with topical corticosteroids in adult patients with moderate-to-severe atopic dermatitis." Opinion adopted on 21.11.2024.	Positive Opinion adopted by consensus on 21.11.2024.
Ontozry - Cenobamate - EMEA/H/C/005377/II/0029 Angelini S.p.A., Rapporteur: Fátima Ventura, "Update of sections 4.2 and 5.2 of the SmPC to	

include the crushed tablets method of administration and section 4.5 of the SmPC in order to present the existing information on DDI in a tabular format. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement an editorial correction of the contact details of the manufacturer ACRAF SPA in Annex II and Package Leaflet.”	
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.” Request for Supplementary Information adopted on 19.09.2024.	
Padcev - Enfortumab vedotin - EMEA/H/C/005392/II/0020 Astellas Pharma Europe B.V., Rapporteur: Boje Kvorning Pires Ehmsen, “Update of section 4.8 of the SmPC in order to add skin hyperpigmentation, skin discoloration, pigmentation disorder with frequency 'not known' based on available clinical, post marketing, and preclinical data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.” Opinion adopted on 28.11.2024.	Positive Opinion adopted by consensus on 28.11.2024.
Remicade – Infliximab - EMA/VR/0000229576 Janssen Biologics B.V., Rapporteur: Kristina Dunder, “Update of section 4.8 of the SmPC in order to add ‘paradoxical drug-induced immune disorders’ to the list of adverse drug reactions	

(ADRs) with frequency uncommon, based on the results of a cumulative review for paradoxical reactions. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to delete the reference to the core Patient Reminder Card messages from the Annex II in accordance with GVP XVI, to add information about polysorbates in line with revision 4 of the Annex to the EU Excipients Guideline, as well as to introduce minor editorial changes, update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template."	
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." Request for Supplementary Information adopted on 12.09.2024.	
RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0059 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, "Update of section 4.4 of the SmPC in order to include a precaution regarding medication residue in stool 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."	
Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0010, Orphan Biogen Netherlands B.V., Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.8 of the SmPC in order to add hypersensitivity, including urticaria and rash, to the list of adverse drug reactions (ADRs) with frequency not known based on post-marketing experience. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce corrections and minor changes to the PI and to update the list of local representatives in the Package Leaflet."	

Request for Supplementary Information adopted on 07.11.2024, 03.10.2024.	
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." Request for Supplementary Information adopted on 19.09.2024.	
Xenpozyme - Olipudase alfa - EMEA/H/C/004850/II/0013/G, Orphan Sanofi B.V., Rapporteur: Patrick Vrijlandt, "A grouped application consisting of: C.I.4: Update of section 4.2 of the SmPC in order to update the 'Missed Doses' section to facilitate the appropriate clinical management of patients based on pre-existing data from the clinical trials. C.I.4: Update of section 4.2 of the SmPC in order to include a clarification of the infusion rate during the home infusion based on pre-existing data from the clinical trials."	
Zykadia - Ceritinib - EMEA/H/C/003819/II/0057 Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes, "Submission of the final report from study CLDK378A2301; a phase III multicentre, randomized study evaluating oral LDK378 against standard chemotherapy in previously untreated adults with ALK rearranged (ALK-positive), stage IIIB or IV, non- squamous non-small cell lung cancer." Request for Supplementary Information adopted on 28.11.2024.	Request for supplementary information adopted with a specific timetable.
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." Request for Supplementary Information adopted on 19.09.2024.

WS2762
Finlee-EMEA/H/C/005885/WS2762/0010
Spexotras-
EMEA/H/C/005886/WS2762/0009
Novartis Europharm Limited, Lead Rapporteur: Filip Josephson, "Update of sections 4.2 and 5.2 of the SmPC in order to modify administration instructions and pharmacokinetic properties on food effect based on final results from study CDRB436G2102. This is a randomized, open-label, two independent part, 2 x 2 cross-over study to investigate the relative bioavailability of trametinib and dabrafenib liquid formulations under fasted vs. low-fat low-calorie meal conditions in adult healthy participants. In addition, the MAH took the opportunity to implement editorial changes to the PI."

B.5.3. CHMP-PRAC assessed procedures

Apretude - Cabotegravir -
EMEA/H/C/005756/II/0004
ViiV Healthcare B.V., Duplicate of Vocabria, Rapporteur: Fátima Ventura, 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." Request for Supplementary Information adopted on 19.09.2024.	
BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/II/0017 Hipra Human Health S.L., Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Zane Neikena, "Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update safety information and remove the warning for immunocompromised individuals, based on final results from study HIPRA-HH-4 listed as a category 3 study in the RMP; this is a Phase IIb/III, open label, single arm, multi-centre trial to assess the immunogenicity and safety of an additional dose vaccination with a recombinant protein RBD fusion heterodimer candidate (PHH-1V) against SARS-CoV-2, in adults with pre-existing immunosuppressive conditions vaccinated against COVID-19. The Package Leaflet is updated accordingly. The RMP version 1.5 has also been submitted. In addition, the MAH took the opportunity to include information on excipient polysorbate 80, to introduce minor editorial changes to the PI and to bring the PI in line with QRD template version 10.4." Request for Supplementary Information adopted on 28.11.2024.	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 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." Request for Supplementary Information adopted on 19.09.2024.	
Cufence - Trientine - EMEA/H/C/004111/II/0020 Univar Solutions BV, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Ana Sofia Diniz Martins, "Submission of the PK/PD sub-study report for study UNV-TR-004 (UNITED) listed as a PAES in the Annex II of the Product Information. This is an open label, prospective	Request for supplementary information adopted with a specific timetable.

study to characterize the pharmacokinetics and pharmacodynamics of Cufence and to investigate the efficacy and safety in Wilson's disease. The Annex II and the RMP (version 5.0) are updated accordingly." Request for Supplementary Information adopted on 28.11.2024.	
ELREXFIO - Elranatamab - EMEA/H/C/005908/II/0005 Pfizer Europe Ma EEIG, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Barbara Kovacic Bytyqi, "Update of section 4.2 of the SmPC to add every four-week dosing schedule after at least 24 weeks of every two-week dosing and to update the recommendations for restarting therapy following dose delay, and update of sections 4.8, 5.1 and 5.2 of the SmPC with long-term efficacy, safety, and clinical pharmacology results (≥2 years of follow-up after the last participant initial dose), based on the final study report of Study C1071003; a Phase 2, open-label, multicentre, non-randomised study of elranatamab monotherapy in participants with MM who are refractory to at least one PI, one IMiD, and one anti-CD38 Ab. The Package Leaflet has been updated in accordance. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to update the list of local representatives in the Package Leaflet. Further, the provision of the final study report addresses SOB 001, and Annex II has been updated accordingly. A revised RMP version 1.2 was provided as part of the application."	
Krazati - Adagrasib - EMEA/H/C/006013/II/0010/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Kimmo Jaakkola, "A grouped application consisting of: C.I.4: Update of section 5.1 of the SmPC based on final results from study 849-012 (KRYSTAL-12) listed as a specific obligation in the Annex II. This is a Randomized Phase 3 Study of MRTX849 versus Docetaxel in Patients with Previously Treated Non-Small Cell Lung Cancer with KRAS G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took	See 9.1

the opportunity to update Annex IIE of the PI. C.I.4: Update of section 4.8 of the SmPC in order to update safety information based on an integrated analysis of data from interventional studies 849-012 (KRYSTAL-12), 849-007 (KRYSTAL-7) and 849-001 (KRYSTAL-1)."	
LysaKare - L-lysine hydrochloride / L-arginine hydrochloride - EMEA/H/C/004541/II/0018 Advanced Accelerator Applications, Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Update of sections 4.2, 4.3, 4.4, 4.8 and 5.1 of the SmPC in order to remove the contraindication and update the warning on 'Hyperkalaemia' as well as on 'Metabolic acidosis' and to update safety information based on final results from study CAAA001A12401 listed as a category 3 study in the RMP. This is a multicentre, open-label post authorization safety study to evaluate the effect of LysaKare infusion on serum potassium levels in GEP-NET patients eligible for Lutathera treatment. The RMP version 3.0 has also been submitted."	
Nyxoid - Naloxone - EMEA/H/C/004325/II/0019 Mundipharma Corporation (Ireland) Limited, Rapporteur: Fátima Ventura, PRAC Rapporteur: Liana Martirosyan, "Submission of the interim report from the PAES MR903-9501 listed as an obligation in the Annex II, supported by Real World Evidence from literature and European Take-Home Naloxone programs (THN) demonstrating the effectiveness of Nyxoid in a real-world setting. Study MR903-9501 is a non-interventional multi-national, prospective, mixed methods study of the effectiveness of naloxone (including intranasal Nyxoid) administration by lay people in reversing opioid overdose. The Annex II and the RMP version 3.0 are updated accordingly. In addition, the MAH took the opportunity to introduce minor administrative changes to the Package Leaflet." Request for Supplementary Information adopted on 25.07.2024.	
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0057/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Martin Huber,	See 9.1

