19 February 2024
EMA/CHMP/39398/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 19-22 February 2024

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

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

20 February 2024, 08:30 – 19:30, virtual meeting/room 1C

21 February 2024, 08:30 – 19:30, virtual meeting/room 1C

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 19-22 February 2024. See February 2024 CHMP minutes (to be published post March 2024 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 19-22 February 2024.

1.3. Adoption of the minutes

CHMP minutes for 22-25 January 2024.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 12 February 2024.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Bevacizumab - EMEA/H/C/005723

Treatment of neovascular (wet) age-related macular degeneration (nAMD).

Scope: Oral explanation

Action: Possible oral explanation to be held on 20 February 2024 at 14:00

List of Outstanding Issues adopted on 09.11.2023. List of Questions adopted on 26.04.2023.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0134

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant, treatment of resectable Stage II, IIIA, or IIIB (T3 4N2) non-small cell lung carcinoma in adults for Keytruda based on study KEYNOTE-671, a phase III, randomized, double-blind trial of platinum doublet chemotherapy +/- pembrolizumab as neoadjuvant/adjuvant therapy for participants with resectable stage II, IIIA, and resectable IIIB (T3-4N2) non-small cell lung cancer. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 41.1 of the RMP has also been submitted."

Scope: Oral explanation

Action: Oral explanation to be held on 21 February 2024 at 14:00

Request for Supplementary Information adopted on 14.12.2023, 22.06.2023.

See 5.1

2.3.2. Orencia - Abatacept - EMEA/H/C/000701/II/0152

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include the prophylaxis of acute Graft versus Host Disease (aGvHD) in the adult and paediatric population for Orencia, based on final results from studies IM101311 - Abatacept Combined With a Calcineurin Inhibitor and Methotrexate for Graft Versus Host Disease Prophylaxis and IM101841 - Overall Survival In 7/8 HLA-Matched Hematopoietic Stem Cell Transplantation Patients Treated With Abatacept Combined With A Calcineurin Inhibitor And Methotrexate - An Analysis Of The Center For International Blood And Marrow Transplant Research (Cibmtr) Database. 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 and Labelling are updated in accordance. Version 28.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Scope: Oral explanation

Action: Oral explanation to be held on 20 February 2024 at 16:00

Request for Supplementary Information adopted on 12.10.2023, 30.03.2023.

See 5.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Apremilast - EMEA/H/C/006208

treatment of psoriatic arthritis, psoriasis, Behçet's disease

Scope: Opinion

Action: For adoption

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

3.1.2. Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - EMEA/H/C/006052

active immunisation for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 09.11.2023. List of Questions adopted on 26.04.2023.

3.1.3. Sparsentan - Orphan - EMEA/H/C/005783

Vifor France; for the treatment of primary immunoglobulin A nephropathy (IgAN).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.12.2023, 12.10.2023, 25.05.2023. List of Questions adopted on 15.12.2022.

3.1.4. Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures) - EMEA/H/C/006051

prophylaxis of influenza

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 09.11.2023. List of Questions adopted on 26.04.2023.

3.1.5. Nintedanib - EMEA/H/C/006179

treatment of idiopathic pulmonary fibrosis (IPF), chronic fibrosing interstitial lung diseases (ILDs) and lung diseases (ILDs) systemic sclerosis associated interstitial lung disease (SSc-ILD)

Scope: Opinion

Action: For adoption

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

3.1.6. Ustekinumab - EMEA/H/C/006183

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.12.2023. List of Questions adopted on 14.09.2023.

3.1.7. Tofersen - Orphan - EMEA/H/C/005493

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

Scope: Opinion

Action: For adoption

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

3.1.8. Flortaucipir (18F) - EMEA/H/C/006064

indicated for Positron Emission Tomography (PET) imaging of the brain

Scope: Opinion

Action: For adoption

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

3.1.9. Tislelizumab - EMEA/H/C/005542

treatment of locally advanced or metastatic non-squamous non-small cell lung cancer in adults, treatment of locally advanced or metastatic squamous non-small cell lung cancer in adults, locally advanced or metastatic non-small cell lung cancer after prior chemotherapy in adults

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.03.2023. List of Questions adopted on 21.07.2022.

3.1.10. Danicopan - PRIME - Orphan - EMEA/H/C/005517

Alexion Europe; Treatment of extravascular haemolysis (EVH) in patients with paroxysmal nocturnal haemoglobinuria

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 09.11.2023. List of Questions adopted on 20.07.2023.

3.1.11. Retifanlimab - Orphan - EMEA/H/C/006194

Incyte Biosciences Distribution B.V.; Treatment of Merkel cell carcinoma (MCC).

Scope: Opinion

Action: For adoption

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

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

3.2.1. Dantrolene sodium, hemiheptahydrate - Orphan - EMEA/H/C/006009

Norgine B.V.; treatment of malignant hyperthermia (including suspected cases)

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 22.06.2023. List of Questions adopted on 10.11.2022.

3.2.2. Concizumab - EMEA/H/C/005938

routine prophylaxis to prevent or reduce the frequency of bleeding in patients with: haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors ≥ 12 years of age; haemophilia B (congenital factor IX deficiency) with FIX inhibitors of any age

Scope: List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 14.12.2023, 12.10.2023. List of Questions adopted on 25.05.2023.

3.2.3. Insulin icodec - EMEA/H/C/005978

treatment of diabetes mellitus in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

3.2.4. Capivasertib - EMEA/H/C/006017

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

3.2.5. Aztreonam / Avibactam - EMEA/H/C/006113

Accelerated assessment

treatment of complicated Intra-Abdominal Infection (cIAI), complicated Urinary Tract Infection (cUTI), including pyelonephritis, Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), and aerobic Gram-negative infections with limited treatment options

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2023.

3.2.6. Eribulin - EMEA/H/C/006191

treatment of breast cancer and liposarcoma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

3.2.7. Iptacopan - PRIME - Orphan - EMEA/H/C/005764

Novartis Europharm Limited; treatment of paroxysmal nocturnal haemoglobinuria

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

3.2.8. Fruquintinib - EMEA/H/C/005979

treatment of metastatic colorectal cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.10.2023.

3.2.9. Omalizumab - EMEA/H/C/005958

treatment of asthma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

3.2.10. Ustekinumab - EMEA/H/C/006415

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

3.2.11. Vibegron - EMEA/H/C/005957

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

3.2.12. Ustekinumab - EMEA/H/C/006132

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 14.09.2023.

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

3.3.1. Guanfacine - EMEA/H/C/006312

treatment of ADHD

Scope: List of questions

Action: For adoption

3.3.2. Apremilast - EMEA/H/C/006193

treatment of psoriatic arthritis, psoriasis, Behçet's disease

Scope: List of questions

Action: For adoption

3.3.3. Troriluzole - Orphan - EMEA/H/C/006068

Biohaven Bioscience Ireland Limited; is indicated for the treatment of adult patients with spinocerebellar ataxia genotype 3 (SCA3)

Scope: List of questions

Action: For adoption

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

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

Scope: List of questions

Action: For adoption

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

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

Scope: List of questions

Action: For adoption

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

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

Scope: List of questions

Action: For adoption

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

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

Scope: List of questions

Action: For adoption

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

Ipsen Pharma; treatment of primary biliary cholangitis (PBC)

Scope: List of questions

Action: For adoption

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

Accelerated assessment

prevention of disease caused by chikungunya (CHIKV) virus

Scope: List of questions

Action: For adoption

3.3.10. Clascoterone - EMEA/H/C/006138

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

Scope: List of questions

Action: For adoption

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

3.4.1. givinostat - Orphan - EMEA/H/C/006079

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

Scope: Letter by the applicant dated 16.02.2024 requesting an extension to the clock stop to respond to the list of questions adopted in December 2023.

Action: For adoption

List of Questions adopted on 14.12.2023.

3.4.2. vilobelimab - EMEA/H/C/006123

treatment of adult patients with SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).

Scope: Letter by the applicant dated 13.02.2024 requesting an extension to the clock stop to respond to the list of questions adopted in December 2023.

Action: For adoption

List of Questions adopted on 14.12.2023.

3.4.3. serplulimab - Orphan - EMEA/H/C/006170

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

Scope: Update on procedure

Action: For discussion

List of Outstanding Issues adopted on 14.12.2023. List of questions adopted on 20.03.2023.

3.4.4. lecanemab - EMEA/H/C/005966

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

Scope: Draft list of experts for SAG

Action: For adoption

List of Outstanding Issues adopted on 09.11.1023. List of Questions adopted on 25.05.2023.

3.4.5. amino acids - Orphan - EMEA/H/C/005557

Recordati Rare Diseases; treatment of decompensation episodes in MSUD patients

Scope: Letter by the applicant dated 15.02.2024 requesting an extension to the clock stop to respond to the list of questions adopted in January 2024.

Action: For adoption

List of Questions adopted on 25.01.2024.

3.4.6. epinephrine - EMEA/H/C/006139

Treatment of allergic reactions (anaphylaxis) and idiopathic or exercise induced anaphylaxis

Scope: Letter by the applicant dated 23.01.2024 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in October 2023.

Action: For adoption

List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 23.02.2023.

3.4.7. teriparatide - EMEA/H/C/005687

treatment of osteoporosis

Scope: Letter by the applicant dated 08.02.2024 requesting an clock stop to respond to the list of questions adopted in November 2023.

Action: For adoption

List of Questions adopted on 09.11.2023.

3.4.8. tocilizumab - EMEA/H/C/005984

treatment of rheumatoid arthritis, active systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA) and COVID-19

Scope: Letter by the applicant dated 13.02.2024 requesting an extension to the clock stop to respond to the list of outstanding issues adopted in May 2023.

Action: For adoption

List of outstanding issues adopted on 25.05.2023. List of Questions adopted on 26.01.2023.

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

3.5.1. Nezglyal - leriglitazone - Orphan - EMEA/H/C/005757

Minoryx Therapeutics S.L.; the treatment of cerebral progression and myelopathy in male patients with adrenoleukodystrophy (ALD)

Re-examination Rapporteur: TBC, Re-examination Co-Rapporteur: TBC

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

Action: For adoption

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

Opinion adopted on 25.01.2023. List of Outstanding Issues adopted on 14.09.2023. List of Questions adopted on 15.12.2022.

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

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

Re-examination Rapporteur: TBC, Re-examination Co-Rapporteur: TBC

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

Action: For adoption

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

Opinion adopted on 25.01.2023. List of Outstanding Issues adopted on 12.10.2023. List of Questions adopted on 25.05.2023.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

4.1.1. Kalydeco - Ivacaftor - EMEA/H/C/002494/X/0115/G

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Extension application to introduce a new strength (13.4 mg of ivacaftor granules in sachet), grouped with a type II variation (C.I.6.a) in order to extend the indication of the granule presentations to include children with cystic fibrosis aged 1 to less than 4 months of age and weighing 3 kg or more who have an R117H CFTR mutation or one of the approved 9 gating (class III) mutations based on interim results from study VX15-770-124 (study 124); this is a phase 3, 2-part, open-label study to evaluate the safety, pharmacokinetics, and pharmacodynamics of ivacaftor (IVA) in subjects with CF who are less than 24 months of age at treatment initiation and have a CFTR gating mutation. As a consequence, sections 1, 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3 and 8 of the SmPC of the granules presentations and sections 4.2, 4.8, 5.1 and 5.2 of the SmPC of the tablets presentations are updated. The Labelling for the 13.4 mg granule presentation and the Package Leaflet of the granules and tablets presentations are updated in accordance. Version 15.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.
Type IA A.5.b
Type IA B.II.b.2.a"

Action: For adoption

List of Outstanding Issues adopted on 14.12.2023, 12.10.2023. List of Questions adopted on 25.05.2023.

4.1.2. Teriflunomide Accord - Teriflunomide - EMEA/H/C/005960/X/0002

Accord Healthcare S.L.U.

Rapporteur: Kristina Nadrah, PRAC Rapporteur: Martin Huber

Scope: "Extension application to add a new strength of 7 mg film-coated tablets. The

bioequivalence study data were submitted."

Action: For adoption

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

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

4.2.1. Betmiga - Mirabegron - EMEA/H/C/002388/X/0039/G

Astellas Pharma Europe B.V.

Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (8 mg/ml prolonged-release granules for oral suspension), grouped with a type II variation (C.I.6.a) to include treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 to less than 18 years. The RMP (version 9.0) is updated in accordance."

Action: For adoption

List of Outstanding Issues adopted on 15.09.2022. List of Questions adopted on 22.04.2022.

4.2.2. Rozlytrek - Entrectinib - EMEA/H/C/004936/X/0017/G

Roche Registration GmbH

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to:
1) Introduce a new pharmaceutical form (coated granules) associated with a new strength (50 mg).
2) Introduce a new route of administration (gastroenteral use) for the already authorised 100 mg and 200 mg hard capsules presentations.
The above two line extensions are grouped with 3 type II variations:
- C.I.6.a - To extend the currently approved indication in solid tumours with NTRK gene fusion to patients from birth to 12 years of age (both for the coated granules and already approved hard capsules presentations).
- C.I.6.a - To add a new paediatric indication from birth to 18 years of age for patients with solid tumours with a ROS1 gene fusion (both for the coated granules and already approved hard capsules presentations).
Based on final results from studies CO40778 (STARTRK-NG), GO40782 (STARTRK-2) and BO41932 (TAPISTRY). Study CO40778 is a Phase I/II open-label, dose-escalation and expansion study of entrectinib in pediatrics with locally advanced or metastatic solid or primary CNS tumors and/or who have no satisfactory treatment options; study GO40782 is an open-label, multicenter, global Phase II basket study of entrectinib for the treatment of patients with solid tumors that harbor an NTRK1/2/3, ROS1, or ALK gene rearrangement (fusion), and study BO41932 is a Phase II, global, multicenter, open-label, multi-cohort

study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in rational, specified combinations in participants with unresectable, locally advanced or metastatic solid tumors determined to harbor specific oncogenic genomic alterations or who are tumor mutational burden (TMB)-high as identified by a validated next-generation sequencing (NGS) assay.
As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated accordingly. The Package Leaflet and Labelling are updated in accordance.
- C.I.4 - To add a wording regarding the option of suspension in water of the content of the capsules to be used orally or via the e.g., gastric or nasogastric tube (in sections 4.2 and 5.2 of the SmPC).
The RMP (version 5) is updated in accordance.
The MAH took the opportunity to introduce minor editorial changes to the PI and to update Annex II of the SmPC."

Action: For adoption

List of Questions adopted on 14.09.2023.

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. Mounjaro - Tirzepatide - EMEA/H/C/005620/X/0015

Eli Lilly Nederland B.V.

Rapporteur: Martina Weise

Scope: "Extension application to add 6 new strengths of 2.5 mg (4.17 mg/ml), 5 mg (8.33 mg/ml), 7.5 mg (12.5 mg/ml), 10 mg (16.67 mg/ml), 12.5 mg (20.83 mg/ml) and 15 mg (25 mg/ml) for Mounjaro solution for injection in pre-filled pen (KwikPen), multidose. The Package Leaflet and Labelling are updated in accordance."

Action: For adoption

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

Boehringer Ingelheim International GmbH

Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Nikica Mirošević Skvrce

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

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

Janssen-Cilag International N.V.

Rapporteur: Maria Concepcion Prieto Yerro, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension application to introduce a new pharmaceutical form associated with new strengths (1 and 2.5 mg dispersible tablet) grouped with an extension of indication (C.I.6.a) to include, as monotherapy or in combination, the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged 1 month to less than 18 years of age of WHO Functional Class (FC) I to III for OPSUMIT, based on interim results from AC-055-312 study (TOMORROW). This is a multicenter, open-label, randomized study with single-arm extension period to assess the pharmacokinetics, safety, and efficacy of macitentan versus standard of care in children with pulmonary arterial hypertension. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1 and 5.2 of the SmPC for film-coated tablets are updated. The Package Leaflet and Labelling are updated in accordance. Version 14.1 of the RMP has also been submitted."

Action: For adoption

4.3.4. Ozempic - Semaglutide - EMEA/H/C/004174/X/0043

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: quality

Action: For adoption

4.3.5. Rybelsus - Semaglutide - EMEA/H/C/004953/X/0038

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: "Extension application to introduce three new strengths of tablets (1.5 mg, 4 mg and 9 mg) for semaglutide."

Action: For adoption

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

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

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

Action: For adoption

4.3.7. Wegovy - Semaglutide - EMEA/H/C/005422/X/0016

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: quality

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. CARVYKTI - Ciltacabtagene autoleucel - Orphan - ATMP - EMEA/H/C/005095/II/0021

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Jo Robays

Scope: "Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 1 prior therapy, including an IMiD and a PI, have demonstrated disease progression on or after the last therapy and are refractory to lenalidomide for CARVYKTI, based on interim results from study MMY3002 listed as a specific obligation (SOB/006) in the Annex II. This is an ongoing, Phase 3, randomized, open-label, multicentre study to determine whether treatment with cilta-cel provides an efficacy benefit compared to standard therapy in participants with relapsed and lenalidomide-refractory multiple myeloma. As a consequence, sections 4.1, 4.4, 4.5, 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 MAH took the opportunity to update Annex II of 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 08.12.2023, 08.09.2023.

5.1.2. Cibinqo - Abrocitinib - EMEA/H/C/005452/II/0010

Pfizer Europe MA EEIG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Nikica Mirošević Skvrce

Scope: "Extension of indication to include treatment of adolescents 12 to < 18 years of age with moderate to severe atopic dermatitis for CIBINQO based on final results from non-clinical study 00655292 [21GR211] and interim results from clinical study B7451015; this is a Phase III multi-center, long-term extension study investigating the efficacy and safety of abrocitinib, with or without topical medications, administered to subjects aged 12 years and older with moderate to severe atopic dermatitis. 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 4.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023, 14.09.2023.

5.1.3. Hepcludex - Bulevirtide - Orphan - EMEA/H/C/004854/II/0031

Gilead Sciences Ireland Unlimited Company

Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include treatment of chronic hepatitis delta virus (HDV) infection in paediatric patients 3 years of age and older weighing at least 10 kg with compensated liver disease for Hepcludex, based on a modelling and simulation study and an extrapolation study to evaluate the use of Bulevirtide for the treatment of chronic hepatitis D infection in children from 3 to less than 18 years of age. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet has been updated accordingly. Version 4.1 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

5.1.4. Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0134

Merck Sharp & Dohme B.V.

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant, treatment of resectable Stage II, IIIA, or IIIB (T3 4N2) non-small cell lung carcinoma in

adults for Keytruda based on study KEYNOTE-671, a phase III, randomized, double-blind trial of platinum doublet chemotherapy +/- pembrolizumab as neoadjuvant/adjuvant therapy for participants with resectable stage II, IIIA, and resectable IIIB (T3-4N2) non-small cell lung cancer. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 41.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 14.12.2023, 22.06.2023.

See 2.3

5.1.5. Nilemdo - Bempedoic acid - EMEA/H/C/004958/II/0031

Daiichi Sankyo Europe GmbH

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk, based on results from study 1002-043 (CLEAR). CLEAR Outcomes Study is a phase 3 multi-centre randomised, double-blind, placebo-controlled study to evaluate whether long-term treatment with bempedoic acid reduces the risk of major adverse cardiovascular events (MACE) in patients with, or at high risk for, cardiovascular disease who are statin intolerant. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 4.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting 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 09.11.2023.

5.1.6. Nustendi - Bempedoic acid / Ezetimibe - EMEA/H/C/004959/II/0035

Daiichi Sankyo Europe GmbH

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk for NUSTENDI, based on results from study 1002-043, known as the CLEAR [Cholesterol Lowering via Bempedoic Acid, an ATP citrate lyase (ACL) Inhibiting Regimen] Outcomes Trial; this is a Phase 3, randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease who are statin intolerant; As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 09.11.2023.

5.1.7. Orencia - Abatacept - EMEA/H/C/000701/II/0152

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include the prophylaxis of acute Graft versus Host Disease (aGvHD) in the adult and paediatric population for Orencia, based on final results from studies IM101311 - Abatacept Combined With a Calcineurin Inhibitor and Methotrexate for Graft Versus Host Disease Prophylaxis and IM101841 - Overall Survival In 7/8 HLA-Matched Hematopoietic Stem Cell Transplantation Patients Treated With Abatacept Combined With A Calcineurin Inhibitor And Methotrexate - An Analysis Of The Center For International Blood And Marrow Transplant Research (Cibmtr) Database. 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 and Labelling are updated in accordance. Version 28.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 12.10.2023, 30.03.2023.

See 2.3

5.1.8. Pegasys - Peginterferon alfa-2a - EMEA/H/C/000395/II/0119/G

Pharmaand GmbH

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Grouped application consisting of:
Extension of indication to include treatment of Polycythaemia Vera (PV) and Essential thrombocytopenia (ET) for PEGASYS, based on published data of clinical studies conducted in support of the efficacy and safety of Pegasys for the treatment of ET and PV. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3."

Action: For adoption

5.1.9. Reblozyl - Luspatercept - Orphan - EMEA/H/C/004444/II/0021

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Daniela Philadelphy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jo Robays

Scope: "Extension of indication to include treatment of adult patients with anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (MDS), who may require RBC transfusions for Reblozyl, based on results from study ACE-536-MDS-002 (COMMANDS), an active-controlled, open-label, randomized Phase 3 study comparing the efficacy and safety of luspatercept vs epoetin alfa in adult subjects with anemia due to

IPSS-R very low, low or intermediate risk MDS, who are ESA naïve and require RBC transfusions, and studies ACE-536-MDS-001(MEDALIST), ACE-536-MDS-004, A536-03, A536-05 and ACE-536-LTFU-001. 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 2.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 12.10.2023, 22.06.2023.

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

Janssen-Cilag International N.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of indications by removal of the restriction for use of SIRTURO (bedaquiline [BDQ]), based on final results from study STREAM Stage 2; this is an multicenter, open-label, parallel-group, randomized, active-controlled study in participants aged 15 years or older with RR/MDR-TB to evaluate an investigational BDQ-containing, all-oral, 40-week regimen of anti-TB drugs (Regimen C) compared to an injectable-containing 40-week control regimen (Regimen B). As a consequence of the data emerging from the submitted study, sections 2, 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. In addition, section E of Annex II has also been updated. The Labelling and Package Leaflet are updated in accordance. Version 10.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3. As part of the application, the MAH is requesting the switch from a conditional MA to standard MA."

Action: For adoption

5.1.11. Tepkinly - Epcoritamab - Orphan - EMEA/H/C/005985/II/0001

AbbVie Deutschland GmbH & Co. KG

Rapporteur: Peter Mol, Co-Rapporteur: Ingrid Wang, PRAC Rapporteur: Monica Martinez Redondo

Scope: "Extension of indication to include treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy for TEPKINLY, based on results from the indolent Non-Hodgkins Lymphoma (iNHL) expansion cohort of Study GCT3013-01, the First In Human (FIH) Phase 1/2 study in R/R B-NHL, with key supportive data from the Phase 1b/2 Study GCT3013-04 in Japanese subjects. Study GCT3013-01 is an ongoing global, single-arm, Phase 1/2 study designed to evaluate epcoritamab as monotherapy in R/R B-NHL. As a consequence, sections 1, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3, 6.4, 6.5 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.12. Xromi - Hydroxycarbamide - EMEA/H/C/004837/II/0019

Nova Laboratories Ireland Limited

Rapporteur: Anastasia Mountaki, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Jo Robays

Scope: "Extension of indication to include the prevention of vaso-occlusive complications of sickle cell disease in children from 6 months to 2 years of age for Xromi, based on final results from the paediatric study INV543, listed as a category 3 study in the RMP; this is a single-arm, open-label, multi-center study in children with sickle cell anaemia over 6 months of age.
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."

Action: For adoption

Request for Supplementary Information adopted on 09.11.2023, 26.04.2023.

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

Vertex Pharmaceuticals (Ireland) Limited

Lead Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

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

Action: For adoption

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

No items

6.4. Companion diagnostics – follow-up consultation

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. Sepiapterin - H0006331

For the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with phenylketonuria (PKU).

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

Action: For adoption

8.1.2. Chikungunya Virus Virus-Like Particle Vaccine – H0005470

Active immunisation to prevent disease caused by chikungunya virus infection in individuals age 12 years and older

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. Truvelog Mix 30 - insulin aspart - EMEA/H/C/005635

Sanofi Winthrop Industrie; treatment of diabetes mellitus

Rapporteur: Martina Weise, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Mari Thorn

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.2. Zoledronic acid Actavis – zoledronic acid – EMEA/H/C/002488

Actavis Group PTC ehf.; prevention of skeletal related events and treatment of tumour-induced hypercalcaemia (TIH)

Rapporteur: Christian Gartner

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.3. Zoledronic acid Hospira – zoledronic acid – EMEA/H/C/002365

Pfizer Europe MA EEIG; prevention of skeletal related events and treatment of tumour-induced hypercalcaemia (TIH)

Rapporteur: Kristina Dunder

Scope: Withdrawal of marketing authorisation

Action: For information

10. Referral procedures

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

No items

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

10.2.1. Colistimethate sodium (CMS) – EMEA/H/A-5(3)/1524

Various MAHs

Referral Rapporteur: Martina Weise, Referral Co-Rapporteur: Ewa Balkowiec Iskra

Scope: List of outstanding issues/opinion

Action: For adoption

Review of the ratio of polymyxins E1 and E2 in colistin starting material and of the (sulfomethylation) composition profile of CMS finished product.

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

10.4.1. Ibuprofen NVT – ibuprofen - EMEA/H/A-29(4)/1533

Laboratorios Liconsa, S.A.

Referral Rapporteur: Vilma Petrikaite, Referral Co-Rapporteur: Maria Concepcion Prieto Yerro

Scope: Opinion

Action: For adoption

Mutual Recognition Procedure number: LT/H/0162/002/E/001, notification sent by the Agency of Lithuania dated 17 November 2023 notifying of the start of a referral under Article 29(4) of Directive 2001/83/EC.

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

10.11.1. Lorazepam Macure – lorazepam - EMEA/H/A-13/1536

Macure Pharma ApS

Referral Rapporteur: TBC, Referral Co-Rapporteur: TBC

Scope: Appointment of Rapporteurs, list of questions (TBC), timetable

Action: For adoption

Variation number in decentralised procedure: NL/H/4353/001/II/004, notification sent by the Agency of The Netherlands dated 01 February 2024 notifying of the start of a referral under Article 13(1) of Regulation No 1234/2008.

11. Pharmacovigilance issue

11.1. Early Notification System

February 2024 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

Information related to GMP inspections will not be published as it undermines the purpose of such inspections

12.2. GCP inspections

Information related to GCP inspections will not be published as it undermines the purpose of such inspections

12.3. Pharmacovigilance inspections

Information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections

12.4. GLP inspections

Information related to GLP inspections will not be published as it undermines the purpose of such inspections

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

No items

13.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. CHMP co-opted membership

The 3-year co-opted member mandate for Carla Torre comes to an end on 21.02.2024.

The 3-year co-opted member mandate for Blanka Hirschlerova comes to an end on 18.03.2024.

The CHMP agreed that co-opted members should be appointed in the following areas of expertise:

- Position 1: Quality (non-biologicals),
- Position 2: Pharmacoepidemiology; especially for methodological analysis and interpretation of data in particular study designs*.

  *The experience in pharmacoepidemiology should be applied to regulatory decision-making processes. The interpretation of data in particular study designs should include strengths and weaknesses (observational studies, RWD from different sources).

A call for nomination of co-opted members was launched following the January 2024 plenary.

Nomination(s) received

Action: For election

14.1.2. SharePoint – CHMP presentations

Use of SharePoint for final power point presentations for CHMP plenaries as of March 2024.

Action: For information

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 February 2024

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

Agenda of the February 2024 PDCO plenary meeting.

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Francesca Luciani

Reports from BWP February 2024 meeting to CHMP for adoption:

- 16 reports on products in scientific advice and protocol assistance
- 14 reports on products in pre-authorisation procedures
- 4 reports on products in post-authorisation procedures
- 3 reports on products in plasma master file

Action: For adoption

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 13-14 February 2024.