"Grouped application consisting of: C.I.4: Update of sections 4.2, 4.4, 4.8 and 5.2 of the SmPC in order to provide a new dosing recommendation in patients with severe renal impairment based on final results from study C4671028; this is a Phase 1, Open-Label, Non-Randomized Study to Investigate the Safety and PK Following Multiple Oral Doses of PF-07321332 (Nirmatrelvir)/Ritonavir in Adult Participants With COVID-19 and Severe Renal Impairment Either on Hemodialysis or Not on Hemodialysis. The Package Leaflet and Labelling are updated accordingly. The updated RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. B.II.e.5.a.2: To introduce a new pack size specific to severe renal impairment." Request for Supplementary Information adopted on 25.07.2024.	
Scemblix - Asciminib - EMEA/H/C/005605/II/0017, Orphan Novartis Europharm Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová, "Submission of a comprehensive final analysis of the data from study CABL001X2101, listed as a category 3 study in the RMP. This is a phase I, multicentre, open-label study of oral asciminib in patients with chronic myelogenous leukaemia or Philadelphia Chromosome-positive acute lymphoblastic leukaemia. The RMP version 2.0 has also been submitted." Request for Supplementary Information adopted on 28.11.2024.	Request for supplementary information adopted with a specific timetable.
Tecentriq - Atezolizumab - EMEA/H/C/004143/II/0087 Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, 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." Request for Supplementary Information adopted on 14.11.2024, 19.09.2024.	
Tivicay - Dolutegravir - EMEA/H/C/002753/II/0093 ViiV Healthcare B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber, "Submission of the final study report for Study ING112578 (IMPAACT P1093) (Category 3 PASS); an open-label, Phase 1/2 study designed to select a DTG dose for chronic dosing of infants, children, and adolescents based on PK, safety, and tolerability. As a consequence, a revised RMP version 21 to remove long-term safety data as an area of missing information has been approved." Opinion adopted on 28.11.2024.	Positive Opinion adopted by consensus on 28.11.2024.
VELSIPITY - Etrasimod - EMEA/H/C/006007/II/0002/G Pfizer Europe MA EEIG, Rapporteur: Janet Koenig, PRAC Rapporteur: Karin Bolin, "A grouped application comprised of two Type II variations, as follows: C.I.4: Update of sections 4.2, 4.3 and 5.2 of the SmPC in order to amend recommendation regarding administration to patients with severe hepatic impairment and remove contraindication for severe hepatic impairment, based on in vitro studies to further characterise the drug-drug interaction (DDI) potential of metabolites M3 and M6. The Annex II and Package Leaflet are updated accordingly. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.13: Submission of the final report from study 24GR036 (hERG Channel Automated Patch-Clamp Test); this is an assessment of the effects of PF-08034694, PF-08034742, PF-08039030, and PF-08039032 on the Kv11.1 (hERG) potassium current." Request for Supplementary Information adopted on 25.07.2024.	
Zejula - Niraparib - EMEA/H/C/004249/II/0056, Orphan	Request for supplementary information adopted with a specific timetable.

GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang, PRAC Rapporteur: Jan Neuhauser, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from PRIMA study (PR-30-5017-C) listed as a PAES in the Annex II; this is a Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicentre Study of Niraparib Maintenance Treatment in Patients with Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy. The RMP version 9.0 has also been submitted. In addition, the MAH took the opportunity to update section D of Annex II, and to implement editorial changes to the PI." Request for Supplementary Information adopted on 28.11.2024.	See 9.1
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.	See 9.1
WS2738 **Entresto- EMEA/H/C/004062/WS2738/0065** **Neparvis- EMEA/H/C/004343/WS2738/0062** Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt, Lead PRAC Rapporteur: Karin Erneholm, "Update of sections 4.8 and 5.3 of the SmPC in order to update information on long-term data in paediatric patients, based on final results from study CLCZ696B2319E1(PANAROMA-HF OLE) listed as a category 3 study in the RMP (MEA/009); this is a phase 3, multicentre, uncontrolled study to evaluate long-term safety and tolerability of open label sacubitril/valsartan in paediatric patients with heart failure due to systemic left ventricle systolic dysfunction who have	Positive Opinion adopted by consensus on 28.11.2024.

completed study CLCZ696B2319 (PANORAMA-HF); the RMP version 8 has also been submitted." Opinion adopted on 28.11.2024. Request for Supplementary Information adopted on 03.10.2024.	

B.5.4. PRAC assessed procedures

PRAC Led **BLINCYTO - Blinatumomab - EMEA/H/C/003731/II/0054, Orphan** Amgen Europe B.V., PRAC Rapporteur: Jana Lukacisinova, PRAC-CHMP liaison: Petr Vrbata, "To update sections 4.2, 4.4, 4.8 of the SmPC to include Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS); and to update section D of Annex II to remove educational materials for physicians, pharmacists and nurses and to include ICANS within neurologic events in educational material for patient/caregivers and patient alert card following the outcome of PSUR procedure EMEA/H/C/PSUSA/00010460/202212. The Package Leaflet is updated accordingly. The RMP version 17.0 has also been submitted." Request for Supplementary Information adopted on 28.11.2024, 11.07.2024, 08.02.2024.	Request for supplementary information adopted with a specific timetable.
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 versions 8.2 has been approved with this procedure." Opinion adopted on 28.11.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 28.11.2024.
PRAC Led **Dengvaxia - Dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171/II/0032** Sanofi Pasteur, Rapporteur: Christophe Focke,	Positive Opinion adopted by consensus on 28.11.2024.

PRAC Rapporteur: Sonja Hrabcik, PRAC-CHMP liaison: Daniela Philadelphy, "Submission of the final study report for DNG16 (category 3 PASS); a non-interventional Pregnancy Registry for DENGVAXIA, CYD-TDV Dengue Vaccine used to evaluate the safety of CYD-TDV in pregnant women and their offsprings inadvertently exposed during pregnancy or up to 30 days preceding their last menstrual period with regards to maternal, pregnancy, birth, neonatal, and infant outcomes. This submission fulfils MEA/FSR 002." Opinion adopted on 28.11.2024.	
PRAC Led **Entyvio - Vedolizumab - EMEA/H/C/002782/II/0086** Takeda Pharma A/S, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Submission of amendment 2 (version 3) to the final clinical study report (CSR) for the post authorisation safety study MLN0002-401, listed as a category 3 study in the RMP. This was a prospective, observational, international, multicenter, cohort study comparing vedolizumab with other biologic agents in patients with UC or CD. The final CSR (versions 1 and 2) was submitted and assessed in procedure EMEA/H/C/002782/II/0073. Further review and additional inconsistencies were identified in the analyses and reporting of safety, which are addressed in CSR amendment 2 (version 3)." Opinion adopted on 28.11.2024.	Positive Opinion adopted by consensus on 28.11.2024.
PRAC Led **Eurartesim - Piperaquine tetraphosphate / Artenimol - EMEA/H/C/001199/II/0040/G** Alfasigma S.p.A., PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "C.I.13: Submission of the final report from the effectiveness evaluation survey for Eurartesim (protocol no. 3366) listed as a category 3 study in the RMP. This is a European multi-centre online survey to assess physician understanding of the revised edition of the educational material. Consequential changes to RMP version 16.1 have been implemented. C.I.11.b: Submission of an updated RMP version 16.1 in order to delete "Severe Malaria" from the Missing Information."	Positive Opinion adopted by consensus on 28.11.2024.

Request for Supplementary Information adopted on 05.09.2024, 16.05.2024, 11.01.2024, 28.09.2023, 08.06.2023.	
PRAC Led **EXJADE - Deferasirox - EMEA/H/C/000670/II/0090** Novartis Europharm Limited, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Update of section 4.2 of the SmPC in order to update information on posology based on the non-interventional study CICL670A2429 listed as a category 3 study in the RMP. This is a survey to assess physicians' knowledge of Exjade posology and biological monitoring recommendations as described in the Educational Materials (EMs)."	Request for supplementary information adopted with a specific timetable.
PRAC Led **Farydak - Panobinostat - EMEA/H/C/003725/II/0030, Orphan** Pharmaand GmbH, Rapporteur: Peter Mol, PRAC Rapporteur: Sofia Trantza, PRAC-CHMP liaison: Konstantina Alexopoulou, "Submission of an updated RMP version 7.0 in order to align the RMP with GVP V and GVP XVII. As a consequence, the MAH proposes to remove severe haemorrhage and severe infections (including sepsis/pneumonia/reactivation of hepatitis B infection) as important identified risks, and developmental toxicity, carcinogenicity/second primary malignancy (SPM), and medication error as important potential risks. In addition, the MAH proposes to revise the Annex II to reflect the removal of the Patient Card and educational programme as additional risk minimisation measures." Opinion adopted on 28.11.2024.	Positive Opinion adopted by consensus on 28.11.2024.
PRAC Led **Gazyvaro - Obinutuzumab - EMEA/H/C/002799/II/0059, Orphan** Roche Registration GmbH, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 10.0 in order to remove the guided questionnaires (GQ) for secondary malignancies, progressive multifocal leukoencephalopathy and hepatitis B reactivation as well as to update the ATC code and to introduce additional updates." Opinion adopted on 28.11.2024.	Positive Opinion adopted by consensus on 28.11.2024.