Action: For adoption

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 05-08 February 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

No items

Explanatory notes

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

Oral explanations *(section 2)*

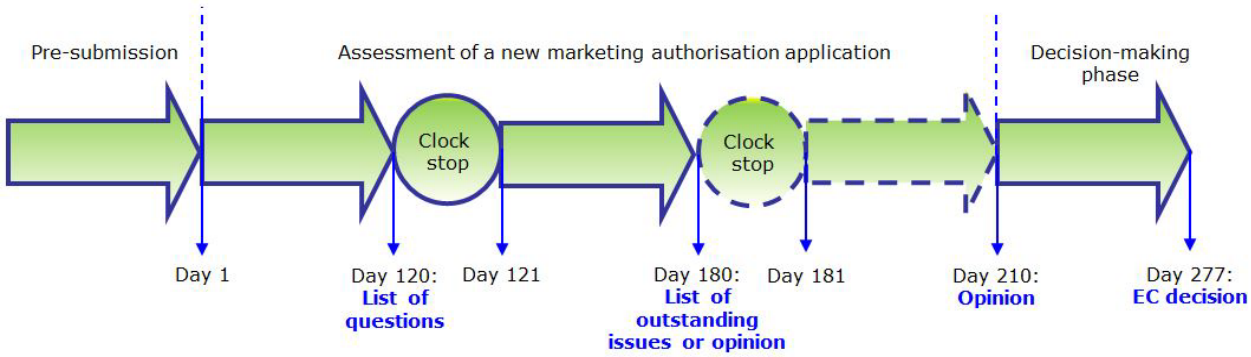
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 February 2024
EMA/CHMP/40566/2024

Annex to 19-22 February 2024 CHMP Agenda

Pre-submission and post-authorisations issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for February 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

IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/S/0095
Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer
Request for Supplementary Information adopted on 14.12.2023.

Lojuxta - Lomitapide - EMEA/H/C/002578/S/0057
Amryt Pharmaceuticals DAC, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder
Request for Supplementary Information adopted on 14.12.2023.

NULIBRY - Fosdenopterin - EMEA/H/C/005378/S/0006, Orphan
TMC Pharma (EU) Limited, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber

NYXTHRACIS - Obiltoxaximab - EMEA/H/C/005169/S/0013, Orphan
SFL Pharmaceuticals Deutschland GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Liana Martirosyan

Orphacol - Cholic acid -
EMEA/H/C/001250/S/0053
Theravia, Rapporteur: Anastasia Mountaki, PRAC Rapporteur: Sofia Trantza

Raxone - Idebenone -
EMEA/H/C/003834/S/0035, Orphan
Chiesi Farmaceutici S.p.A., Rapporteur: John Joseph Borg, PRAC Rapporteur: Amelia Cupelli

Upstaza - Eladocagene exuparvovec -
EMEA/H/C/005352/S/0017, Orphan, ATMP
PTC Therapeutics International Limited, Rapporteur: Joseph DeCourcey, PRAC Rapporteur: Gabriele Maurer
Request for Supplementary Information adopted on 08.12.2023.

Vedrop - Tocofersolan -
EMEA/H/C/000920/S/0049
Recordati Rare Diseases, Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Melinda Palfi

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

Lacosamide UCB - Lacosamide -
EMEA/H/C/005243/R/0020
UCB Pharma S.A., Informed Consent of Vimpat, Rapporteur: Filip Josephson, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Ulla Wändel Liminga

LysaKare - L-lysine hydrochloride / L-arginine hydrochloride -
EMEA/H/C/004541/R/0016
Advanced Accelerator Applications, Rapporteur: Janet Koenig, Co-Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Adam Przybylkowski
Request for Supplementary Information adopted on 25.01.2024.

Zydelig - Idelalisib -
EMEA/H/C/003843/R/0059
Gilead Sciences Ireland UC, Rapporteur: Filip Josephson, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Grasustek - Pegfilgrastim -
EMEA/H/C/004556/R/0014
Juta Pharma GmbH, Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Bianca Mulder
Request for Supplementary Information adopted on 14.12.2023.

Palynziq - Pegvaliase -
EMEA/H/C/004744/R/0038, Orphan
BioMarin International Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Rhea Fitzgerald
Request for Supplementary Information adopted on 09.11.2023.

Posaconazole Accord - Posaconazole -
EMEA/H/C/005005/R/0014
Accord Healthcare S.L.U., Generic, Generic of Noxafil, Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Nathalie Gault

Posaconazole AHCL - Posaconazole -
EMEA/H/C/005028/R/0011
Accord Healthcare S.L.U., Generic, Generic of Noxafil, Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Nathalie Gault

Talzenna - Talazoparib -
EMEA/H/C/004674/R/0017
Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, Co-Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Carla Torre
Request for Supplementary Information adopted on 25.01.2024.

Ultomiris - Ravulizumab -
EMEA/H/C/004954/R/0040
Alexion Europe SAS, Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Kimmo Jaakkola
Request for Supplementary Information adopted on 25.01.2024.

B.2.3. Renewals of Conditional Marketing Authorisations

Koselugo - Selumetinib -
EMEA/H/C/005244/R/0015, Orphan
AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Ulla Wändel Liminga

Lunsumio - Mosunetuzumab - EMEA/H/C/005680/R/0008, Orphan
Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga

Pandemic influenza vaccine H5N1 AstraZeneca - Pandemic influenza vaccine (H5N1) (live attenuated, nasal) - EMEA/H/C/003963/R/0071
AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sonja Hrabcik

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 05-08 February 2024 PRAC:

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

EMEA/H/C/PSUSA/00010066/202306
(avanafil)
CAPS:
Spedra (EMEA/H/C/002581) (Avanafil), Menarini International Operations Luxembourg S.A., Rapporteur: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Maria del Pilar Rayon, "22/06/2020 To: 21/06/2023"

EMEA/H/C/PSUSA/00010369/202306
(tedizolid phosphate)
CAPS:
Sivextro (EMEA/H/C/002846) (Tedizolid phosphate), Merck Sharp & Dohme B.V., Rapporteur: Bruno Sepodes, PRAC Rapporteur: Maria del Pilar Rayon, "20/06/2020 To: 20/06/2023"

EMEA/H/C/PSUSA/00010742/202307
(voretigene neparvovec)
CAPS:
Luxturna (EMEA/H/C/004451) (Voretigene neparvovec), Novartis Europharm Limited, Rapporteur: Sol Ruiz, CHMP Coordinator: Maria Concepcion Prieto Yerro, PRAC Rapporteur: Gabriele Maurer, "24/07/2022 To: 23/07/2023"

EMEA/H/C/PSUSA/00010903/202307
(brexucabtagene autoleucel)

CAPS: **Tecartus** (EMEA/H/C/005102) (Brexucabtagene autoleucel), Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "24/01/2023 To: 23/07/2023"	

B.4. EPARs / WPARs

EXBLIFEP - Cefepime / Enmetazobactam - EMEA/H/C/005431 Advanz Pharma Limited, treatment of the following infections in adults: • Complicated urinary tract infections (cUTI), including pyelonephritis. • Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP). Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Consideration should be given to official guidance on the appropriate use of antibacterial agents., 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.
Niapelf - Paliperidone - EMEA/H/C/006185 Neuraxpharm Pharmaceuticals S.L., Treatment of schizophrenia, Generic, Generic of Xeplion, Generic application (Article 10(1) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Ryzneuta - Efbemalenograstim alfa - EMEA/H/C/005828 Evive Biotechnology Ireland Limited, Reduction in the duration of neutropenia and the incidence of febrile neutropenia., New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Abiraterone Krka - Abiraterone acetate - EMEA/H/C/005649/II/0004 KRKA, d.d., Novo mesto, Generic, Generic of Zytiga, Rapporteur: Andreja Kranjc Opinion adopted on 15.02.2024. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 15.02.2024.

on 14.12.2023.	
Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0001 Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 14.12.2023.	
Accofil - Filgrastim - EMEA/H/C/003956/II/0060/G Accord Healthcare S.L.U., Rapporteur: Outi Mäki-Ikola Opinion adopted on 15.02.2024.	Positive Opinion adopted by consensus on 15.02.2024.
Adtralza - Tralokinumab - EMEA/H/C/005255/II/0015 LEO Pharma A/S, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 01.02.2024.	Request for supplementary information adopted with a specific timetable.
Apretude - Cabotegravir - EMEA/H/C/005756/II/0002/G ViiV Healthcare B.V., Duplicate, Duplicate of Vocabria, Rapporteur: Bruno Sepodes Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
Aybintio - Bevacizumab - EMEA/H/C/005106/II/0019/G Samsung Bioepis NL B.V., Rapporteur: Christian Gartner Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
Bevespi Aerosphere - Glycopyrronium / Formoterol fumarate dihydrate - EMEA/H/C/004245/II/0019/G AstraZeneca AB, Rapporteur: Kristina Dunder	
Bortezomib SUN - Bortezomib - EMEA/H/C/004076/II/0022 Sun Pharmaceutical Industries Europe B.V., Generic, Generic of VELCADE, Rapporteur: Margareta Bego Opinion adopted on 01.02.2024.	Positive Opinion adopted by consensus on 01.02.2024.
Cablivi - Caplacizumab - EMEA/H/C/004426/II/0047/G, Orphan Ablynx NV, Rapporteur: Filip Josephson Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
Cerezyme - Imiglucerase - EMEA/H/C/000157/II/0131 Sanofi B.V., Rapporteur: Patrick Vrijlandt Opinion adopted on 15.02.2024.	Positive Opinion adopted by consensus on 15.02.2024.

Request for Supplementary Information adopted on 14.12.2023.	
Cetrotide - Cetrorelix - EMEA/H/C/000233/II/0090 Merck Europe B.V., Rapporteur: Martina Weise Request for Supplementary Information adopted on 01.02.2024, 29.06.2023.	Request for supplementary information adopted with a specific timetable.
Circadin - Melatonin - EMEA/H/C/000695/II/0071/G RAD Neurim Pharmaceuticals EEC SARL, Rapporteur: Bruno Sepodes Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Diacomit - Stiripentol - EMEA/H/C/000664/II/0045/G BIOCODEX, Rapporteur: Alar Irs Opinion adopted on 15.02.2024. Request for Supplementary Information adopted on 23.11.2023.	Positive Opinion adopted by consensus on 15.02.2024.
Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0002 Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Elonva - Corifollitropin alfa - EMEA/H/C/001106/II/0067 Organon N.V., Rapporteur: Patrick Vrijlandt	
Empliciti - Elotuzumab - EMEA/H/C/003967/II/0037/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol Request for Supplementary Information adopted on 15.02.2024.	Request for supplementary information adopted with a specific timetable.
Empliciti - Elotuzumab - EMEA/H/C/003967/II/0038/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol Opinion adopted on 15.02.2024.	Positive Opinion adopted by consensus on 15.02.2024.
Enhertu - Trastuzumab - EMEA/H/C/005124/II/0043/G Daiichi Sankyo Europe GmbH, Rapporteur: Aaron Sosa Mejia Request for Supplementary Information adopted on 15.02.2024.	Request for supplementary information adopted with a specific timetable.
Eptifibatide Accord - Eptifibatide -	Request for supplementary information adopted

EMEA/H/C/004104/II/0015/G Accord Healthcare S.L.U., Generic, Generic of Integrilin, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 08.02.2024, 26.10.2023, 12.05.2023.	with a specific timetable.
Fasturtec - Rasburicase - EMEA/H/C/000331/II/0069 Sanofi Winthrop Industrie, Rapporteur: Peter Mol	
Flucelvax Tetra - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/004814/II/0044 Seqirus Netherlands B.V., Rapporteur: Sol Ruiz Request for Supplementary Information adopted on 18.01.2024.	
Fulphila - Pegfilgrastim - EMEA/H/C/004915/II/0046 Biosimilar Collaborations Ireland Limited, Rapporteur: Martina Weise Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
Hetlioz - Tasimelteon - EMEA/H/C/003870/II/0037, Orphan Vanda Pharmaceuticals Netherlands B.V., Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Iasibon - Ibandronic acid - EMEA/H/C/002025/II/0025 Pharmathen S.A., Generic, Generic of Bondronat, Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 01.02.2024. Request for Supplementary Information adopted on 21.09.2023.	Positive Opinion adopted by consensus on 01.02.2024.
Insuman - Insulin human - EMEA/H/C/000201/II/0146 Sanofi-Aventis Deutschland GmbH, Rapporteur: Karin Janssen van Doorn Request for Supplementary Information adopted on 15.02.2024.	Request for supplementary information adopted with a specific timetable.
Ixiaro - Japanese encephalitis vaccine (inactivated, adsorbed) - EMEA/H/C/000963/II/0116 Valneva Austria GmbH, Rapporteur: Jan Mueller-Berghaus	Positive Opinion adopted by consensus on 08.02.2024.

Opinion adopted on 08.02.2024.	
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0144 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini Opinion adopted on 15.02.2024. Request for Supplementary Information adopted on 14.12.2023.	Positive Opinion adopted by consensus on 15.02.2024.
Latuda - Lurasidone - EMEA/H/C/002713/II/0041 Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Rapporteur: Filip Josephson Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Nordimet - Methotrexate - EMEA/H/C/003983/II/0033/G Nordic Group B.V., Rapporteur: Bruno Sepodes Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
Nplate - Romiplostim - EMEA/H/C/000942/II/0090 Amgen Europe B.V., Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
Ontruzant - Trastuzumab - EMEA/H/C/004323/II/0049 Samsung Bioepis NL B.V., Rapporteur: Karin Janssen van Doorn Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
Palynziq - Pegvaliase - EMEA/H/C/004744/II/0039/G, Orphan BioMarin International Limited, Rapporteur: Patrick Vrijlandt Opinion adopted on 08.02.2024. Request for Supplementary Information adopted on 09.11.2023.	Positive Opinion adopted by consensus on 08.02.2024.
Pedmarqsi - Sodium thiosulfate - EMEA/H/C/005130/II/0002/G Fennec Pharmaceuticals (EU) Limited, Rapporteur: Elita Poplavska Request for Supplementary Information adopted on 01.02.2024.	Request for supplementary information adopted with a specific timetable.
Pemetrexed Accord - Pemetrexed - EMEA/H/C/004072/II/0028 Accord Healthcare S.L.U., Generic, Generic of Alimta, Rapporteur: John Joseph Borg Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 15.02.2024.	
Qarziba - Dinutuximab beta - EMEA/H/C/003918/II/0056/G, Orphan Recordati Netherlands B.V., Rapporteur: Peter Mol Request for Supplementary Information adopted on 15.02.2024.	Request for supplementary information adopted with a specific timetable.
Reblozyl - Luspatercept - EMEA/H/C/004444/II/0027, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Daniela Philadelphy Request for Supplementary Information adopted on 15.02.2024.	Request for supplementary information adopted with a specific timetable.
Ryzodeg - Insulin aspart / Insulin degludec - EMEA/H/C/002499/II/0054 Novo Nordisk A/S, Rapporteur: Kristina Dunder Opinion adopted on 15.02.2024. Request for Supplementary Information adopted on 14.12.2023.	Positive Opinion adopted by consensus on 15.02.2024.
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0046/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Skytrofa - Lonapegsomatropin - EMEA/H/C/005367/II/0024, Orphan Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 01.02.2024.	Request for supplementary information adopted with a specific timetable.
Skytrofa - Lonapegsomatropin - EMEA/H/C/005367/II/0025/G, Orphan Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Spectrila - Asparaginase - EMEA/H/C/002661/II/0036 medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Christian Gartner	
Sugammadex Mylan - Sugammadex - EMEA/H/C/005403/II/0010/G Mylan Ireland Limited, Generic, Generic of Bridion, Rapporteur: Hrefna Gudmundsdottir	