PRAC Led **Grepid - Clopidogrel - EMEA/H/C/001059/II/0058** Pharmathen S.A., Generic of Plavix, PRAC Rapporteur: Carla Torre, PRAC-CHMP liaison: Fátima Ventura, "Submission of an RMP version 0.1 following procedure EMEA/H/C/001059/IB/0057/G." Opinion adopted on 28.11.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 28.11.2024.
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. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to correct a numerical error in the SmPC." Opinion adopted on 28.11.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 28.11.2024.
PRAC Led **Mosquirix - Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0085/G** GlaxoSmithkline Biologicals SA, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "A grouped application comprised of two type II variations, as follows: C.I.4: Update of sections 4.4 and 5.1 of the SmPC in order to remove meningitis from the list of important potential risks and add effectiveness data based on EPI-MAL-003 study listed as a category 3 study in the RMP. This is a prospective study to evaluate the safety, effectiveness and impact of the RTS,S/AS01E vaccine in young children in sub-Saharan Africa countries. The Package Leaflet is updated accordingly. The RMP version 6.0 has also been submitted. C.I.13: Submission of the final report from study MVPE (Malaria Vaccine Pilot Evaluation)	Request for supplementary information adopted with a specific timetable.

listed as a category 3 study in the RMP. This is a observational study in the context of a cluster-randomized pilot implementation in order to assess the feasibility of delivery, safety, and impact on mortality of the RTS,S/AS01E malaria vaccine delivered through the routine immunization services in Kenya, Malawi, and Ghana over 4 years." Request for Supplementary Information adopted on 28.11.2024.	
PRAC Led **Moventig - Naloxegol - EMEA/H/C/002810/II/0043** Gruenenthal GmbH, PRAC Rapporteur: Eamon O Murchu, PRAC-CHMP liaison: Finbarr Leacy, "Submission of the final report from the PASS study D3820R0008 listed as a category 3 study in the RMP. This is a US post-marketing, comparative, observational study to evaluate the cardiovascular safety of Naloxegol in patients with non-cancer pain in comparison to other treatments for opioid induced constipation. The RMP version 9.0 has also been submitted." Opinion adopted on 28.11.2024. Request for Supplementary Information adopted on 03.10.2024, 16.05.2024.	Positive Opinion adopted by consensus on 28.11.2024.
PRAC Led **Mysimba - Naltrexone hydrochloride / Bupropion hydrochloride - EMEA/H/C/003687/II/0066** Orexigen Therapeutics Ireland Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of final report from study NB-453 study, listed as a category 3 study in the RMP. This is a non-interventional qualitative research using online focus groups to assess understanding, attitude and behaviour for usage of the Mysimba Physician Prescribing Checklist (PPC) among physicians in the European Union (EU), following a previous cross-sectional survey that aimed at evaluating the effectiveness of the same PPC (Study NB-452). The RMP version 14 has been submitted." Opinion adopted on 28.11.2024. Request for Supplementary Information adopted on 11.04.2024, 11.01.2024.	Positive Opinion adopted by consensus on 28.11.2024.
PRAC Led **Nucala - Mepolizumab -**	Request for supplementary information adopted with a specific timetable.

EMEA/H/C/003860/II/0071 GlaxoSmithKline Trading Services Limited, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final report from the Mepolizumab (Nucala) Pregnancy Exposure Study 200870: a VAMPSS post marketing surveillance study of Mepolizumab safety in pregnancy, listed as a category 3 study in the RMP. This is a non-interventional study to monitor planned and unplanned pregnancies exposed to mepolizumab and to evaluate the possible teratogenic effect of this medication relative to the pregnancy outcomes of major birth defects, preterm delivery, small for gestational age infants and spontaneous abortion or stillbirth. The RMP version 13.0 has also been submitted." Request for Supplementary Information adopted on 28.11.2024.	
PRAC Led **Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0131** Moderna Biotech Spain S.L., PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report from study mRNA-1273-919 - An Observational Study to Assess Maternal and Infant Outcomes Following Exposure to Spikevax During Pregnancy, listed as a category 3 study in the RMP." Opinion adopted on 28.11.2024. Request for Supplementary Information adopted on 11.07.2024, 13.06.2024.	Positive Opinion adopted by consensus on 28.11.2024.
PRAC Led **Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0142** Moderna Biotech Spain S.L., PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report from study mRNA-1273-P920 listed as a category 3 study in the RMP; this was a retrospective observational cohort study to characterise the safety of the elasomeran/davesomeran (Spikevax bivalent Original/Omicron BA.4-5) and andusomeran (Spikevax XBB.1.5) vaccines as used in routine clinical practice." Opinion adopted on 28.11.2024.	Positive Opinion adopted by consensus on 28.11.2024.
PRAC Led	Request for supplementary information adopted

TachoSil - Human thrombin / Human fibrinogen - EMEA/H/C/000505/II/0131 Corza Medical GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 4.2 of the SmPC to emphasise correct product handling and section 4.8 of the SmPC to reflect the fact that cases of product non-adhesion issues have been reported, upon request by PRAC following the outcome of the PSUR procedure EMEA/H/C/PSUSA/00010297/202306. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC." Request for Supplementary Information adopted on 28.11.2024.	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 changes to the study design and objectives for the Pregnancy PASS (D5180R00010), following procedure EMEA/H/C/005588/MEA/001.2.	Positive Opinion adopted by consensus on 28.11.2024.

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." Opinion adopted on 28.11.2024. Request for Supplementary Information adopted on 05.09.2024.	
PRAC Led **WS2125** **Soliris-EMEA/H/C/000791/WS2125/0133** **Ultomiris-EMEA/H/C/004954/WS2125/0047** Alexion Europe SAS, Lead PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gomez-Outes, "Submission of an updated RMP version 21.0 for SOLIRIS and RMP version 9.0 for ULTOMIRIS in order to revise the controlled distribution additional risk minimisation measures and to add a new post-authorisation safety study (PASS) intended to evaluate the effectiveness of the revised additional risk minimisation measures for minimising the risk of meningococcal infections in the EU, following the PRAC outcome for PSUSA/00001198/202310 for SOLIRIS. The Annex II is updated accordingly. In addition, the MAH introduced minor updates to the SmPC to align the wording with the updated Annex II." Request for Supplementary Information adopted on 28.11.2024.	Request for supplementary information adopted with a specific timetable.
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: Antonio Gomez-Outes, "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 23.1, 17.1 and 11.1 are also submitted	Positive Opinion adopted by consensus on 28.11.2024.

for Jardiance, Synjardy and Glyxambi, respectively."
Opinion adopted on 28.11.2024.
Request for Supplementary Information adopted on 05.09.2024.

B.5.5. CHMP-CAT assessed procedures

Casgevy - Exagamglogene autotemcel - EMEA/H/C/005763/II/0009/G, Orphan, ATMP
Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Ebvallo - Tabelecleucel - EMEA/H/C/004577/II/0011/G, Orphan, ATMP
Pierre Fabre Medicament, Rapporteur: Egbert Flory, CHMP Coordinator: Jan Mueller-Berghaus
Request for Supplementary Information adopted on 08.11.2024, 13.09.2024.

Hemgenix - Etranacogene dezaparvovec - EMEA/H/C/004827/II/0018, Orphan, ATMP
CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy, "Update of sections 4.4 and 5.1 of the SmPC in order to reflect a modified 9-point anti-AAV5 Neutralising Antibody (NAb) assay. 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 and bring the PI in line with the QRD version 10.4."
Request for Supplementary Information adopted on 08.11.2024.

Kymriah - Tisagenlecleucel - EMEA/H/C/004090/II/0086/G, Orphan, ATMP
Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, "A grouped application consisting of:
C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on cytokine release syndrome based on literature.
C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on neurological adverse reaction based on literature. The Package Leaflet is updated accordingly.

C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on hypersensitivity reactions 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 PI."
Request for Supplementary Information adopted on 11.10.2024.

Upstaza - Eladocagene exuparvovec - EMEA/H/C/005352/II/0023/G, Orphan, ATMP
PTC Therapeutics International Limited, Rapporteur: Joseph DeCourcey, CHMP Coordinator: Finbarr Leacy
Request for Supplementary Information adopted on 11.10.2024.

Yescarta - Axicabtagene ciloleucel - EMEA/H/C/004480/II/0077, Orphan, ATMP
Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus,
Request for Supplementary Information adopted on 19.07.2024.

Zolgensma - Onasemnogene abeparvovec - EMEA/H/C/004750/II/0052, Orphan, ATMP
Novartis Europharm Limited, Rapporteur: Emmely de Vries CHMP Coordinator: Peter Mol,
"Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and vector shedding data following request in procedure EMA/H/C/004750/P46/022 and based on data from study COAV101A12306. In addition, a reference to section 5.2 is added to section 4.4, as requested in final Assessment report of procedure EMA/H/C/004750/P46/022."
Request for Supplementary Information adopted on 11.10.2024.

WS2500
Tecartus-
EMEA/H/C/005102/WS2500/0040
Yescarta-
EMEA/H/C/004480/WS2500/0068
Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Request for Supplementary Information adopted on 11.10.2024, 24.05.2024, 16.02.2024.

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
Request for Supplementary Information adopted on 13.09.2024.

B.5.6. CHMP-PRAC-CAT assessed procedures

Alofisel - Darvadstrocel -
EMEA/H/C/004258/II/0051/G, Orphan, ATMP
Takeda Pharma A/S, Rapporteur: Maria Luttgen, CHMP Coordinator: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer, "A grouped application comprised of 4 Type II Variations, as follows:
(C.I.4): Update of sections 4.8 and 5.1 of the SmPC in order to update the safety information, based on pooled safety data from the two phase 3 controlled studies (ADMIRE-CD & ADMIRE-CD II) and to update efficacy information based on final results from study ADMIRE-CD II, listed as an obligation in the Annex II. ADMIRE-CD II (Cx601-0303) is a Phase III randomised double blind, placebo-controlled study to assess efficacy and safety of Cx601, adult allogeneic expanded adipose-derived stem cells (eASC) for the treatment of complex perianal fistula(s) in patients with Crohn's disease. The Annex II is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI, including to section 4.2 of the SmPC and to the Package Leaflet.