Suliqua - Insulin glargine / Lixisenatide - EMEA/H/C/004243/II/0037/G Sanofi Winthrop Industrie, Rapporteur: Kristina Dunder Opinion adopted on 15.02.2024. Request for Supplementary Information adopted on 14.12.2023.	Positive Opinion adopted by consensus on 15.02.2024.
Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0015/G Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
TEPMETKO - Tepotinib - EMEA/H/C/005524/II/0012 Merck Europe B.V., Rapporteur: Filip Josephson Request for Supplementary Information adopted on 18.01.2024.	
Tresiba - Insulin degludec - EMEA/H/C/002498/II/0060 Novo Nordisk A/S, Rapporteur: Kristina Dunder Opinion adopted on 15.02.2024. Request for Supplementary Information adopted on 14.12.2023.	Positive Opinion adopted by consensus on 15.02.2024.
Trumenba - Meningococcal group B vaccine (recombinant, adsorbed) - EMEA/H/C/004051/II/0050/G Pfizer Europe MA EEIG, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 14.12.2023.	
Zebinix - Eslicarbazepine acetate - EMEA/H/C/000988/II/0089/G Bial - Portela & Cª, S.A., Rapporteur: Martina Weise Request for Supplementary Information adopted on 15.02.2024.	Request for supplementary information adopted with a specific timetable.
Zirabev - Bevacizumab - EMEA/H/C/004697/II/0032 Pfizer Europe MA EEIG, Rapporteur: Eva Skovlund Request for Supplementary Information adopted on 01.02.2024.	Request for supplementary information adopted with a specific timetable.
Zoonotic Influenza Vaccine Seqirus - Zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - EMEA/H/C/006375/II/0001	

Seqirus S.r.l., Informed Consent of Aflunov, Rapporteur: Maria Grazia Evandri Request for Supplementary Information adopted on 25.01.2024.	
WS2598/G **Ambirix-** **EMEA/H/C/000426/WS2598/0131/G** **Fendrix-** **EMEA/H/C/000550/WS2598/0084/G** **Infanrix hexa-** **EMEA/H/C/000296/WS2598/0338/G** **Twinrix Adult-** **EMEA/H/C/000112/WS2598/0166/G** **Twinrix Paediatric-** **EMEA/H/C/000129/WS2598/0167/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke	
WS2600 **Infanrix hexa-** **EMEA/H/C/000296/WS2600/0339** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 15.02.2024.	Positive Opinion adopted by consensus on 15.02.2024.
WS2608/G **Apretude-** **EMEA/H/C/005756/WS2608/0001/G** **Vocabria-** **EMEA/H/C/004976/WS2608/0020/G** ViiV Healthcare B.V., Duplicate, Duplicate of Vocabria, Lead Rapporteur: Bruno Sepodes Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
WS2616/G **Hexacima-** **EMEA/H/C/002702/WS2616/0153/G** **Hexyon-** **EMEA/H/C/002796/WS2616/0157/G** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus	
WS2625 **Hukyndra-** **EMEA/H/C/005548/WS2625/0020** **Libmyris-** **EMEA/H/C/005947/WS2625/0009** STADA Arzneimittel AG, Lead Rapporteur: Outi Mäki-Ikola Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.

Mosquirix- **EMEA/H/W/002300/WS2585/0078** **Shingrix-** **EMEA/H/C/004336/WS2585/0071** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 01.02.2024.	Positive Opinion adopted by consensus on 01.02.2024.

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

BIMERVAX - PHH-1V81 / Selvacovatein - EMEA/H/C/006058/II/0004 Hipra Human Health S.L., Rapporteur: Beata Maria Jakline Ullrich, "Update of sections 4.8 and 5.1 of the SmPC in order to add safety and immunogenicity information after a fourth dose based on interim results from study HIPRA-HH-2) listed as a category 3 study in the RMP; this is A Phase IIb, Double-Blind, Randomised, Active -Controlled, Multicentre, Non-Inferiority Trial Followed By A Phase III, Single-Arm, Open-Label Trial To Assess Immunogenicity And Safety Of A Booster Vaccination With A Recombinant Protein RBD Fusion Dimer Candidate (PHH-1V) Against SARS-COV-2 In Adults Fully Vaccinated Against Covid-19 Followed By An Extension Period To Study A Fourth Dose Administration Of PHH-1V. The Package Leaflet is updated accordingly. In addition, the MAH submitted the full user consultation with target patient groups." Request for Supplementary Information adopted on 14.12.2023, 14.09.2023.	
BLINCYTO - Blinatumomab - EMEA/H/C/003731/II/0053/G, Orphan Amgen Europe B.V., Rapporteur: Alexandre Moreau, "A grouped application consisting of: Type II (C.I.4): Update of sections 4.2, 5.1 and 6.6 of the SmPC in order to update the dexamethasone premedication guidance for paediatric patients with relapsed/refractory and high-risk first relapsed ALL, to add dexamethasone premedication information from study MT103-205 and study 20120215, and to add a statement that the administration of Blincyto for BSA of less than 0.4 m2 has not been established. In addition, the MAH took the opportunity to update the name of ATC pharmacological subgroup according to WHO ATC Index and to delete "intravenous catheter"	

from the important note statement regarding flushing and to introduce minor editorial changes to the PI. The Package Leaflet is updated accordingly. Type IB (C.I.11.z): Update of the due dates for post-authorisation safety studies 20150136 and 20180130 in the Annex II D in order to align with the RMP version 16.0, following commitment agreed on during procedure EMEA/H/C/003731/IB/0050." Request for Supplementary Information adopted on 14.09.2023.	
Brilique - Ticagrelor - EMEA/H/C/001241/II/0061 AstraZeneca AB, Rapporteur: Patrick Vrijlandt, "Update of sections 4.2 and 4.4 of the SmPC in order to include a warning related to Single Antiplatelet Therapy (SAPT) in Patients with Acute Coronary Syndrome (ACS) who have undergone a Percutaneous Coronary Intervention (PCI) procedure and who have an increased risk of bleeding based on literature." Request for Supplementary Information adopted on 14.09.2023.	
BYANNLI - Paliperidone - EMEA/H/C/005486/II/0005 Janssen-Cilag International N.V., Informed Consent of Xeplion, Rapporteur: Kristina Dunder, "Submission of the Environmental Risk Assessment Report and environmental risk studies (OECD 232, OECD 307 and OECD 308)." Opinion adopted on 01.02.2024.	Positive Opinion adopted by consensus on 01.02.2024.
Darzalex - Daratumumab - EMEA/H/C/004077/II/0070, Orphan Janssen-Cilag International N.V., Rapporteur: Aaron Sosa Mejia, "Update of section 5.1 of the SmPC in order to update efficacy information based on the final overall survival analysis results from study MMY3007. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes." Opinion adopted on 15.02.2024.	Positive Opinion adopted by consensus on 15.02.2024.
Evrysdi - Risdiplam - EMEA/H/C/005145/II/0021 Roche Registration GmbH, Rapporteur: Bruno Sepodes, "Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy and safety	Positive Opinion adopted by consensus on 01.02.2024.

information based on primary analysis results from study BN40703 (RAINBOWFISH); this is an open-label, single-arm, multicenter clinical study to investigate the efficacy, safety, pharmacokinetics, and pharmacodynamics of risdiplam in patients aged from birth to 6 weeks (at first dose) who are genetically diagnosed with SMA (SMN1 deletion and any SMN2 copies) but not yet presenting with symptoms. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the Instructions for Use." Opinion adopted on 01.02.2024.	
Jentadueto - Linagliptin / Metformin hydrochloride - EMEA/H/C/002279/II/0070 Boehringer Ingelheim International GmbH, Rapporteur: Patrick Vrijlandt, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on final results from study DINAMO 1218-0091; this is a double-blind, randomised, placebo-controlled, parallel group trial to evaluate the efficacy and safety of empagliflozin and linagliptin over 26 weeks, with a double-blind active treatment safety extension period up to 52 weeks, in children and adolescents with type 2 diabetes mellitus. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0147 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study KEYNOTE-B61; this is a Phase 2, Single-arm, Open-label Clinical Trial of Pembrolizumab Plus Lenvatinib in Participants with First-line Advanced/Metastatic Non-clear Cell Renal Cell Carcinoma (nccRCC)." Request for Supplementary Information adopted on 01.02.2024.	Request for supplementary information adopted with a specific timetable.
Kineret - Anakinra - EMEA/H/C/000363/II/0092 Swedish Orphan Biovitrum AB (publ), Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.8 of the SmPC in order to	Positive Opinion adopted by consensus on 08.02.2024.

add 'Injection site amyloid deposits' to the list of adverse drug reactions (ADRs) with frequency not known, based on a review of the clinical study and post-marketing data to evaluate a possible causal association between anakinra (Kineret) and amyloidosis. The Package Leaflet is updated accordingly." Opinion adopted on 08.02.2024.	
Kisplyx - Lenvatinib - EMEA/H/C/004224/II/0058 Eisai GmbH, Rapporteur: Karin Janssen van Doorn, "Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study KEYNOTE-B61; this is a phase 2, single-arm, open-label clinical trial of pembrolizumab plus lenvatinib in participants with first-line advanced/metastatic non-clear cell Renal Cell Carcinoma (nccRCC). In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 01.02.2024.	Request for supplementary information adopted with a specific timetable.
Kisqali - Ribociclib - EMEA/H/C/004213/II/0041/G Novartis Europharm Limited, Rapporteur: Filip Josephson, "Grouped application comprising two type II variations as follows: - Update of section 5.2 of the SmPC in order to update absorption information based on final results from study CLEE011A2117, a Phase I, single center, two-period, two-treatment, open label, randomized crossover study to investigate the absolute bioavailability of a single oral dose of 600 mg of ribociclib relative to an intravenous (i.v.) infusion of 150 mg ribociclib in healthy subjects. - Update of sections 4.2 and 4.5 of the SmPC in order to update the recommended dose modification when ribociclib is administered in combination with CYP3A4 inhibitors and update the drug-drug interaction information on substances that may increase ribociclib plasma concentrations based on the updated PBPK modelling. In addition, the MAH took this opportunity to introduce minor editorial changes to the Package Leaflet." Request for Supplementary Information adopted on 25.01.2024, 12.10.2023, 22.06.2023.	

Mavenclad - Cladribine - EMEA/H/C/004230/II/0032 Merck Europe B.V., Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.4 of the SmPC in order to update an existing warning on infections. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce an editorial update to the PI." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Nexviadyme - Avalglucosidase alfa - EMEA/H/C/005501/II/0015 Sanofi B.V., Rapporteur: Christian Gartner, "Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update safety and efficacy information based on final results from study EFC14028 - COMparative Enzyme replacement Trial with neoGAA versus rhGAA (COMET), listed as a category 3 study in the RMP. This is a phase 3 randomized, multicenter, multinational, double-blinded study comparing the efficacy and safety of repeated biweekly infusions of avalglucosidase alfa (neoGAA, GZ402666) and alglucosidase alfa in treatment naive patients with late onset Pompe disease. In addition, the MAH took this opportunity to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Olumiant - Baricitinib - EMEA/H/C/004085/II/0046 Eli Lilly Nederland B.V., Rapporteur: Peter Mol, "Update of section 5.1 of the SmPC in order to add information on JIA-associated uveitis or chronic anterior antibody positive uveitis based on interim results from study I4VMC-JAHW; this is an open-label, active-controlled, safety, and efficacy study of oral baricitinib in patients from 2 years to less than 18 years old with active juvenile idiopathic arthritis-associated uveitis or chronic anterior antinuclear antibody-positive uveitis." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Oxlumo - Lumasiran - EMEA/H/C/005040/II/0017, Orphan Alnylam Netherlands B.V., Rapporteur: Martina Weise, "Submission of the final report from	Positive Opinion adopted by consensus on 08.02.2024.

study ALN-GO1-002 (study 002), listed as a category 3 study in the RMP. This is a phase 2, multicenter, open-label, extension study to evaluate the long-term administration of ALN-GO1 in patients with primary hyperoxaluria type 1." Opinion adopted on 08.02.2024.	
OZAWADE - Pitolisant - EMEA/H/C/005117/II/0007 Bioprojet Pharma, Rapporteur: Peter Mol, "Submission of the final report from study P21-03. This is an open label, single center, drug-drug interaction study to evaluate the effect of a combination of itraconazole and paroxetine treatment on the pitolisant pharmacokinetics at steady-state in eighteen healthy male Caucasian subjects." Request for Supplementary Information adopted on 01.02.2024.	Request for supplementary information adopted with a specific timetable.
PONVORY - Ponesimod - EMEA/H/C/005163/II/0014 Janssen-Cilag International N.V., Rapporteur: Peter Mol, "Update of section 4.5 of the SmPC to amend an existing interaction wording for carbamazepine under the sub-heading "Effect of other medicinal products on ponesimod" based on study 67896153MSC1001. This is a Phase 1, Open-label, Parallel-group Study to Assess the Effect of Steady-state Carbamazepine on the Pharmacokinetics of Ponesimod in Healthy Adult Participants. In addition, the MAH took the opportunity to update the contact details of local representatives in the Package Leaflet." Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
QUVIVIQ - Daridorexant - EMEA/H/C/005634/II/0013/G Idorsia Pharmaceuticals Deutschland GmbH, Rapporteur: Alexandre Moreau, "Update of sections 4.4, 4.5 and 5.1 of the SmPC in order to reflect the conclusions of studies ID-075-121, ID-078-122 and ID-078-118, respectively. The Package Leaflet was updated accordingly. Study ID-078-121 is a randomized, double-blind, placebo-controlled, 2-way crossover study to investigate the effects of daridorexant on nighttime respiratory function and sleep in subjects with severe obstructive sleep apnea; study ID-078-122 is a prospective, open-label, single-dose Phase 1 study to measure	Request for supplementary information adopted with a specific timetable.

daridorexant in breast milk of healthy lactating women; and study ID-078-118 is a single-center, randomized, double-blind, single-dose, 3-way crossover study to compare the effects of daridorexant and placebo on postural stability, the auditory awakening threshold, and cognitive function in the middle of the night following evening administration to healthy adult and elderly subjects." Request for Supplementary Information adopted on 01.02.2024.	
Spinraza - Nusinersen - EMEA/H/C/004312/II/0032, Orphan Biogen Netherlands B.V., Rapporteur: Bruno Sepodes, "Update of section 4.8 of the SmPC in order to add 'Arachnoiditis' to the list of adverse drug reactions (ADRs) with frequency not known, based on postmarketing review. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
TAGRISSO - Osimertinib - EMEA/H/C/004124/II/0054 AstraZeneca AB, Rapporteur: Carolina Prieto Fernandez, "Update of section 4.8 of the SmPC to add 'Skin Hyperpigmentation' to the list of adverse drug reactions (ADRs) with frequency 'uncommon' based on literature. The package leaflet has been updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the package leaflet." Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
TEPMETKO - Tepotinib - EMEA/H/C/005524/II/0011 Merck Europe B.V., Rapporteur: Filip Josephson, "Update of section 4.2 of the SmPC in order to add alternative methods of administration dispersed in water, as oral drinking suspension or via feeding tubes based on the available physicochemical and clinical pharmacology data. The Package Leaflet is updated accordingly."	
Translarna - Ataluren - EMEA/H/C/002720/II/0074, Orphan PTC Therapeutics International Limited, Rapporteur: Peter Mol, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to change posology recommendations in the paediatric	

population, to update the summary of safety profile and to update efficacy, safety and pharmacokinetic information on the paediatric population based on the final results from study PTC124-GD-048-DMD "A Phase 2, multiple-dose, open-label study evaluating the safety and PK of ataluren in patients with nmDMD aged ≥6 months to <2 years old" (MEA-018). The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes to the PI." Request for Supplementary Information adopted on 14.12.2023.	
Venclyxto - Venetoclax - EMEA/H/C/004106/II/0047 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Filip Josephson, "Submission of the final report from study GO28667 (MURANO) listed as a category 3 study in the RMP. This is a Multicenter, Phase III, Open-Label, Randomized Study in Relapsed/Refractory Patients with Chronic Lymphocytic Leukemia to Evaluate the Benefit of GDC-0199 (ABT-199) Plus Rituximab Compared with Bendamustine Plus Rituximab." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
VidPrevtyn Beta - SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant - EMEA/H/C/005754/II/0007/G Sanofi Pasteur, Rapporteur: Jan Mueller-Berghaus, "A grouped application consisting of: Type II (C.I.4): Update of section 4.8 of the SmPC in order to include additional safety data based on safety update reports from studies VAT00008 booster extension and VAT00002 Cohort 2, in order to fulfill REC 20. Type IA (A.6): To change the ATC Code of the COVID-19 protein subunit vaccine from J07BX03 to J07BN04." Opinion adopted on 15.02.2024. Request for Supplementary Information adopted on 14.12.2023.	Positive Opinion adopted by consensus on 15.02.2024.
Vocabria - Cabotegravir - EMEA/H/C/004976/II/0019 ViiV Healthcare B.V., Rapporteur: Jean-Michel Race, "Update of section 4.2 of the SmPC in order to update administration instructions to mitigate product leakage related to the correct	Positive Opinion adopted by consensus on 08.02.2024.

use of the vial adapter, based on Human Factor studies. The Package Leaflet (Instructions for Use) is updated accordingly." Opinion adopted on 08.02.2024.	
Xevudy - Sotrovimab - EMEA/H/C/005676/II/0024 Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC in order to include virology information based on data from various pharmacology studies on the in vitro activity of sotrovimab in a pseudotyped virus assay against the SARS-CoV-2 Omicron variants named XBB.1.16 and XBB.2.3, XBB.1.16.1, XBB.1.5.10 as well as data on the in vitro activity of sotrovimab in an authentic virus assay against the SARS-CoV-2 XBB.1.16, BA.2.75, BA.4.6 and BQ.1.1 variants. Based on the data reported in PC-23-0139, under this variation application, in addition to the proposed SmPC updates, the MAH also proposed a change to the current methodology for assessment of the in vitro neutralization potency of sotrovimab against SARS-CoV-2 variants (change in target cells used for the authentic virus neutralization assay, from the currently used Vero-TMPRSS2 cells, back to the previously used VeroE6 cells)." Opinion adopted on 15.02.2024. Request for Supplementary Information adopted on 11.01.2024.	Positive Opinion adopted by consensus on 15.02.2024.
Zeffix - Lamivudine - EMEA/H/C/000242/II/0087 GlaxoSmithKline (Ireland) Limited, Duplicate, Duplicate of Epivir, Rapporteur: Jean-Michel Race, "Update of section 4.4 of the SmPC in order to amend an existing warning on HIV co-infection. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI. The requested variation proposed amendments to the Summary of Product Characteristics and Package Leaflet." Opinion adopted on 15.02.2024.	Positive Opinion adopted by consensus on 15.02.2024.
WS2544 **Ebymect-** **EMEA/H/C/004162/WS2544/0064** **Komboglyze-**	Positive Opinion adopted by consensus on 08.02.2024.

EMEA/H/C/002059/WS2544/0057 **Xigduo-EMEA/H/C/002672/WS2544/0074** AstraZeneca AB, Lead Rapporteur: Kristina Dunder, "Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Vitamin B12 decrease/deficiency' and to change the frequency of 'Vitamin B12 decrease/deficiency' in the list of adverse drug reactions (ADRs) from frequency 'very rare' to 'common'. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the contact details of the local representative in the Netherlands in the Package Leaflet." Opinion adopted on 08.02.2024. Request for Supplementary Information adopted on 21.09.2023.	
WS2583 **Stayveer-EMEA/H/C/002644/WS2583/0040** **Tracleer-EMEA/H/C/000401/WS2583/0105** Janssen-Cilag International N.V., Lead Rapporteur: Alexandre Moreau, "Update of section 4.6 of the SmPC to update the wording concerning breast feeding based on literature and post-marketing data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
WS2597 **OPDIVO-EMEA/H/C/003985/WS2597/0138** **Yervoy-EMEA/H/C/002213/WS2597/0107** Bristol-Myers Squibb Pharma EEIG, Lead Rapporteur: Carolina Prieto Fernandez, "Update of sections 4.4 and 4.8 of the SmPC in order to add 'myelitis' as a warning under the subsection "Other immune-mediated adverse reactions" and to the list of adverse drug reactions (ADRs) with their calculated frequencies for monotherapy (not known) and in combination (rare), based on 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 in line with the QRD." Opinion adopted on 15.02.2024.	Positive Opinion adopted by consensus on 15.02.2024.

Request for Supplementary Information adopted on 11.01.2024.	

B.5.3. CHMP-PRAC assessed procedures

Beyfortus - Nirsevimab - EMEA/H/C/005304/II/0018/G Sanofi Winthrop Industrie, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Kimmo Jaakkola, "Grouped application comprising two type II variations as follows: C.I.13: Submission of the final report from study D5290C00004 (MELODY) listed as a category 3 study in the RMP. This is a phase III study, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of MEDI8897, a monoclonal antibody with an extended half-life against respiratory syncytial virus, in healthy late preterm and term infants. C.I.13: Submission of the final report from study D5290C00005 (MEDLEY) listed as a category 3 study in the RMP. This is a phase II/III study, randomized, double-blind, placebo-controlled study to evaluate the safety of Beyfortus (nirsevimab) in high-risk children. The RMP version 2.3 has also been submitted." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
GAVRETO - Pralsetinib - EMEA/H/C/005413/II/0012 Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2, 4.4 and 4.5 of the SmPC in order to amend posology recommendations, warnings and drug-drug interaction information regarding the co-administration with CYP3A4 inhibitors, P-gp inhibitors and CYP3A4 inducers based on final results from the DDI study GP43162, listed as a category 3 study in the RMP, as well as results from the physiologically based pharmacokinetic (PBPK) analyses summarised in the PBPK Report 1120689. Study GP43162 is a phase 1, open-label, fixed-sequence study to evaluate the effect of a single dose of cyclosporine on the single dose pharmacokinetics of pralsetinib in healthy subjects. The RMP version 1.6 has also been submitted." Request for Supplementary Information adopted	

on 09.11.2023, 22.06.2023, 30.03.2023.	
GAVRETO - Pralsetinib - EMEA/H/C/005413/II/0017 Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2 and 5.2 of the SmPC in order to include information regarding moderate and severe hepatic impairment based on final results from study GP43163 listed as a category 3 study in the RMP; this is a Phase I, open-label, single-dose study to evaluate the pharmacokinetics and safety of pralsetinib in subjects with moderate or severe hepatic impairment compared to healthy subjects. The RMP version 1.8 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to update the marketing authorisation renewal date in Annex I." Request for Supplementary Information adopted on 14.12.2023.	
Inrebic - Fedratinib - EMEA/H/C/005026/II/0019, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, PRAC Rapporteur: Sonja Hrabcik, "Update of sections 4.2 and 5.2 of the SmPC in order to update posology recommendations in patients with severe hepatic impairment and to update pharmacokinetic information based on final results from study FEDR-CP-001 listed as a category 3 study in the RMP; this is a phase 1, open-label, single-dose study to assess the pharmacokinetics, safety, and tolerability of fedratinib in subjects with moderate and severe hepatic impairment compared with healthy subjects. The RMP version 2.0 has also been submitted."	
Onpattro - Patisiran - EMEA/H/C/004699/II/0034, Orphan Alnylam Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Rhea Fitzgerald, "Submission of the final report from study ALN-TTR02-006 (study 006), listed a category 3 study in the RMP. This is a multicenter, open-label, extension study to evaluate the long-term safety and efficacy of patisiran in patients with familial amyloidotic polyneuropathy who have completed a prior clinical study with patisiran. The RMP version 2.2 has also been submitted."	Positive Opinion adopted by consensus on 08.02.2024.

Opinion adopted on 08.02.2024. Request for Supplementary Information adopted on 28.09.2023.	
Piqray - Alpelisib - EMEA/H/C/004804/II/0022/G Novartis Europharm Limited, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder, "Grouped application comprising two type II variations (C.I.4) as follows: - Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update information on prophylactic use of metformin for hyperglycaemia based on the results from study CBYL719CES01T (METALLICA). METALLICA is a Phase II study aimed to evaluate the effect of prophylactic use of metformin for hyperglycaemia in HR-positive, HER2-negative, PIK3CA-mutated advanced breast cancer patients treated with alpelisib plus endocrine therapy. - Update of section 4.8 of the SmPC in order to add "uveitis" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on a cumulative review of the MAH safety database and literature. The Package Leaflet and Annex II are updated accordingly. The RMP version 7.0 has also been submitted." Request for Supplementary Information adopted on 30.11.2023.	
Reagila - Cariprazine - EMEA/H/C/002770/II/0034 Gedeon Richter Plc., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ana Sofia Diniz Martins, "Update of sections 4.3 and 4.5 of the SmPC in order to update an existing contraindication and update drug-drug interaction information with CYP3A4 inhibitors, based on final results from study RGH-188-301 (CYPRESS) listed as a category 3 study in the RMP; this is an open-label, single-arm, fixed-sequence study to investigate the effect of erythromycin, a moderate CYP3A4 inhibitor on the pharmacokinetics of cariprazine in male patients with schizophrenia. The Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	Request for supplementary information adopted with a specific timetable.

Request for Supplementary Information adopted on 08.02.2024, 26.10.2023.	
SARCLISA - Isatuximab - EMEA/H/C/004977/II/0026 Sanofi Winthrop Industrie, Rapporteur: Peter Mol, PRAC Rapporteur: Monica Martinez Redondo, "Update of sections 4.2, 4.4 and 5.2 of the SmPC based on final results from study TED16414, listed as a category 3 study in the RMP; this is a phase 1b/2 open label, non-randomized, multi center study to evaluate the safety, pharmacokinetics, and preliminary efficacy of isatuximab (SAR650984) in patients awaiting kidney transplantation. The Package Leaflet is updated accordingly. The RMP version 1.4 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	
Tecentriq - Atezolizumab - EMEA/H/C/004143/II/0083/G Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, PRAC Rapporteur: Carla Torre, "A grouped application comprising of 2 Type II variations, as follows: C.I.4: Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study IMvigor210 (GO29293) listed as a PAES in the Annex II; this is a Phase II, multicenter, single-arm study of atezolizumab in patients with locally advanced or metastatic urothelial bladder cancer. The Annex II is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template. C.I.13: Submission of the final report from study SAUL (MO29983) listed as a category 3 study in the RMP. This is an open-label, single arm, multicenter, safety study of atezolizumab in locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract. The RMP version 30.0 has also been submitted." Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
Vabysmo - Faricimab - EMEA/H/C/005642/II/0009 Roche Registration GmbH, Rapporteur: Jayne Crowe, PRAC Rapporteur: Carla Torre, "Update of section 4.8 of the SmPC in order to add 'Retinal Vasculitis' and 'Retinal Occlusive	Positive Opinion adopted by consensus on 08.02.2024.

Vasculitis' to the list of adverse drug reactions (ADRs) with frequency not known, based on a drug safety report and post-marketing data; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to add study CR45271 as a category 3 study in the RMP, to introduce minor changes and corrections to the PI and to update the list of local representatives in the Package Leaflet." Opinion adopted on 08.02.2024.	
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0096 AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.8 and 5.1 of the SmPC based on final results from study D7220C00001; this is a phase 2/3 partially double-blinded, randomised, multinational, active-controlled study in both previously vaccinated and unvaccinated adults to determine the safety and immunogenicity of AZD2816, a vaccine for the prevention of COVID-19 caused by variant strains of SARS-CoV-2. The RMP version 8 s1 has also been submitted." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Vaxzevria - COVID 19 Vaccine (ChAdOx1 S [recombinant]) - EMEA/H/C/005675/II/0097 AstraZeneca AB, Rapporteur: Sol Ruiz, PRAC Rapporteur: Jean-Michel Dogné, "Submission of the final report from study D8110C00001 listed as a category 3 study in the RMP (SOB/020). This is a phase III, randomised, placebo-controlled study of AZD1222 (Vaxzevria) conducted in the US, Peru and Chile. The purpose of the final CSR addendum is to provide long-term safety data through to study completion and include the second year of follow-up post-first dose and final day 730 visit. The RMP version 8 s2 has also been submitted." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
Xevudy - Sotrovimab - EMEA/H/C/005676/II/0026 Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC	Request for supplementary information adopted with a specific timetable.