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

The RMP version 8.0 has also been submitted."
Request for Supplementary Information adopted

on 19.07.2024.

B.5.7. PRAC assessed ATMP procedures

PRAC Led

Tecartus - Brexucabtagene autoleucel - EMEA/H/C/005102/II/0051, Orphan, ATMP

Kite Pharma EU B.V., CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Peter Mol, "Submission of the final study report for the non-interventional study KT-EU-472-5966 titled "Quantitative Testing of Health Care Professional Knowledge About Tecartus Risk Minimisation Measures'' listed as a category 3 study in the RMP."

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

WS2737
Olanzapine Glenmark- EMEA/H/C/001085/WS2737/0044
Olanzapine Glenmark Europe- EMEA/H/C/001086/WS2737/0041
Olazax-EMEA/H/C/001087/WS2737/0036
Olazax Disperzi- EMEA/H/C/001088/WS2737/0038

Glenmark Arzneimittel GmbH, Generic of Olansek (SRD), Zyprexa, Zyprexa Velotab, Lead Rapporteur: Alexandre Moreau

WS2763/G
Trimbow- EMEA/H/C/004257/WS2763/0043/G
Trydonis- EMEA/H/C/004702/WS2763/0040/G

Chiesi Farmaceutici S.p.A., Lead Rapporteur: Janet Koenig

WS2764/G
Hefiya- EMEA/H/C/004865/WS2764/0054/G
Hyrimoz- EMEA/H/C/004320/WS2764/0053/G

Sandoz GmbH, Lead Rapporteur: Christian Gartner"C.I.2.a - To update section 4.8 of the SmPC to clarify that the malignancy reported rates come from the spontaneously reported date, following assessment and approval of the same changes in the reference product, Humira.

C.I.z - To update section 2 ("What you need to know before you use Hefiya") to be in line with the reference product, Humira. Furthermore, the Marketing Authorisation Holder has also taken the opportunity to: -Update the local representative details for Luxembourg, Denmark, Slovakia, and Cyprus. -Implement editorial changes in the following translations: CS, DA, DE, EL, ET, FI, FR, HU, LT, MT, NO, PT, RO, SV, SK, and SL."	
WS2766 **Infanrix hexa-** **EMEA/H/C/000296/WS2766/0350** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke	
WS2776/G **Copalia-** **EMEA/H/C/000774/WS2776/0136/G** **Dafiro-** **EMEA/H/C/000776/WS2776/0140/G** **Exforge-** **EMEA/H/C/000716/WS2776/0135/G** Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher	
WS2786 **BiResp Spiromax-** **EMEA/H/C/003890/WS2786/0045** **DuoResp Spiromax-** **EMEA/H/C/002348/WS2786/0045** Teva Pharma B.V., Lead Rapporteur: John Joseph Borg	

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

Niapelf - Paliperidone - **EMEA/H/C/006185/II/0001** Neuraxpharm Pharmaceuticals S.L., Generic of Xeplion, Rapporteur: Larisa Gorobets Withdrawal request submitted on 20.11.2024.	The MAH withdrew the procedure on 20.11.2024.
WS2784/G **Tecartus-** **EMEA/H/C/005102/WS2784/0053/G** **Yescarta-** **EMEA/H/C/004480/WS2784/0083/G** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan	The MAH withdrew the procedure on 21.11.2024.

Mueller-Berghaus Withdrawal request submitted on 21.11.2024.	
WS2799 **Fluenz-EMEA/H/C/006514/WS2799/0006** **Pandemic influenza vaccine H5N1 AstraZeneca-EMEA/H/C/003963/WS2799/0076** AstraZeneca AB, Lead Rapporteur: Christophe Focke Withdrawal request submitted on 02.12.2024.	The MAH withdrew the procedure on 02.12.2024.

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

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

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

Clesrovimab - EMEA/H/C/006497 prevention of respiratory syncytial virus (RSV)
Denosumab - EMEA/H/C/006239 prevention of skeletal related events with advanced malignancies
In vitro diagnostic medical device - EMEA/H/D/006648 use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC) tissue, using EnVision FLEX visualization system on Dako Omnis
In vitro diagnostic medical device - EMEA/H/D/006668 to detect EGFR mutations in FFPE tissue from adult patients diagnosed with non-small cell lung cancer (NSCLC)
Doxecitine / Doxribtimine - EMEA/H/C/005119 indicated for the treatment of paediatric and adult patients with thymidine kinase 2 deficiency (TK2d) with an age of symptom onset on or before 12 years
Ustekinumab - EMEA/H/C/006649 for the treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis

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

Enzalutamide Viatris - Enzalutamide - EMEA/H/C/006299/X/0003

Viatris Limited, Generic of Xtandi, Rapporteur: Tomas Radimersky, PRAC Rapporteur: Maria del Pilar Rayon, "Extension application to add a new strength of 160 mg for film-coated tablets. The RMP (version 0.4) is updated in accordance."

Livmarli - Maralixibat - EMEA/H/C/005857/X/0016, Orphan

Mirum Pharmaceuticals International B.V., Rapporteur: Janet Koenig, "Extension application to add a new strength of 19 mg/ml for maralixibat oral solution (bottle 30 ml). Furthermore, the PI is brought in line with the latest QRD template version Y.y. Version 6.0 of the RMP has also been submitted."

Pyrukynd - Mitapivat - EMEA/H/C/005540/X/0010/G, Orphan

Agios Netherlands B.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adam Przybylkowski, "Extension application to introduce a new strength (100 mg film-coated tablet) associated with a new orphan indication for the "treatment of adult patients with non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassaemia". The extension application is grouped with a type II quality variation (C.I.4) to update of sections 4.2 and 5.2 of the SmPC in order to update pharmacokinetic information based on final results from study AG348-C-024 listed as a category 3 study in the RMP; this is a Phase 1, Open-label, Single-dose, Pharmacokinetic Study of Mitapivat in Subjects with Moderate Hepatic Impairment Compared to Matched Healthy Control Subjects with Normal Hepatic Function. The RMP (version 1.1) is updated in accordance."

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

Troriluzole - EMEA/H/C/006068, Orphan

Biohaven Bioscience Ireland Limited, is indicated for the treatment of adult patients with spinocerebellar ataxia genotype 3 (SCA3) List of Questions adopted on 22.02.2024.

Trastuzumab - EMEA/H/C/006219
treatment of metastatic and early breast cancer
List of Questions adopted on 30.05.2024.

Diflunisal - EMEA/H/C/006248, Orphan
AO Pharma AB, Treatment of ATTR amyloidosis
List of Questions adopted on 30.05.2024.

Evrysdi - Risdiplam - EMEA/H/C/005145/X/0024/G
Roche Registration GmbH, Rapporteur: Fátima Ventura, "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."
List of Questions adopted on 19.09.2024.

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
Request for Supplementary Information adopted on 14.11.2024.

AMINO ACIDS - EMEA/H/C/005557, Orphan
Recordati Rare Diseases, treatment of decompensation episodes in MSUD patients
List of Questions adopted on 25.01.2024.

OPDIVO - Nivolumab - EMEA/H/C/003985/X/0144
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Gabriele Maurer, "Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (600 mg) and a new route of administration (subcutaneous use).

Version 40.0 of the RMP has also been submitted."
List of Questions adopted on 17.10.2024.

Rybrevant - Amivantamab - EMEA/H/C/005454/X/0014
Janssen-Cilag International N.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer, "Extension application to introduce a new pharmaceutical form (solution for injection), two new strengths of 1600 mg and 2240 mg (160 mg/ml concentration) and a new route of administration (subcutaneous use)."
List of Questions adopted on 17.10.2024.

Taltz - Ixekizumab - EMEA/H/C/003943/X/0051
Eli Lilly and Co (Ireland) Limited, Rapporteur: Kristina Dunder, "Extension application to add a new strength of 40 mg for Taltz, Solution for injection"
List of Questions adopted on 17.10.2024.

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
List of Questions adopted on 25.07.2024.

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

NULIBRY - Fosdenopterin - EMEA/H/C/005378/S/0012, Orphan
TMC Pharma (EU) Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Martin Huber,

Orphacol - Cholic acid - EMEA/H/C/001250/S/0056
Theravia, Rapporteur: Anastasia Mountaki, PRAC Rapporteur: Sofia Trantza,

Raxone - Idebenone - EMEA/H/C/003834/S/0041, Orphan
Chiesi Farmaceutici S.p.A., Rapporteur: John Joseph Borg, PRAC Rapporteur: Amelia Cupelli,

Vedrop - Tocofersolan - EMEA/H/C/000920/S/0050
Recordati Rare Diseases, Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Melinda Palfi

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

Aybintio - Bevacizumab -
EMEA/H/C/005106/R/0022
Samsung Bioepis NL B.V., Rapporteur: Christian Gartner, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Karin Erneholm

Incellipan - Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) -
EMEA/H/C/006051/R/0002
Seqirus Netherlands B.V., Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Mari Thorn

Lorviqua - Lorlatinib -
EMEA/H/C/004646/R/0040
Pfizer Europe MA EEIG, Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Barbara Kovacic Bytyqi

Omidria - Phenylephrine / Ketorolac -
EMEA/H/C/003702/R/0030
Rayner Surgical (Ireland) Limited, Rapporteur: Jayne Crowe, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Jan Neuhauser

Ondexxya - Andexanet alfa -
EMEA/H/C/004108/R/0049
AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Bianca Mulder

Pandemic influenza vaccine H5N1 AstraZeneca - Pandemic influenza vaccine (H5N1) (live attenuated, nasal) -
EMEA/H/C/003963/R/0074
AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sonja Hrabcik

WAYLIVRA - Volanesorsen -
EMEA/H/C/004538/R/0029, Orphan
Akcea Therapeutics Ireland Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Martin Huber

B.6.6. VARIATIONS – START OF THE PROCEDURE

Timetables for adoption provided that the validation has been completed.

B.6.7. Type II Variations scope of the Variations: Extension of indication

Darzalex - Daratumumab -

EMEA/H/C/004077/II/0077, Orphan
Janssen-Cilag International N.V., Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Carla Torre, "Extension of indication to include daratumumab for the treatment of adult patients with smouldering multiple myeloma (SMM) at high risk of developing multiple myeloma based on results from studies 54767414SMM3001 (AQUILA) and 54767414SMM2001 (CENTAURUS). SMM3001 (AQUILA) is a Phase 3 Randomized, Multicentre Study of Subcutaneous Daratumumab Versus Active Monitoring in Subjects with High-risk Smoldering Multiple Myelom. SMM2001 (CENTAURUS) is a Randomized Phase 2 Trial to Evaluate Three Daratumumab Dose Schedules in Smoldering Multiple Myeloma.
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 11.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the PI in accordance with the latest EMA excipients guideline."

Mounjaro - Tirzepatide - EMEA/H/C/005620/II/0038
Eli Lilly Nederland B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder, "Extension of indication to include treatment of symptomatic chronic heart failure with preserved ejection fraction (HFpEF) in adults with obesity for MOUNJARO, based on results from the Phase 3 trial I8F-MC-GPID (SUMMIT). SUMMIT was a randomized, multicentre, international, placebo-controlled, double-blind, parallel-arm study in participants with HFpEF and obesity. The study was designed to evaluate the effect of tirzepatide compared with placebo on both clinical and symptomatic or functional outcomes. As a consequence, sections 4.1, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0017
Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca

Mulder, "Extension of indication to include, in combination with gemcitabine and cisplatin, the first-line treatment of adult patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) for TEVIMBRA based on final results from study BGB-A317-309 (study 309). Study 309 was a Phase 3 randomised, double-blind, placebo-controlled, Asia-only study that compared the efficacy and safety of tislelizumab combined with gemcitabine plus cisplatin (GC) versus placebo combined with GC as 1L treatment for recurrent or metastatic NPC. 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 2.6 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial and administrative changes to the PI as well as to update the PI in line with the Excipients Guideline."	
Uplizna - Inebilizumab - EMEA/H/C/005818/II/0012 Horizon Therapeutics Ireland DAC, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Amelia Cupelli, "Extension of indication to include treatment of adult patients with Immunoglobulin G4-Related Disease (IgG4-RD) for UPLIZNA, based on primary analysis results from study MITIGATE (VIB0551.P3.S2) for all subjects from the completed 52-week randomised-controlled period. This is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adult subjects with IgG4-RD. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to bring it in line with the latest QRD template version 10.4. 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)	

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Abiraterone Accord - Abiraterone acetate - EMEA/H/C/005408/II/0007
Accord Healthcare S.L.U., Generic of Zytiga, Rapporteur: Alar Irs

Alprolix - Eftrenonacog alfa - EMEA/H/C/004142/II/0048, Orphan
Swedish Orphan Biovitrum AB (publ), Rapporteur: Daniela Philadelphy

Amsparity - Adalimumab - EMEA/H/C/004879/II/0011
Pfizer Europe MA EEIG, Rapporteur: Outi Mäki-Ikola

BIMERVAX - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/006058/II/0018/G
Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich

Brukinsa - Zanubrutinib - EMEA/H/C/004978/II/0026/G
BeiGene Ireland Ltd, Rapporteur: Boje Kvorning Pires Ehmsen

Champix - Varenicline - EMEA/H/C/000699/II/0085/G
Pfizer Europe MA EEIG, Rapporteur: Thalia Marie Estrup Blicher

COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000233365
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000231382
BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson

Emadine – Emedastine – EMA/VR/0000222987 WS
Immedica Pharma AB, Rapporteur: Alexandre Moreau

Emselex – Darifenacin - EMA/VR/0000235700
pharmaand GmbH, Rapporteur: Antonio Gomez-Outes

Flixabi - Infliximab - EMEA/H/C/004020/II/0090/G
Samsung Bioepis NL B.V., Rapporteur: Jan

Mueller-Berghaus

Gardasil 9 - Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed) - EMEA/H/C/003852/II/0077/G
Merck Sharp & Dohme B.V., Rapporteur: Kristina Dunder

Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0161
CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus

Ituxredi - Rituximab - EMEA/H/C/006224/II/0001
Reddy Holding GmbH, Rapporteur: Jan Mueller-Berghaus

Omvoh - Mirikizumab - EMEA/H/C/005122/II/0010/G
Eli Lilly Nederland B.V., Rapporteur: Finbarr Leacy

Opdualag - Nivolumab / Relatlimab - EMEA/H/C/005481/II/0011/G
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol

Otulfi - Ustekinumab - EMEA/H/C/006544/II/0001/G
Fresenius Kabi Deutschland GmbH, Duplicate of Fymskina, Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Ovitrelle - Choriogonadotropin alfa - EMA/VR/0000238672
Merck Europe B.V., Rapporteur: Patrick Vrijlandt

Prevenar 20 - Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0031/G
Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphy

Ranibizumab Midas - Ranibizumab - EMEA/H/C/006528/II/0001/G
MIDAS Pharma GmbH, Rapporteur: Jan Mueller-Berghaus

Respreeza - Human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0078/G
CSL Behring GmbH, Rapporteur: Kristina Dunder

Shingrix - Herpes zoster vaccine (recombinant, adjuvanted) - EMA/VR/0000237484
GlaxoSmithKline Biologicals, Rapporteur: Christophe Focke

SIMBRINZA - Brinzolamide / Brimonidine - EMEA/H/C/003698/II/0027/G
Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes

Simulect - Basiliximab - EMEA/H/C/000207/II/0122
Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus

Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0016, Orphan
Biogen Netherlands B.V., Rapporteur: Thalia Marie Estrup Blicher

Skyrizi - Risankizumab - EMEA/H/C/004759/II/0052/G
AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy

Sogroya - Somapacitan - EMEA/H/C/005030/II/0016, Orphan
Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt

Spedra – Avanafil - EMA/VR/0000236039
Menarini International Operations Luxembourg S.A., Rapporteur: Antonio Gomez-Outes

Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0148/G
Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus

Steglujan - Ertugliflozin / Sitagliptin - EMEA/H/C/004313/II/0030/G
Merck Sharp & Dohme B.V., Rapporteur: Kristina Dunder

STEQEYMA - Ustekinumab - EMEA/H/C/005918/II/0004/G
Celltrion Healthcare Hungary Kft., Rapporteur: Jayne Crowe

Strensiq - Asfotase alfa - EMEA/H/C/003794/II/0073/G, Orphan
Alexion Europe SAS, Rapporteur: Paolo Gasparini

Uzpruvo - Ustekinumab - EMEA/H/C/006101/II/0005

STADA Arzneimittel AG, Rapporteur: Christian Gartner

Vazkepa - Icosapent ethyl - EMEA/H/C/005398/II/0028/G
Amarin Pharmaceuticals Ireland Limited, Rapporteur: Janet Koenig

VEYVONDI - Vonicog alfa - EMEA/H/C/004454/II/0037
Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus

WS2563
Axura-EMEA/H/C/000378/WS2563/0090
Memantine Merz-EMEA/H/C/002711/WS2563/0025
Merz Pharmaceuticals GmbH, Lead Rapporteur: Antonio Gomez-Outes

WS2741
Flebogamma DIF-EMEA/H/C/000781/WS2741/0086
Instituto Grifols, S.A., Lead Rapporteur: Jan Mueller-Berghaus

WS2773/G
ProQuad-EMEA/H/C/000622/WS2773/0169/G
Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus

WS2777/G
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-EMEA/H/W/005362/WS2777/0020/G
Qdenga-EMEA/H/C/005155/WS2777/0021/G
Takeda GmbH, Lead Rapporteur: Sol Ruiz

WS2782/G
Januvia-EMEA/H/C/000722/WS2782/0088/G
Ristaben-EMEA/H/C/001234/WS2782/0082/G
TESAVEL-EMEA/H/C/000910/WS2782/0088/G
Xelevia-EMEA/H/C/000762/WS2782/0097/G
Merck Sharp & Dohme B.V., Lead Rapporteur: Patrick Vrijlandt

WS2789
Ervebo-EMEA/H/C/004554/WS2789/0039

Gardasil-
EMEA/H/C/000703/WS2789/0109
Gardasil 9-
EMEA/H/C/003852/WS2789/0078
HBVAXPRO-
EMEA/H/C/000373/WS2789/0082
M-M-RvaxPro-
EMEA/H/C/000604/WS2789/0130
ProQuad-
EMEA/H/C/000622/WS2789/0171
Vaxneuvance-
EMEA/H/C/005477/WS2789/0028
Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus

WS2796
Fluenz-EMEA/H/C/006514/WS2796/0005
Pandemic influenza vaccine H5N1
AstraZeneca-
EMEA/H/C/003963/WS2796/0075
AstraZeneca AB, Lead Rapporteur: Christophe Focke

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

ADCETRIS - Brentuximab vedotin -
EMEA/H/C/002455/II/0113, Orphan
Takeda Pharma A/S, Rapporteur: Peter Mol, "Update of section 5.1 of the SmPC in order to update clinical information based on final results from ECHELON-1 final OS analysis data (C25003 CSR addendum 3). This is a randomized, open-label, phase 3 trial of A+AVD versus ABVD as frontline therapy in patients with advanced classical Hodgkin lymphoma. In addition, the MAH took the opportunity to update the PI according to the Excipients Guideline and to introduce minor formatting changes to the PI."