Rapporteur: Liana Martirosyan, "To update sections 4.2, 4.8 and 5.2 of the SmPC in order to update information on the paediatric population based on final results from study COMET-PACE (215226), a category 3 study in the RMP; this is an open-label, non-comparator, multicentre study to describe the pharmacokinetics (PK), pharmacodynamics (PD; viral load) and safety following a single intravenous or intramuscular dose of sotrovimab in paediatric participants with mild to moderate COVID-19 at high risk of disease progression. The updated RMP version 1.1 has also been submitted." Request for Supplementary Information adopted on 08.02.2024.	
WS2631 **Kisplyx-EMEA/H/C/004224/WS2631/0059** **Lenvima-EMEA/H/C/003727/WS2631/0054** Eisai GmbH, Lead Rapporteur: Karin Janssen van Doorn, Lead PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC for Kisplyx and sections 4.8 and 5.1 of the SmPC for Lenvima, in order to reflect the results of two completed paediatric clinical studies E7080-G000-216 and E7080-G000-231. Study 231 is a Phase 2, open-label, multicenter basket study to evaluate the antitumor activity and safety of Lenvatinib in children, adolescents, and young adults with relapsed or refractory solid malignancies. Study 216 is a Phase 1/2, multicenter, open-label, single arm study of lenvatinib in combination with everolimus in pediatric subjects (and young adults aged ≤21 years) with relapsed or refractory malignant solid tumors. The Package Leaflet for Kisplyx is updated accordingly. The RMP version 15.3 has also been submitted."	

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 and 4.8 of the SmPC to include Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS);	Request for supplementary information adopted with a specific timetable.

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 08.02.2024.	
PRAC Led **Entyvio - Vedolizumab - EMEA/H/C/002782/II/0081** Takeda Pharma A/S, PRAC Rapporteur: Adam Przybylkowski, PRAC-CHMP liaison: Ewa Balkowiec Iskra, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from study Vedolizumab-5001 (OTIS Entyvio Pregnancy Exposure Registry); this is a non-interventional study to monitor planned and unplanned pregnancies in female patients with ulcerative colitis or Crohn's disease. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes and corrections to the PI and bring it in line with the latest QRD template." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **HEPLISAV B - Hepatitis B surface antigen (rDNA) - EMEA/H/C/005063/II/0031** Dynavax GmbH, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of section 4.6 of the SmPC in order to update information on pregnancy based on final results from study DV2-HBV-28 - Post-marketing observational surveillance study to evaluate pregnancy outcomes among women who receive HEPLISAV-B or Engerix-B; HBV-28 was conducted using the same patient population as two observational post-marketing surveillance studies designed to evaluate the incidence of AMI (HBV-25) or new-onset immunemediated diseases, herpes zoster, and anaphylaxis (HBV-26) in recipients of HEPLISAV-B compared with recipients of Engerix-B. The primary objective of this study	Positive Opinion adopted by consensus on 08.02.2024.

was to describe and compare pregnancy outcomes in recipients of HEPLISAV-B and recipients of Engerix-B. The Package Leaflet is updated accordingly. The RMP version 1.4 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3." Opinion adopted on 08.02.2024. Request for Supplementary Information adopted on 30.11.2023.	
PRAC Led **MabThera - Rituximab - EMEA/H/C/000165/II/0201/G** Roche Registration GmbH, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Aaron Sosa Mejia, "A grouped application comprising of: Type II (C.I.3.b): Update of sections 4.1, 4.2, 4.3, 4.8, 5.1, 6.2, 6.4 and 6.5 of the SmPC in order to introduce several structural and editorial changes to align with the current SmPC guideline and to remove the educational materials for HCPs and patients, following the request by the PRAC in the AR for the PSUSA procedure EMA/PRAC/257005/2023. The Annex II, Labelling and Package Leaflet are updated accordingly. The RMP version 25.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet. Type I (A.6): To change the ATC Code of rituximab from L01XC02 to L01FA01. Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Mysimba - Naltrexone hydrochloride / Bupropion hydrochloride - EMEA/H/C/003687/II/0063** Orexigen Therapeutics Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "To update sections 4.3, 4.4 and 4.5 of the SmPC to update and streamline the relevant wording on opioids following the assessment of PSUSA/00010366/202209 procedure. The Package Leaflet is updated accordingly. The RMP version 12.9 has also been submitted." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 09.02.2024, 31.08.2023.	
PRAC Led **RAYVOW - Lasmiditan - EMEA/H/C/005332/II/0005** Eli Lilly Nederland B.V., PRAC Rapporteur: Anna Mareková, PRAC-CHMP liaison: Frantisek Drafi, "Submission of an updated RMP version 1.1 in order to include a descriptive interim analysis in the study design of study H8H-MC-B006, listed as a category 3 study in the RMP. This is a non-interventional study titled 'Lasmiditan Use and Motor Vehicle Accidents in Real-World Settings in the US'." Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
PRAC Led **SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0049, Orphan** Clinuvel Europe Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "To remove study CUV-RCR-001 (Scenesse (Afamelanotide 16mg) Retrospective Chart Review) listed as an obligation in the Annex II of the Product Information. This is a retrospective study comparing long-term safety data and outcome endpoints in patients receiving and not receiving Scenesse, or having discontinued Scenesse use. The Annex II and the RMP (version 9.6) are updated accordingly." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Spravato - Esketamine - EMEA/H/C/004535/II/0021** Janssen-Cilag International N.V., PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of an updated RMP version 5.2 in order to remove "use during pregnancy" as missing information from the list of safety concerns, with the consequential removal of the associated category 3 additional pharmacovigilance activity, the National Pregnancy Registry for Antidepressants ("Massachusetts General Hospital (MGH) pregnancy registry)." Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
PRAC Led **Stelara - Ustekinumab - EMEA/H/C/000958/II/0101/G**	Positive Opinion adopted by consensus on 08.02.2024.

Janssen-Cilag International N.V., PRAC Rapporteur: Rhea Fitzgerald, PRAC-CHMP liaison: Jayne Crowe, "Update of section 4.4 of the SmPC in order to remove a warning on cardiovascular events based on final results from non-interventional PASS studies NDI-MACE (CNTO1275PSO4005) and Quantify MACE (PCSIMM004697), listed as category 3 studies in the RMP (MEA/053 and MEA/054). NDI-MACE is a Nordic Database Initiative for Exposure to Ustekinumab: A Review and Analysis of Major Adverse Cardiovascular Events from the Swedish and Danish National Registry Systems; Quantify MACE is an Observational Longitudinal Post-authorisation Safety Study of STELARA in the Treatment of Psoriasis and Psoriatic Arthritis: Analysis of Major Adverse Cardiovascular Events (MACE) using Swedish National Health Registers. The Package Leaflet is updated accordingly. The RMP version 27.1 has also been submitted." Opinion adopted on 08.02.2024. Request for Supplementary Information adopted on 28.09.2023.	
PRAC Led **TachoSil - Human thrombin / Human fibrinogen - EMEA/H/C/000505/II/0124** Corza Medical GmbH, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of an updated RMP version 9.1 in order to reflect the extension of indication to include the paediatric population and to update the details of the planned non-interventional post-authorisation safety study: PASS-TachoSil Evaluation (PasTel)." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Zessly - Infliximab - EMEA/H/C/004647/II/0033** Sandoz GmbH, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of an updated RMP version 4.0 in order to remove the UKIBD (UK) registry from the additional pharmacovigilance activities." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2587**	Request for supplementary information adopted with a specific timetable.

TECFIDERA-EMEA/H/C/002601/WS2587/0085 **Vumerity-EMEA/H/C/005437/WS2587/0015** Biogen Netherlands B.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Submission of the final report from study 109MS401, a multicenter, global, observational study to collect information on safety and to document the drug utilisation of Tecfidera (Dimethyl Fumarate) when used in routine medical practice in the treatment of Multiple Sclerosis (ESTEEM), listed as a category 3 study in the RMP (MEA007.6). The RMPs version 16.1 for Tecfidera and version 2.1 for Vumerity, have also been submitted." Request for Supplementary Information adopted on 08.02.2024.	
PRAC Led **WS2615** **Abseamed-EMEA/H/C/000727/WS2615/0108** **Binocrit-EMEA/H/C/000725/WS2615/0108** **Epoetin alfa Hexal-EMEA/H/C/000726/WS2615/0108** Sandoz GmbH, Lead PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Submission of the final report from Non-Interventional Post-authorisation Safety Study, NI-PASS HX575-507 listed as a category 3 study in the RMP. The non-interventional study (NIS PASS) study HX575-507 was conducted to address a post-approval requirement (MEA 13.5) to evaluate the safety profile of HX575 administered s.c. in patients with CKD-induced anemia under real-life conditions, in order to increase confidence on the safe use of s.c. HX575. The RMP version 19.0 has also been submitted." Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **WS2620** **Dovato-EMEA/H/C/004909/WS2620/0047** **Juluca-EMEA/H/C/004427/WS2620/0056** **Tivicay-EMEA/H/C/002753/WS2620/0092** **Triumeq-EMEA/H/C/002754/WS2620/0118**	Request for supplementary information adopted with a specific timetable.

ViiV Healthcare B.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, "Update of section 4.6 of the SmPC in order to update information about the use of DTG-containing regimens in pregnancy and at conception based on final results from non-interventional Tsepamo study and the Eswatini Birth Outcomes Surveillance study. In addition, data from other cohort studies and pregnancy registries, including the APR, DOLOMITE-EPPICC (study 208613) and DOLOMITE-NEAT-ID Network study (study 208759) both listed as category 3 studies in the RMP; and the US Chart Review (study 212976) as well as data from literature are included. DOLOMITE-EPPICC (study 208613) is a non-interventional study to assess "real-world" maternal and foetal outcomes following DTG use during pregnancy and to describe patterns of DTG utilisation; DOLOMITE NEAT ID Network Study (208759) is a non-interventional, multi-site observational study to define the safety and effectiveness of Dolutegravir use in HIV positive pregnant women. The Package Leaflet is updated accordingly. The RMP version 19 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to sections 4.4 and 4.5 of the SmPC." Request for Supplementary Information adopted on 08.02.2024.	

B.5.5. CHMP-CAT assessed procedures

Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0032, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini Request for Supplementary Information adopted on 08.12.2023.	
Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0036/G, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini, "Grouped application comprising two variations as follows: C.I.4 – Update of sections 4.4 and 4.8 of the SmPC in order to add immune effector cell-	Request for supplementary information adopted with a specific timetable.

associated neurotoxicity syndrome (ICANS) as an adverse drug reaction (ADR) based on the cumulative review of MAH safety database and literature. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes. A.6 – To include the ATC Code L01XL08 in section 5.1 of the SmPC." Request for Supplementary Information adopted on 16.02.2024.	
Kymriah - Tisagenlecleucel - EMEA/H/C/004090/II/0071, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, "Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic information based on final results from study CCTL019B2202 (a phase II, single arm, multicenter trial to determine the efficacy and safety of CTL019 in pediatric patients with relapsed and refractory B-cell acute lymphoblastic leukemia). Submission of cellular kinetic report for the B-cell acute lymphoblastic leukaemia (ALL) indication based on data from pivotal study CCTL019B2202 and the supportive study CCTL019B2205J involving paediatric ALL patients (partially fulfil REC). In addition, the MAH took this opportunity to introduce editorial changes." Opinion adopted on 16.02.2024. Request for Supplementary Information adopted on 31.10.2023.	
Kymriah - Tisagenlecleucel - EMEA/H/C/004090/II/0079/G, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang Opinion adopted on 16.02.2024.	
Upstaza - Eladocagene exuparvovec - EMEA/H/C/005352/II/0013, Orphan, ATMP PTC Therapeutics International Limited, Rapporteur: Joseph DeCourcey, CHMP Coordinator: Finbarr Leacy Request for Supplementary Information adopted on 19.01.2024, 08.09.2023.	
WS2500	Request for supplementary information adopted

Tecartus- **EMEA/H/C/005102/WS2500/0040** **Yescarta-** **EMEA/H/C/004480/WS2500/0068** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 16.02.2024.	with a specific timetable.

B.5.6. CHMP-PRAC-CAT assessed procedures

Kymriah - Tisagenlecleucel - **EMEA/H/C/004090/II/0075, Orphan, ATMP** Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, PRAC Rapporteur: Gabriele Maurer, "Update of sections 5.1 and 5.2 of the SmPC in order to update efficacy and pharmacokinetic information based on final results from study CCTL019C2201 PAES in the Annex II (ANX008); this is a Phase II, single arm, multicenter trial to determine the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The RMP version 6 has also been submitted. In addition, the MAH took the opportunity to update Annex II.D of the PI." Opinion adopted on 16.02.2024. Request for Supplementary Information adopted on 31.10.2023.	

B.5.7. PRAC assessed ATMP procedures

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

WS2533 **Jentadueto-** **EMEA/H/C/002279/WS2533/0071** **Trajenta-** **EMEA/H/C/002110/WS2533/0053** Boehringer Ingelheim International GmbH, Lead Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 01.02.2024.	Request for supplementary information adopted with a specific timetable.
WS2576 **Elebrato Ellipta-** **EMEA/H/C/004781/WS2576/0037** **Relvar Ellipta-**	Positive Opinion adopted by consensus on 15.02.2024.

EMEA/H/C/002673/WS2576/0064 **Revinty Ellipta-** **EMEA/H/C/002745/WS2576/0061** **Trelegy Ellipta-** **EMEA/H/C/004363/WS2576/0034** GlaxoSmithKline (Ireland) Limited, Lead Rapporteur: Maria Concepcion Prieto Yerro Opinion adopted on 15.02.2024. Request for Supplementary Information adopted on 09.11.2023.	
WS2588 **Mircera-EMEA/H/C/000739/WS2588/0097** **NeoRecormon-** **EMEA/H/C/000116/WS2588/0122** Roche Registration GmbH, Lead Rapporteur: Martina Weise Opinion adopted on 01.02.2024.	Positive Opinion adopted by consensus on 01.02.2024.
WS2594/G **Ambirix-** **EMEA/H/C/000426/WS2594/0132/G** **Twinrix Adult-** **EMEA/H/C/000112/WS2594/0167/G** **Twinrix Paediatric-** **EMEA/H/C/000129/WS2594/0168/G** GlaxoSmithkline Biologicals SA, Lead Rapporteur: Christophe Focke Opinion adopted on 01.02.2024.	Positive Opinion adopted by consensus on 01.02.2024.
WS2595/G **Riltrava Aerosphere-** **EMEA/H/C/005311/WS2595/0009/G** **Trixeo Aerosphere-** **EMEA/H/C/004983/WS2595/0016/G** AstraZeneca AB, Lead Rapporteur: Finbarr Leacy Opinion adopted on 08.02.2024.	Positive Opinion adopted by consensus on 08.02.2024.
WS2605 **HyQvia-EMEA/H/C/002491/WS2605/0095** **Kiovig-EMEA/H/C/000628/WS2605/0126** Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 18.01.2024.	
WS2618 **Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-** **EMEA/H/W/005362/WS2618/0013** **Qdenga-** **EMEA/H/C/005155/WS2618/0014**	Request for supplementary information adopted with a specific timetable.