AGAMREE - Vamorolone -
EMEA/H/C/005679/II/0009, Orphan
Santhera Pharmaceuticals (Deutschland) GmbH, Rapporteur: Janet Koenig, "Type II - C.I.4 - To update sections 4.2 and 6.6 of the SmPC to add information concerning the administration of the product via enteral feeding tubes. The package leaflet is also updated with the information. This variation is submitted to address a recommendation for further quality development that was made at the time of the assessment of the initial application for the

marketing authorisation."

AREXVY - Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E - EMA/VR/0000236493

GlaxoSmithKline Biologicals, Rapporteur: Patrick Vrijlandt, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study 212494 (RSV OA=ADJ-006). This is a phase 3, randomized, placebo-controlled, observer blind, multi-country study to demonstrate the efficacy of a single dose and annual revaccination of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above. In addition, the MAH took the opportunity to implement editorial changes to the PI."

Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0028

Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher, "Update of sections 4.8 and 5.1 based on primary analysis and first-year analysis results from study VAS00006 (HARMONIE). This is an ongoing phase IIIb randomized open-label study of nirsevimab (versus no intervention) in preventing hospitalizations due to respiratory syncytial virus in infants (under 12 months) in order to determine the efficacy and safety of a single intramuscular (IM) dose of nirsevimab. In addition, the MAH took the opportunity to introduce minor formatting changes."

COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000237985

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson "A grouped application consisting of:

C.I.4: Update of sections 4.5 and 4.8 of the SmPC in order to update co-administration of Comirnaty and RSV related information based on final results from C5481001 sub-study A. This is a Phase 1/2 sub-study to evaluate the safety, tolerability and Immunogenicity of Combined Vaccine Candidate(s) against Infectious Respiratory Illnesses, Including COVID-19 and RSV, in Healthy Individuals. The Package Leaflet is updated accordingly.

C.I.4: Update of sections 4.5 and 4.8 of the

SmPC in order to update co-administration of Comirnaty and PCV related information based on final results from interventional study B7471026. This is a Phase 3, Randomized, Double-Blind Trial to Describe the Safety and Immunogenicity of 20-valent Pneumococcal Conjugate Vaccine when co-administered with a Booster Dose of BNT162b2 in Adults 65 Years of Age and Older. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000237985 BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson "Update of section 4.9 of the SmPC in order to update information on overdose based on new information in the paediatric clinical trial population in the interventional study C4591007; this is a phase 1, open-label dose-finding study to evaluate safety, tolerability, and immunogenicity and phase 2/3 placebo controlled, observer blinded safety, tolerability, and immunogenicity study of a SARS-CoV-2 RNA vaccine candidate against COVID-19 in healthy children and young adults. In addition, the MAH took the opportunity to implement editorial changes to sections 3 and 6.6 of the SmPC and section 6 of the Package Leaflet."	
Emblaveo - Aztreonam / Avibactam - EMEA/H/C/006113/II/0002 Pfizer Europe Ma EEIG, Rapporteur: Filip Josephson, "Submission of the corrected report from study C3601002 (REVISIT). This is a Phase 3 Prospective, Randomized, Multicenter, Open-Label, Central Assessor Blinded, Parallel Group, Comparative Study to Determine the Efficacy, Safety and Tolerability of Aztreonam Avibactam (ATM-AVI) ± Metronidazole (MTZ) Versus Meropenem ± Colistin (MER ± COL) for the Treatment of Serious Infections due to Gram Negative Bacteria, Including Metallo β-Lactamase (MBL) Producing Multidrug Resistant Pathogens, for Which There are Limited or no Treatment Options."	
EVOTAZ - Atazanavir / Cobicistat - EMEA/H/C/003904/II/0050 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Fátima Ventura, "Update of sections 4.3 and 4.5	

of the SmPC in order to add a new contraindication and to include Drug-Drug Interactions (DDIs) information for the coadministration of Atazanavir/cobicistat (ATV/COBI) with the kinase inhibitor, fostamatinib, and the gonadotropin-releasing hormone receptor antagonist, elagolix based on post-marketing safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI."

HEPLISAV B - Hepatitis B surface antigen (rDNA) - EMEA/H/C/005063/II/0037
Dynavax GmbH, Rapporteur: Filip Josephson, "Update of section 4.9 of the SmPC in order to revise information regarding overdose to indicate "Not Applicable" following review of overall safety data. In addition, the MAH took the opportunity to make some editorial updates to the PI and bring it in line with the latest QRD template."

Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0088/G
Janssen-Cilag International N.V., Rapporteur: Filip Josephson, "A grouped application consisting of:
C.I.4: Update of section 5.1 of the SmPC based on results from Study CLL3011 (GLOW study). This is a Randomized, Open-label, Phase 3 Study of the Combination of Ibrutinib plus Venetoclax versus Chlorambucil plus Obinutuzumab for the First-line Treatment of Subjects with Chronic Lymphocytic Leukaemia (CLL)/Small Lymphocytic Lymphoma (SLL).
C.I.4: Update of section 5.1 of the SmPC based on results from Study PCYC-1116-CA. This is an Open-label Extension Study in Patients 65 Years or Older with Chronic Lymphocytic Leukaemia (CLL) or Small Lymphocytic Lymphoma (SLL) Who Participated in Study PCYC-1115-CA (Ibrutinib versus Chlorambucil)."

Inrebic - Fedratinib - EMEA/H/C/005026/II/0026, Orphan
Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update of sections 4.4 and 4.8 of the SmPC in order to add 'Uveitis' to the list of adverse drug reactions (ADRs) with frequency 'common' based on a cumulative safety review. The Package Leaflet is updated accordingly. In

addition, the MAH took the opportunity to introduce editorial changes to the PI."

JEMPERLI - Dostarlimab - EMEA/H/C/005204/II/0040

GlaxoSmithKline (Ireland) Limited, Rapporteur: Antonio Gomez-Outes, "Update of section 4.8 of the SmPC in order to add 'Guillain-Barre syndrome' to the list of adverse drug reactions (ADRs) in patients treated with dostarlimab in combination with chemotherapy with frequency 'uncommon' based on new safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the PI in accordance with the latest EMA excipients guideline. Also, the MAH has taken the opportunity to update the list of local representatives in the Package Leaflet and introduce editorial changes to the PI."

LysaKare - L-lysine hydrochloride / L-arginine hydrochloride - EMEA/H/C/004541/II/0019

Advanced Accelerator Applications, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4 and 4.9 of the SmPC in order to align it with Lutathera SmPC based on post-marketing data and literature. In addition, the MAH took the opportunity to implement editorial changes to the PI and to update the list of local representatives in the Package Leaflet."

Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0090

Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-301 (Adolescent part) listed as a category 3 study in the RMP. This is a phase 3 study of efficacy, effectiveness, safety, and immunogenicity in adolescents."

Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0093

Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from study 2019nCoV-314 listed as a category 3 study in the RMP. This is a phase 3, randomized, double-blinded study to evaluate the safety and immunogenicity of omicron subvariant and bivalent SARS-CoV-2 rS vaccines in adolescents (12 – 18 years) previously vaccinated with

mRNA COVID-19 vaccines. ”

Orserdu - Elacestrant - EMEA/H/C/005898/II/0009

Stemline Therapeutics B.V., Rapporteur: Peter Mol, “Update of section 5.2 of the SmPC in order to provide additional pharmacokinetic information following the PAM procedure for study MRPO-2023-PDE004 and based on the report SLP 43753974; this is an assessment of the potential role of P-gp in the supra-proportional exposure of elacestrant and the potential impact of P-gp inhibitors on elacestrant exposure at the dose of 100 mg. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.4.”

Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0059/G

Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, “A grouped application consisting of:
C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information with albendazole based on the post-marketing data and literature and to update information on drug-drug interactions with methadone and ethinyl estradiol based on the literature; the Package Leaflet is updated accordingly.
C.I.4: Update of section 4.5 of the SmPC in order to update information on drug-drug interactions with calcium channel antagonists based on the cumulative safety data and literature.”

Phesgo - Pertuzumab / Trastuzumab - EMEA/H/C/005386/II/0027

Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, “Update of sections 4.2 and 4.4 of the SmPC in order to update administration instructions based on final results from studies AL42478 and WP42873.
AL42478 is an Expanded Access, Single-Arm, Multicenter Study to Provide At Home Subcutaneous Administration of Pertuzumab and Trastuzumab Fixed-Dose Combination (PH FDC SC) for Patients with HER2-positive Breast Cancer During the COVID-19 Pandemic.
WP42873 is a randomized, open-label, 2-arm, parallel group, single dose, multi-centre study in healthy male subjects to investigate the

comparability of pharmacokinetics of the fixed-dose combination of pertuzumab and trastuzumab administered subcutaneously using a handheld syringe or using the on-body delivery system. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0210 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.4 of the SmPC in order to update the existing warning on 'Aseptic Meningitis Syndrome (AMS)' to add a class monitoring precaution for recurrent AMS, associated with IVIg treatment, potentially progressing to brain oedema (cerebral oedema). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Rystiggo - Rozanolixizumab - EMEA/H/C/005824/II/0009/G, Orphan UCB Pharma, Rapporteur: Thalia Marie Estrup Blicher, "A grouped application comprised of two type II variations, as follows: C.I.4: Update of section 4.2 of the SmPC in order to modify administration instructions to include the option of self-administration (by the patient or a caregiver) based on the results from study MG0020. This is a phase 3, open-label, crossover study to evaluate Rozanolixizumab self-administration by study participants with generalized myasthenia gravis. C.I.4: Update of sections 4.2 and 6.6 of the SmPC in order to modify administration instructions to include additional supportive data for the manual push (MP) method based on the results from the following clinical studies MG0007 phase 3 open label extension (OLE) and UP0106 phase 1 exploratory study. UP0106A is a randomized, participant-blind, investigator-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of Rozanolixizumab administered subcutaneously via manual push versus syringe driver to	

healthy participants. While, MG007 is an open-label extension study to evaluate Rozanolixizumab in study participants with generalized myasthenia gravis. The Package Leaflet and Labelling are updated accordingly.”	
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0147 Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, “Submission of the final report from study mRNA-1273-P205 listed as a category 3 study in the RMP. This is a Phase 2/3 Study to Evaluate the Immunogenicity and Safety of mRNA Vaccine Boosters for SARS-CoV-2 Variants.”	
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0149 Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, “Submission of the final report from study mRNA-1273-P204 listed as a category 3 study in the RMP. This is interventional Phase 2/3, 3-part, dose-escalation, open-label, age de-escalation and randomized, observer-blind, placebo-controlled expansion study to evaluate the safety, reactogenicity, and effectiveness of mRNA-1273 in children 6 months through 11 years of age.”	
Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0025 Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, “Update of sections 4.2 and 4.4 of the SmPC in order to reinforce the importance of injecting Sunlenca subcutaneously and not intradermally, and to add a new warning on ‘Injection Site Reactions with Improper Administration’ to describe that intradermal administration has been associated with serious injection site reactions including necrosis and ulcer, based on a cumulative safety review. The Package Leaflet is updated accordingly. The Instructions for Use (IFU) of Sunlenca solution for injection have also been updated to improve readability for healthcare professionals. In addition, the MAH took the opportunity to introduce editorial and formatting changes to the PI.”	
Trodelvy - Sacituzumab govitecan - EMEA/H/C/005182/II/0037	

Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2, 4.4 and 6.6 of the SmPC in order to add information on the timing of fatal infections as well as recommendations on the use of primary prophylaxis with G-CSF in patients who are at high risk for neutropenia, based on clinical trials data, post-marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC."

Truqap - Capivasertib - EMEA/H/C/006017/II/0002

AstraZeneca AB, Rapporteur: Janet Koenig, "Update of section 5.1 of the SmPC in order to update clinical efficacy information based on interim results from study D3615C00001 (CAPItello-291); this is a Phase III Double-blind Randomised Study Assessing the Efficacy and Safety of Capivasertib + Fulvestrant Versus Placebo + Fulvestrant as Treatment for Locally Advanced (Inoperable) or Metastatic Hormone Receptor Positive, Human Epidermal Growth Factor Receptor 2 Negative (HR+/HER2−) Breast Cancer Following Recurrence or Progression On or After Treatment with an Aromatase Inhibitor. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI and to update the list of local representatives in the Package Leaflet."

Voydeya - Danicopan - EMEA/H/C/005517/II/0004/G, Orphan

Alexion Europe, Rapporteur: Antonio Gomez-Outes, "A grouped application comprised of two Type II variations, as follows:

C.I.4: Update of sections 4.8 and 5.1 of the SmPC in order to update the list of adverse drug reactions and update clinical efficacy and safety information, based on final results from study ALXN2040-PNH-301; this is a Phase 3 Study of Danicopan (ALXN2040) as Add-on Therapy to a C5 Inhibitor (Eculizumab or Ravulizumab) in patients with Paroxysmal Nocturnal Hemoglobinuria who have clinically evident Extravascular Hemolysis (EVH). 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 it in line with the latest QRD template

version.

C.I.13: Submission of the final report from study ACH471-101; this is a multicentre, open-label, multiple dose Phase 2 study to assess efficacy, safety, and tolerability of add-on danicopan to background eculizumab therapy in adult participants with PNH."

Vyloy - Zolbetuximab - EMEA/H/C/005868/II/0003/G, Orphan

Astellas Pharma Europe B.V., Rapporteur: Jan Mueller-Berghaus, "Submission of results from studies GLOW (8951-CL-0302) and SPOTLIGHT (8951-CL-0301). GLOW is a Phase 3, Global, Multi-Centre, Double-Blind, Randomized, Efficacy Study of Zolbetuximab (IMAB362) Plus CAPOX Compared with Placebo Plus CAPOX as First-line Treatment of Subjects with Claudin (CLDN) 18.2-Positive, HER2-Negative, Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma. SPOTLIGHT is a Phase 3, Global, Multicentre, Double-Blind, Randomized, Efficacy Study of Zolbetuximab (IMAB362) Plus mFOLFOX6 Compared with Placebo Plus mFOLFOX6 as First-line Treatment of Subjects with Claudin (CLDN) 18.2-Positive, HER2-Negative, Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma."

WS2758

Vfend-EMEA/H/C/000387/WS2758/0155

Pfizer Europe MA EEIG, Lead Rapporteur: Patrick Vrijlandt, "Update of section 4.3 of the SmPC in order to add a contraindication for concomitant use with finerenone based on post-marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement administrative changes to section 4.5 of the SmPC and other editorial changes to the PI, as well as to update the list of local representatives in the Package Leaflet."

B.6.10. CHMP-PRAC assessed procedures

ASPAVELI - Pegcetacoplan - EMEA/H/C/005553/II/0028, Orphan

Swedish Orphan Biovitrum AB (publ),

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Kimmo Jaakkola, "Update of section 4.8 of the SmPC in order to add urticaria/hives to the list of adverse drug reactions (ADRs) with frequency "common" and to add anaphylactic reaction and anaphylactic shock to the list of ADRs with frequency "uncommon", based on post-marketing data and literature; the Package Leaflet is updated accordingly. The RMP version 3.1 has also been submitted."

Bylvay - Odevixibat - EMEA/H/C/004691/II/0022/G, Orphan

Ipsen Pharma, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski, "A grouped application including two type II variations:

- Update of sections 4.2, 4.4, 4.8, and 5.1 of the SmPC based on the clinical study report for the completed 72 weeks of Study A4250-008; an open-label, phase III study to evaluate the long-term efficacy and safety of odevixibat in children with PFIC (category 3 study in the RMP; MEA 002).

The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and the Package Leaflet. An updated RMP version 6.1 is included in this submission.

- Submission of the clinical study report for Study A4250-J001; a Phase I PK study in healthy Japanese adult male patients."

COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000231586

BioNTech Manufacturing GmbH, Rapporteur: Filip Josephson, PRAC Rapporteur: Liana Martirosyan "A grouped application consisting of:

C.I.11.b: Submission of an updated RMP version 13.1 in order to include Protocol amendment no. 5 where the study design and objectives were revised for an interventional study C4591048, 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, listed as a category 3 study in the RMP.

C.I.13: Submission of the final report from study C4591044 listed as a category 3 study in the RMP. This is an interventional randomized,

active controlled, Phase 2/3 Study to Investigate the Safety, Tolerability, and Immunogenicity of Bivalent BNT162b RNA-Based Vaccine Candidates as A Booster Dose In COVID-19 Vaccine–Experienced Healthy Individuals. The RMP version 13.1 has also been submitted."

Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0007

Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan, "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC in order to introduce an alternative posology regimen based on results from study PB-102-F50 (BRIGHT) and interim results from its extension study CLI-06657AA1-03 (formerly presented as PB-102-F51), as well as results of the observational patient reporting outcome study CLI-06657AA1-05. CLI-06657AA1-03 is an Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Pegunigalsidase Alfa (PRX-102)2 mg/kg Administered by Intravenous Infusion Every 4 Weeks in Patients with Fabry Disease. The Package Leaflet is updated accordingly. 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 and to bring the PI in line with the latest QRD template version 10.4."

Pluvicto - Lutetium (177Lu) vipivotide tetraxetan - EMEA/H/C/005483/II/0022

Novartis Europharm Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: John Joseph Borg, "Update of section 4.8 of the SmPC in order to update safety information based on final results from study PSMA-617-01 (CAAA617A12301 – VISION) listed as a category 3 study in the RMP; this is an international, prospective, open-label, multicentre, randomized Phase 3 study of 177Lu-PSMA-617 in the treatment of patients with progressive PSMA-positive metastatic castration-resistant prostate cancer. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI."