Takeda GmbH, Lead Rapporteur: Sol Ruiz Request for Supplementary Information adopted on 15.02.2024.	
WS2621/G **Suboxone-EMEA/H/C/000697/WS2621/0059/G** Indivior Europe Limited, Lead Rapporteur: Janet Koenig Opinion adopted on 01.02.2024.	Positive Opinion adopted by consensus on 01.02.2024.
WS2629/G **Eviplera-EMEA/H/C/002312/WS2629/0115/G** **Stribild-EMEA/H/C/002574/WS2629/0122/G** **Truvada-EMEA/H/C/000594/WS2629/0180/G** **Viread-EMEA/H/C/000419/WS2629/0211/G** Gilead Sciences Ireland UC, Lead Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 08.02.2024.	Request for supplementary information adopted with a specific timetable.
WS2643 **Nuwiq-EMEA/H/C/002813/WS2643/0059** **Vihuma-EMEA/H/C/004459/WS2643/0041** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 15.02.2024.	Positive Opinion adopted by consensus on 15.02.2024.
WS2649 **Luveris-EMEA/H/C/000292/WS2649/0099** **Pergoveris-EMEA/H/C/000714/WS2649/0090** Merck Europe B.V., Lead Rapporteur: Thalia Marie Estrup Blicher	

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

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

Acoramidis - EMEA/H/C/006333, Orphan BridgeBio Europe B.V., for the treatment of

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

Trastuzumab - EMEA/H/C/006219
treatment of metastatic and early breast cancer

Diflunisal - EMEA/H/C/006248, Orphan
AO Pharma AB, Treatment of ATTR amyloidosis

Ivermectin / Albendazole - EMEA/H/W/005186, Article 58
prevention and treatment of lymphatic filariasis, and soil-transmitted helminths infections.

Lazertinib - EMEA/H/C/006074
treatment of adult patients with advanced non-small cell lung cancer (NSCLC)

Linvoseltamab - EMEA/H/C/006370
monotherapy for the treatment of adult patients with relapsed or refractory multiple myeloma

Nemolizumab - EMEA/H/C/006149
for the treatment of moderate-to-severe atopic dermatitis and for the treatment of prurigo nodularis

Pegfilgrastim - EMEA/H/C/006348, PUMA
treatment of neutropenia in paediatric patients

Tisotumab vedotin - EMEA/H/C/005363
treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy

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

Human albumin solution - EMEA/H/D/006410
assisted reproductive technology (ART)

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

Lyrica - Pregabalin - EMEA/H/C/000546/X/0127
Upjohn EESV, Rapporteur: Peter Mol, PRAC Rapporteur: Liana Martirosyan, "Extension application to introduce a new pharmaceutical form (orodispersible tablet)"

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

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

Ceplene - Histamine dihydrochloride -
EMEA/H/C/000796/S/0048
Laboratoires Delbert, Rapporteur: Jayne Crowe, PRAC Rapporteur: Eamon O Murchu

LIVMARLI - Maralixibat -
EMEA/H/C/005857/S/0012, Orphan
Mirum Pharmaceuticals International B.V., Rapporteur: Martina Weise, PRAC Rapporteur: Adam Przybylkowski

SCENESSE - Afamelanotide -
EMEA/H/C/002548/S/0050, Orphan
Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

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

Epidyolex - Cannabidiol -
EMEA/H/C/004675/R/0031, Orphan
Jazz Pharmaceuticals Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Tomas Radimersky, PRAC Rapporteur: Ana Sofia Diniz Martins

Inbrija - Levodopa -
EMEA/H/C/004786/R/0022
Acorda Therapeutics Ireland Limited, Rapporteur: Peter Mol, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Barbara Kovacic Bytyqi

XOSPATA - Gilteritinib -
EMEA/H/C/004752/R/0017, Orphan
Astellas Pharma Europe B.V., Rapporteur: Ingrid Wang, Co-Rapporteur: Elita Poplavska, 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

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

with AS01E - EMEA/H/C/006054/II/0008

GlaxoSmithkline Biologicals S.A., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Maria del Pilar Rayon, "Extension of indication to include treatment of adults 50-59 years of age who are at increased risk for RSV disease for AREXVY, based on results from study 219238 (RSV OA=ADJ-018); this is a phase 3, observer-blind, placebo-controlled, randomized, multi-country, multi-center, non-inferiority study with 2 cohorts to evaluate immunogenicity, reactogenicity and safety of a single dose of RSVPreF3 OA in adults 50-59 years of age. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI, to bring it in line with the latest QRD template version 10.3, and to update the list of local representatives in the Package Leaflet. As part of the application, the MAH is requesting a 1-year extension of the market protection."

Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

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

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

Inaqovi - Decitabine / Cedazuridine - EMEA/H/C/005823/II/0002

Otsuka Pharmaceutical Netherlands B.V.,

Rapporteur: Filip Josephson, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Grouped application consisting of: C.I.6: Extension of indication to include treatment of adult patients with myelodysplastic syndromes (MDS) for INAQOVI. C.I.6: Extension of indication to include treatment of adult patients with chronic myelomonocytic leukaemia (CMML) for INAQOVI. Based on final results from studies ASTX727-01, ASTX727-02, ASTX727-04, E7727-01, and E7727-02. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.3. As part of the application the MAH is requesting a 1-year extension of the market protection." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
Infanrix hexa - Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed) - EMEA/H/C/000296/II/0340/G GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, "A grouped application consisting of two type II variations, as follows: C.I.6.a: To modify the approved therapeutic indication to include treatment from the age of 6 weeks for the administration of the primary vaccination, section 4.1 of the SmPC is updated accordingly. C.I.4: Update of section 4.2 of the SmPC for the use of mixed hexavalent/pentavalent primary vaccination schedule and vaccine interchangeability. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity implement editorial changes to the SmPC and the Package Leaflet.	
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0150 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder, "Extension of indication to include in	

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

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

Bristol-Myers Squibb Pharma EEIG, Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Martin Huber, "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."

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

Astellas Pharma Europe B.V., Rapporteur: Aaron Sosa Mejia, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Eva Jirsová, "Extension of indication to include in combination with pembrolizumab, the first-line treatment of adult patients with locally advanced or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy for PADCEV, based on the final results from study KEYNOTE-A39/EV-302: "An open label, randomized, controlled phase 3 study of enfortumab vedotin in combination with pembrolizumab versus chemotherapy alone in previously untreated locally advanced (LA) or metastatic urothelial cancer (mUC)"; As a consequence, sections 4.1,

4.2, 4.4, 4.6, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
Pemazyre - Pemigatinib - EMEA/H/C/005266/II/0015, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder, "Extension of indication to include treatment of adults with myeloid/lymphoid neoplasms (MLNs) with Fibroblast Growth Factor Receptor1 (FGFR1) rearrangement for PEMAZYRE, based on final results from study INCB 54828-203 (FIGHT-203); this is a phase 2, open-label, monotherapy, multicenter study to evaluate the efficacy and safety of INCB054828 in subjects with myeloid/lymphoid neoplasms with FGFR1 rearrangement. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0003 Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "Extension of indication to include in combination with platinum-based chemotherapy the first-line treatment of adult patients with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma (OSCC) for TEVIMBRA, based on results from study BGB-A317-306; this is a multi-regional, randomized, placebo-controlled, double-blind phase 3 study evaluating the efficacy and safety of tislelizumab in combination with	

chemotherapy compared to placebo in combination with chemotherapy as first-line treatment in patients with unresectable or locally advanced recurrent or metastatic OSCC. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

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

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

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Adtralza - Tralokinumab - EMEA/H/C/005255/II/0018

LEO Pharma A/S, Rapporteur: Jayne Crowe

Advate - Octocog alfa -

EMEA/H/C/000520/II/0122/G
Takeda Manufacturing Austria AG, Rapporteur:
Jan Mueller-Berghaus

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

AQUIPTA - Atogepant -
EMEA/H/C/005871/II/0001/G
AbbVie Deutschland GmbH & Co. KG,
Rapporteur: Janet Koenig

Elfabrio - Pegunigalsidase alfa -
EMEA/H/C/005618/II/0004/G
Chiesi Farmaceutici S.p.A., Rapporteur:
Alexandre Moreau

Eylea - Aflibercept -
EMEA/H/C/002392/II/0088
Bayer AG, Rapporteur: Jean-Michel Race

GONAL-f - Follitropin alfa -
EMEA/H/C/000071/II/0168/G
Merck Europe B.V., Rapporteur: Patrick Vrijlandt

Herzuma - Trastuzumab -
EMEA/H/C/002575/II/0061/G
Celltrion Healthcare Hungary Kft., Rapporteur:
Jan Mueller-Berghaus

Jivi - Damoctocog alfa pegol -
EMEA/H/C/004054/II/0031/G
Bayer AG, Rapporteur: Thalia Marie Estrup
Blicher

Ogivri - Trastuzumab -
EMEA/H/C/004916/II/0060
Biosimilar Collaborations Ireland Limited,
Rapporteur: Karin Janssen van Doorn

Origio A.R.T. Media - Gentamicin sulfate /
Sargramostim / Heparin sodium / Insulin
human - EMEA/H/D/006090/II/0002
Coopersurgical Inc., Rapporteur: Jayne Crowe

Ruxience - Rituximab -
EMEA/H/C/004696/II/0015
Pfizer Europe MA EEIG, Rapporteur: Peter Mol

Saxenda - Liraglutide -
EMEA/H/C/003780/II/0038
Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt

TEPADINA - Thiotepa -
EMEA/H/C/001046/II/0050/G
ADIENNE S.r.l. S.U., Rapporteur: Alexandre Moreau

Vyvgart - Efgartigimod alfa -
EMEA/H/C/005849/II/0016, Orphan
Argenx, Rapporteur: Thalia Marie Estrup Blicher

WS2634
Hexacima-
EMEA/H/C/002702/WS2634/0154
Hexyon-
EMEA/H/C/002796/WS2634/0158
Sanofi Pasteur Europe, Duplicate, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus

WS2651
Nilemdo-
EMEA/H/C/004958/WS2651/0036
Nustendi-
EMEA/H/C/004959/WS2651/0041
Daiichi Sankyo Europe GmbH, Lead Rapporteur: Patrick Vrijlandt

WS2655/G
GONAL-f-
EMEA/H/C/000071/WS2655/0167/G
Pergoveris-
EMEA/H/C/000714/WS2655/0091/G
Merck Europe B.V., Lead Rapporteur: Patrick Vrijlandt

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

Cresemba - Isavuconazole -
EMEA/H/C/002734/II/0045, Orphan
Basilea Pharmaceutica Deutschland GmbH, Rapporteur: Patrick Vrijlandt, "Update of section 4.5 of the SmPC in order to revise the interactions table to improve guidance for health care professionals in relation to the co-administration of cyclophosphamide with isavuconazole based on literature and postmarketing data. In addition, the MAH took the opportunity to correct a mistake in section 4.5 of the SmPC."

Cuprior - Trientine -
EMEA/H/C/004005/II/0028
Orphalan, Rapporteur: Jayne Crowe, "Submission of the final report from study

TRIUMPH-2: Trientine dihydrochloride (Syprine capsules) vs. tetrahydrochloride (tablets): a Phase 1, single centre, randomised, interventional, open-label, 4-way crossover study in adult healthy male and female subjects to evaluate the pharmacokinetics and the safety and tolerability of 2 different oral formulations."

Glyxambi - Empagliflozin / Linagliptin - EMEA/H/C/003833/II/0057

Boehringer Ingelheim International GmbH, Rapporteur: Patrick Vrijlandt, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update the information on the paediatric population based on final results from study DINAMO 1218-0091 - A double-blind, randomised, placebo-controlled, parallel group trial to evaluate the efficacy and safety of empagliflozin and linagliptin over 26 weeks, with a double-blind active treatment safety extension period up to 52 weeks, in children and adolescents with type 2 diabetes mellitus. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

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

HRA Pharma Rare Diseases, Rapporteur: Carolina Prieto Fernandez, "A grouped application consisting of two Type II variations: Update of sections 4.4, 4.5, 4.6, 4.8 and 4.9 of the SmPC in order to update the special warnings information and to update the pregnancy information, as well as, to add "Corticosteroid binding globulin increased" and "Thyroxin binding globulin increased" to the list of adverse drug reactions (ADRs) with frequency 'Not Known'; based on clinical practice guidance and post-marketing data.
The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3, and to implement editorial changes to the SmPC."