Pyramax - Pyronaridine / Artesunate - EMEA/H/W/002319/II/0036

Shin Poong Pharmaceutical Co., Ltd., Rapporteur: Jean-Michel Race, PRAC Rapporteur: Tiphaine Vaillant, "Update of sections 4.4 and 4.6 of the SmPC with revised recommendations for treatment during pregnancy. The Package Leaflet has been updated accordingly. An updated RMP version 18 was provided as part of the application."

Ranibizumab Midas - Ranibizumab - EMEA/H/C/006528/II/0002/G

MIDAS Pharma GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Bolin

Ranivisio - Ranibizumab - EMEA/H/C/005019/II/0017/G

Midas Pharma GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Bolin

Shingrix - Herpes zoster vaccine (recombinant, adjuvanted) - EMA/VR/0000235389

GlaxoSmithKline Biologicals, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Hrabcik, "Update of sections 4.4 and 5.1 of the SmPC to include the final results of study ZOSTER-062, listed as a category 3 study in the RMP. This is a phase III, randomized, observer-blind, placebo controlled, multicentre clinical trial to assess Herpes Zoster recurrence and the reactogenicity, safety and immunogenicity of Shingrix when administered intramuscularly on a 0- and 2-month schedule to adults $\geqslant$ 50 years of age with a prior episode of Herpes Zoster. The RMP version 9.0 has also been submitted. In addition, the MAH took the opportunity to implement a minor editorial change to Annex II of the PI."

Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0022/G

Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, PRAC Rapporteur: Ana Sofia Diniz Martins, "Grouping of two type II variations:
- Update of section 5.1 of the SmPC to include efficacy and resistance data based on week 156 interim data from Study GS-US-200-4625; a phase 2/3 study to evaluate the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with an optimized background regimen in heavily treatment experienced people living with HIV-1 infection with multidrug

resistance (category 3 study in the RMP).
Additionally, upon request by the CHMP following the assessment of II/0013, the MAH proposes to update section 4.8 of the SmPC to include information related to injection site nodules and induration that were non-resolved at the end of follow-up.
- Provision of the final study report of Study GS-US-200-4334: a phase 2 randomized, open label, active controlled study evaluating the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with other antiretroviral agents in people living with HIV (category 3 study in the RMP).
An updated RMP version 2.1 was included as part of the application."

Vabysmo - Faricimab - EMEA/H/C/005642/II/0016

Roche Registration GmbH, Rapporteur: Jayne Crowe, PRAC Rapporteur: Carla Torre, "Update of section 5.1 of the SmPC to reflect the long-term safety profile of faricimab in patients with diabetic macular edema (DME) based on the final results from study GR41987 (Rhone-X) listed as a category 3 study of the RMP. Rhone-X was a phase III interventional, multicentre, open-label extension study to evaluate the long-term safety and tolerability of faricimab in patients with diabetic macular edema. The RMP version 7.0 has also been submitted."

XALKORI - Crizotinib - EMEA/H/C/002489/II/0084

Pfizer Europe MA EEIG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Tiphaine Vaillant, "Submission of the final report from study CRZ-NBALCL listed as a category 3 study in the RMP. This is a phase I/II study to evaluate the adverse effects of ocular toxicity and bone toxicity and impaired bone growth associated with crizotinib in paediatric and young adult patients with recurrent/refractory anaplastic lymphoma kinase-positive anaplastic large cell lymphoma or neuroblastoma. The RMP version 9.2 is updated accordingly."

B.6.11. PRAC assessed procedures

PRAC Led

Enbrel - Etanercept -

EMEA/H/C/000262/II/0255

Pfizer Europe MA EEIG, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gomez-Outes, "Update of sections 4.2 and 4.4 of the SmPC in order to remove information regarding the Patient Card, based on final results from study B1801309 (BSR Register of Anti-TNF Treated Patients and Prospective Surveillance Study for Adverse Events: Enbrel). This is a non-interventional PASS study listed as a category 3 study in the RMP. The Annex II and Package Leaflet are updated accordingly. The RMP version 7.7 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI as well as to update the list of local representatives in the Package Leaflet and align the PI with the QRD version 10.4."

PRAC Led

Erbitux - Cetuximab -
EMEA/H/C/000558/II/0103

Merck Europe B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Filip Josephson, "Submission of an updated RMP version 19.2 in order to re-classify important identified risks and important potential risks and to remove them from the summary of safety concerns, following the PRAC assessment for PSUSA/00000635/202309."

PRAC Led

Fintepla - Fenfluramine -
EMEA/H/C/003933/II/0028, Orphan

UCB Pharma SA, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Submission of a revised protocol for study EP0218 listed as an obligation in the Annex II of the Product Information. This is a Long-term Registry in approved indications for fenfluramine, with a specific focus on cardiovascular events and growth retardation. The RMP version 4.0 is updated accordingly. In addition, the MAH introduced minor amendments in the targeted follow-up questionnaire for cardiovascular adverse events."

PRAC Led

POTELIGEO - Mogamulizumab -
EMEA/H/C/004232/II/0026, Orphan

Kyowa Kirin Holdings B.V., Rapporteur: Peter Mol, PRAC Rapporteur: Marie Louise Schougaard Christiansen, PRAC-CHMP liaison: Boje Kvorning Pires Ehmsen, "Update of section 4.8 of the SmPC in order to add 'granuloma' to the list of adverse drug reactions (ADRs) with frequency 'unknown', based on post marketing data; the Package Leaflet is updated accordingly."

PRAC Led
Veklury - Remdesivir - EMEA/H/C/005622/II/0062
Gilead Sciences Ireland UC, PRAC Rapporteur: Eva Jirsová, PRAC-CHMP liaison: Petr Vrbata, "Submission of the final report from study COVID-PR (CO-US-540-6127 listed as a category 3 study in the RMP. This is a non-interventional, patient-reporting, post marketing cohort study designed to collect safety data from pregnant and recently pregnant women treated with monoclonal antibodies or antiviral drugs for mild, moderate, or severe COVID-19 at any time from the first day of the last menstrual period to the end of pregnancy. The RMP version 8.2 is updated accordingly."

PRAC Led
WS2794
Segluromet- EMEA/H/C/004314/WS2794/0026
Steglatro- EMEA/H/C/004315/WS2794/0025
Steglujan- EMEA/H/C/004313/WS2794/0029
Merck Sharp & Dohme B.V., Lead PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of the final report from study 8835-062 listed as a category 3 study in the RMP for Steglatro, Steglujan and Segluromet. This is a non-interventional post-authorization safety study (PASS) to assess the risk of diabetic ketoacidosis (DKA) among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents. The RMP version 2.3 have also been submitted."

B.6.12. CHMP-CAT assessed procedures

CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0035, Orphan,

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

Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/II/0068, ATMP
Amgen Europe B.V., Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lähteenvuo

Zolgensma - Onasemnogene abeparvovec - EMEA/H/C/004750/II/0055, Orphan, ATMP
Novartis Europharm Limited, Rapporteur: Emmely de Vries, CHMP Coordinator: Peter Mol

B.6.13. CHMP-PRAC-CAT assessed procedures

Kymriah - Tisagenlecleucel - EMEA/H/C/004090/II/0092, Orphan, ATMP
Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, PRAC Rapporteur: Gabriele Maurer, "Update of section 4.2 of the SmPC in order to update the 'monitoring after infusion' recommendations, based on existing clinical trial data as well as literature references reporting real word experience. The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to introduce a minor change to the HCP educational programme in the Annex II in order to enhance readability."

B.6.14. PRAC assessed ATMP procedures

PRAC Led
CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0034, Orphan, ATMP
Janssen-Cilag International NV, PRAC Rapporteur: Jo Robays, PRAC-CHMP liaison: Karin Janssen van Doorn, "Submission of an updated RMP version 5.2 in order to add a new important identified risk of "Secondary malignancy of T-cell origin", to change the important potential risk of "Second primary malignancies" to "Second primary malignancy except secondary malignancy of T-cell origin",

and to include an additional pharmacovigilance activity for testing of secondary malignancies of T-cell origin, following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040).”	
PRAC Led **WS2771** **Tecartus-** **EMEA/H/C/005102/WS2771/0054** **Yescarta-** **EMEA/H/C/004480/WS2771/0084** Kite Pharma EU B.V., Lead PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Boje Kvorning Pires Ehmsen, “Submission of an updated RMP version 4.3 for Tecartus and version 11.1 for Yescarta following the PRAC recommendation for the Secondary malignancy of T-cell origin signal (EPITT no: 20040), and of a PASS protocol for a framework for the sampling and testing of secondary malignancies of T-cell origin.”	

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

WS2790 **M-M-RvaxPro-** **EMEA/H/C/000604/WS2790/0129** **ProQuad-** **EMEA/H/C/000622/WS2790/0170** Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus	
WS2791/G **Aflunov-** **EMEA/H/C/002094/WS2791/0091/G** **Foclivia-** **EMEA/H/C/001208/WS2791/0095/G** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2791/0009/G** Seqirus S.r.l, Lead Rapporteur: Maria Grazia Evandri	

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. 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