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

Sanofi Pasteur, Rapporteur: Daniela Philadelphy, "Update of sections 4.5 and 5.1 of

the SmPC in order to update immunogenicity and safety information based on final results from study MEQ00071; this is a parallel, multi-center, multinational, randomized, active-controlled phase 3b immunogenicity and safety study of a quadrivalent meningococcal conjugate vaccine versus Nimenrix, and when administered alone or concomitantly with 9vHPV and Tdap-IPV vaccines in healthy adolescents aged 10 to 17 years. In addition, the MAH took the opportunity to introduce minor updates to the PI and to update the list of local representatives in the Package Leaflet."	
NUVAXOVID - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0062 Novavax CZ, a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-505 listed as a category 3 study in the RMP. This is a Phase 2, Randomized, Observer-Blinded Study to Evaluate the Safety and Immunogenicity of a SARS CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix M Adjuvant in People Living with HIV."	
Pombiliti - Cipaglucosidase alfa - EMEA/H/C/005703/II/0010 Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, "Update of sections 4.6 and 5.3 of the SmPC in order to provide information regarding pre-implantation loss based on the reassessment of non-clinical data. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3 and to introduce editorial changes."	
REKAMBYS - Rilpivirine - EMEA/H/C/005060/II/0020 Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, "Update of section 4.2 of the SmPC in order to update administration instructions to mitigate product leakage related to the correct use of the vial adapter, based on Human Factor studies. The Package Leaflet (Instructions for Use) is updated accordingly."	
RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0050 AbbVie Deutschland GmbH & Co. KG,	

Rapporteur: Kristina Dunder, "Update of section 5.1 of the SmPC in order to include long-term efficacy and safety information (up to week 104 data) from study M19-944 (Study 1); this is a phase 3 randomized, placebo-controlled, double-blind program to evaluate efficacy and safety of upadacitinib in adult subjects with axial spondyloarthritis followed by a remission-withdrawal period."	
SARCLISA - Isatuximab - EMEA/H/C/004977/II/0028 Sanofi Winthrop Industrie, Rapporteur: Peter Mol, "Update of sections 4.2 and 5.1 of the SmPC in order to update information on the paediatric population based on final results from study ACT15378 (ISAKIDS). This was a Phase 2, single-arm, multicenter, open-label study evaluating the antitumor activity, safety, and PK of isatuximab in combination with standard salvage chemotherapies in pediatric participants with R/R ALL (including both T-ALL and B-ALL) and AML conducted in 3 separate cohorts. Male and female children from 28 days to less than 18 years of age with R/R T-ALL, B-ALL, or AML in first or second relapse were eligible. Participants under 2 years of age could only be enrolled after the dose reassessment is completed on the first 20 participants who were 2 to less than 18 years of age. The Package Leaflet is updated accordingly."	
Tecentriq - Atezolizumab - EMEA/H/C/004143/II/0084 Roche Registration GmbH, Rapporteur: Aaron Sosa Mejia, "Update of section 4.8 of the SmPC in order to add 'hypophysitis' to the list of adverse drug reactions (ADRs) with frequency 'uncommon' based on interim results from study WO39391 (IMpassion030). This is a Phase III, randomized, open label study comparing atezolizumab in combination with adjuvant anthracycline/taxane-based chemotherapy versus chemotherapy alone in patients with operable triple-negative breast cancer; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the SmPC, Labelling and Package Leaflet."	
Wegovy - Semaglutide - EMEA/H/C/005422/II/0019	

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

Xevudy - Sotrovimab - EMEA/H/C/005676/II/0027

Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC with data on the in vitro activity of sotrovimab in a pseudotyped virus assay against the Omicron HV.1 and BA.2.86 spike variants (PC-23-0165) and the Omicron HK.3 spike variant (PC-23-0179) as well as data on the in vitro activity of sotrovimab in an authentic virus assay against the SARS-COV-2 EG.5.1 variant (PC-23-0176) based on the relevant pharmacology study reports."

XGEVA - Denosumab - EMEA/H/C/002173/II/0084

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

B.6.10. CHMP-PRAC assessed procedures

Ilumetri - Tildrakizumab - EMEA/H/C/004514/II/0055

Almirall S.A, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Adam Przybylkowski

JCOVDEN - COVID-19 Vaccine Janssen (Ad26.COV2.S) - EMEA/H/C/005737/II/0076

Janssen-Cilag International N.V., Rapporteur: Christophe Focke, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.5, 4.8 and 5.1 of the SmPC in order to update

information regarding the co-administration of JCOVDEN with influenza vaccine based on the final report from study VAC31518COV3005 listed as a category 3 study in the RMP; this is a randomized, double-blind, Phase 3 study to evaluate safety, reactogenicity, and immunogenicity of co-administration of Ad26.COV2.S and influenza vaccines in healthy adults 18 years of age and older. The Package Leaflet is updated accordingly. Version 8.1 of the RMP has also been submitted."	
Leqvio - Inclisiran - EMEA/H/C/005333/II/0021 Novartis Europharm Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Kimmo Jaakkola, "Submission of the final report from study ORION-8 - A long-term extension trial of the Phase III lipid-lowering trials to assess the effect of long-term dosing of inclisiran given as subcutaneous injections in subjects with high cardiovascular risk and elevated LDL-C, listed as a category 3 study in the RMP. The RMP version 3.0 has also been submitted."	
Lupkynis - Voclosporin - EMEA/H/C/005256/II/0013 Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Adam Przybylkowski, "Update of section 4.6 of the SmPC in order to updated breast-feeding information based on final results from study AUR-VCS-2021-04. This study is a single-center, open-label, Phase 1, lactation study to investigate the amount of voclosporin excreted in breast milk following a single oral dose of 23.7 mg voclosporin in healthy, lactating, female volunteers. The Package Leaflet is updated accordingly. The updated RMP version 5.0 has also been submitted."	
Prevenar 20 - Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA/H/C/005451/II/0023 Pfizer Europe MA EEIG, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Jean-Michel Dogné, "Submission of the final current B7471015 study protocol, the Statistical Analysis Plan (SAP) and the final country feasibility assessment report for Apexxnar. The	

RMP (version 5.0) is updated accordingly.”

Spikevax - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005791/II/0120

Moderna Biotech Spain, S.L., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Marie Louise Schougaard Christiansen, “Submission of the final report from study mRNA-1273-P301 (Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older) listed as a category 3 study in the RMP. The RMP version 8.2 has also been submitted.”

TAKHZYRO - Lanadelumab - EMEA/H/C/004806/II/0040, Orphan

Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder, PRAC Rapporteur: Kirsti Villikka, “Update of section 4.4 of the SmPC in order to remove the information related to non-availability of clinical data on the use of lanadelumab in HAE patients with normal C1-INH activity, based on results from studies CASPIAN (SHP643-303) and CASPIAN OLE (TAK-743-3001). CASPIAN (SHP643-303) is a Phase 3, multicenter, randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of lanadelumab for prevention against acute attacks of NONHISTAMINERGIC ANGIOEDEMA with Normal C1 Inhibitor (C1-INH); and CASPIAN OLE (TAK-743-3001) is an open-label study to evaluate the long term safety and efficacy of lanadelumab for prevention against acute attacks of Nonhistaminergic Angioedema with Normal C1-Inhibitor (C1-INH).
The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and the Package Leaflet. ”

Tecvayli - Teclistamab - EMEA/H/C/005865/II/0009

Janssen-Cilag International N.V., Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Jana Lukacisinova, “Update of section 4.4 of the SmPC in order to update the warning on Progressive Multifocal Leukoencephalopathy (PML) based on a cumulative safety review. The

Package Leaflet is updated accordingly. The RMP version 4.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor updates to the PI and to update the list of local representatives in the Package Leaflet."	
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0004/G, Orphan Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "A grouped application comprised of 8 Type II variations as follows: 1 Type II (C.I.4): Update of section 5.2 of the SmPC in order to update ganaxolone metabolite pattern at steady state based on re-analysis of 1042-TQT-1001 listed as a category 3 study in the RMP to evaluate the ganaxolone steady-state metabolite. 7 Type II (C.I.13): Submission of the final non-clinical study reports for the in vitro DDI potential and in vivo PK of the metabolite M17 listed as category 3 studies in the RMP. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to introduce updates to the PI that reflect clarifications and typographical corrections, including to sections 4.2 and 4.4 of the SmPC."	
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0006, Orphan Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "Update of section 5.1 of the SmPC in order to update open-label data based on the final report from study 1042-CDD-3001 OLE listed as a category 3 study in the RMP. This was the open-label portion of the pivotal study 1042-CDD-3001; a double-blind, randomized, placebo-controlled trial of adjunctive ganaxolone treatment in children and young adults with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) followed by long-term open-label treatment. The RMP version 1.4 has also been submitted."	
WS2619/G **Invokana-** **EMEA/H/C/002649/WS2619/0066/G** **Vokanamet-** **EMEA/H/C/002656/WS2619/0073/G** Janssen-Cilag International N.V., Lead	

Rapporteur: Martina Weise, Lead PRAC Rapporteur: Martin Huber, "A grouped application consisting of two Type II variations, as follows:
C.I.4: Update of section 4.4 of the SmPC in order to amend an existing warning on Diabetic Ketoacidosis based on literature. The Package Leaflet is updated accordingly.
C.I.4: Update of sections 4.6 and 5.3 of the SmPC in order to update information on pregnancy based on literature.
The RMP version 11.1 has also been submitted."

B.6.11. PRAC assessed procedures

PRAC Led
AJOVY - Fremanezumab - EMEA/H/C/004833/II/0047
TEVA GmbH, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of the final report from the PASS study TV48125-MH-50039 listed as a category 3 study in the RMP. This is a long-term, prospective, observational study to evaluate the safety, including cardiovascular safety, of fremanezumab in patients with migraine in routine clinical practice. The RMP version 6.0 has also been submitted."

PRAC Led
Bavencio - Avelumab - EMEA/H/C/004338/II/0044/G
Merck Europe B.V., PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Grouped application comprising four variations as follows:
Type II (C.I.11.b): To update Annex II and the RMP version 7.1 for Bavencio to change the classification of "safety in patients with autoimmune disease" to the important identified risk "other immune mediated adverse reactions" along with removal of the patient information brochure from the educational material, following the PRAC assessment report PSUSA/00010635/202303.
Type IA (A.6): To change ATC level name from Other antineoplastic agents, monoclonal antibodies to Antineoplastic agents, monoclonal antibodies, PD-1/PDL-1 (Programmed cell death protein 1/death ligand 1) inhibitors in section 5.1 of the Summary of Product Characteristics

(SmPC). The ATC code remains unchanged. Type IA (C.I.z): To update the statement for "infusion-related reactions" in section 4.4 of the SmPC and to align terminology with the RMP for the term "immune-related" versus "immune-mediated". Type IAIN (C.I.12): To remove from the Product Information the black symbol and explanatory statements for medicinal products subject to additional monitoring. In addition, the MAH took this opportunity to introduce editorial changes and to bring the PI in line with the latest QRD template version 10.3."	
PRAC Led **COMIRNATY - COVID-19 mRNA vaccine (nucleoside-modified) - EMEA/H/C/005735/II/0206/G** BioNTech Manufacturing GmbH, PRAC Rapporteur: Liana Martirosyan, PRAC-CHMP liaison: Patrick Vrijlandt, "A grouped application comprised of 3 Type II variations as follows: C.I.13: Submission of the final report from study C4591012 listed as a category 3 study in the RMP. This is a non-interventional Post-Emergency Use Authorisation active safety surveillance study among individuals in the Veteran's Affairs health system receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) vaccine. The RMP version 11.2 has also been submitted. C.I.11.b: Submission of an updated RMP version 11.2 in order to implement changes to an agreed post-authorisation study (C4591052 protocol amendments 1 & 2) in the RMP, where there is an impact on the description of the study. C.I.11.b: Submission of an updated RMP version 11.2 in order to implement changes to an agreed post-authorisation study (C4591021 protocol amendment 4) in the RMP, where there is an impact on the description of the study. In addition, the MAH took the opportunity to update the milestones for the two studies C4591022 and C4591051 in the RMP."	
PRAC Led **DaTSCAN - Ioflupane (123I) - EMEA/H/C/000266/II/0067** GE Healthcare B.V., Rapporteur: Alexandre	

Moreau, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "To update sections 4.4 and 4.5 of the SmPC and section 2 of the Package Leaflet to implement the recommendation of the PRAC following the PSUSA procedure (EMEA/H/C/PSUSA/00001767/202207). In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."

PRAC Led

Flixabi - Infliximab - EMEA/H/C/004020/II/0084/G

Samsung Bioepis NL B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "A grouped application comprised of two Type II variations as follows:
C.I.13: Submission of the final report from study CEDUR listed as a category 3 study in the RMP. This is a nationwide German IBD registry to describe the long-term effectiveness of treatment with IBD therapies such as drug survival, effectiveness, side effects of treatment combination, and disease activity achieved.
C.I.13: Submission of the final report from study CREDIT listed as a category 3 study in the RMP. This is a Czech Register of IBD Patients on Biological Therapy to monitor effectiveness of total population of IBD patients on biological medication in the Czech Republic and regular analytical evaluation of the effectiveness.
The RMP version 13.0 has also been submitted."

PRAC Led

Humira - Adalimumab - EMEA/H/C/000481/II/0218

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

PRAC Led

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

Sanofi Pasteur, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van

Doorn, "Update of section 4.8 of the SmPC in order to add 'Hypersensitivity including anaphylaxis' to the list of adverse drug reactions (ADRs) with frequency not known, based on a cumulative review of cases of hypersensitivity/allergic reaction (including anaphylaxis) following the request by PRAC in the Assessment Report for PSUSA/00010044/202304. The Package Leaflet is updated accordingly."

PRAC Led

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

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

PRAC Led

VEYVONDI - Vonicog alfa - EMEA/H/C/004454/II/0033

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

PRAC Led

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

Pfizer Europe MA EEIG, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Jean-Michel Race, "A grouped application comprised of two Type II Variations, as follows:
C.I.4: Update of the Annex II based on final results from study B3461001 (THAOS) listed as a category 3 study in the RMP. This is a global, multi-center, longitudinal, observational survey of patients with documented transthyretin gene mutations or wild-type transthyretin amyloidosis.
C.I.13: Submission of the final report from

study B3461042 listed as a category 3 study in the RMP. This is a post-marketing safety surveillance study in Japanese patients with AATR-PN. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to provide B3461028 Clinical Study Report (CSR) Errata.”

B.6.12. CHMP-CAT assessed procedures

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

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

WS2635 **Hexacima-** **EMEA/H/C/002702/WS2635/0155** **Hexyon-** **EMEA/H/C/002796/WS2635/0159** **MenQuadfi-** **EMEA/H/C/005084/WS2635/0032** Sanofi Pasteur, Lead Rapporteur: Jan Mueller-Berghaus
WS2644/G **Entresto-** **Neparvis-** Novartis Europharm Limited, Lead Rapporteur: Patrick Vrijlandt
WS2661 **Mirapexin-** **EMEA/H/C/000134/WS2661/0108** **Sifrol-EMEA/H/C/000133/WS2661/0099** Boehringer Ingelheim International GmbH, Lead Rapporteur: Thalia Marie Estrup Blicher
WS2666/G **Ongentys-** **EMEA/H/C/002790/WS2666/0065/G** **Ontilyv-** **EMEA/H/C/005782/WS2666/0020/G** Bial - Portela & Cª, S.A., Lead Rapporteur: Martina Weise

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

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

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

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

G. ANNEX G

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

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

G.2. PRIME

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

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