11 November 2024
EMA/CHMP/491490/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 11-14 November 2024

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

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

12 November 2024, 08:30 – 19:30, virtual meeting/room 1C

13 November 2024, 08:30 – 19:30, virtual meeting/room 1C

14 November 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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1.1. 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 11-14 November 2024. See November 2024 CHMP minutes (to be published post December 2024 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 11-14 November 2024

1.3. Adoption of the minutes

CHMP minutes for October 2024.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 4 November 2024.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 13 November 2024 at 16:00

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

2.2. Re-examination procedure oral explanations

2.2.1. 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: Oral explanation

Action: Oral explanation to be held on 12 November 2024 at 14:00

Participation of patient representatives.

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

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/II/0016

Hipra Human Health S.L., Rapporteur: Daniela Philadelphy

Scope: Oral explanation

Action: Oral explanation to be held on 13 November 2024 at 09:00

Request for Supplementary Information adopted on 19.09.2024, 25.07.2024.

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

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Oral explanation

Action: Oral explanation to be held on 13 November 2024 at 14:00

Request for Supplementary Information adopted on 25.07.2024.

See 5.1

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 12 November 2024 at 16:00

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

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Aflibercept - EMEA/H/C/006607

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.09.2024.

3.1.2. Repotrectinib - EMEA/H/C/006005

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

Scope: Opinion

Action: For adoption

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

3.1.3. Aflibercept - EMEA/H/C/005980

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

Scope: Opinion

Action: For adoption

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

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

Treatment of alopecia areata in children and adolescents

Scope: Opinion

Action: For adoption

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

3.1.5. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024, 27.06.2024. List of Questions adopted on 14.12.2023.

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

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

Scope: Opinion

Action: For adoption

List of Questions adopted on 17.09.2024.

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

Orphelia Pharma; treatment of neuroblastoma

Scope: Opinion

Action: For adoption

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

3.1.8. Lazertinib - EMEA/H/C/006074

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

Scope: Opinion

Action: For adoption

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

3.1.9. Denosumab - EMEA/H/C/006424

Treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 25.07.2024.

3.1.10. Denosumab - EMEA/H/C/006468

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 25.07.2024.

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

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Treatment of rheumatoid arthritis (RA)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.06.2024.

3.2.2. Datopotamab - EMEA/H/C/006547

Treatment of adult patients with inoperable or metastatic HR-positive / HER2-negative breast cancer with disease progression following chemotherapy in the metastatic setting

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.06.2024.

3.2.3. Datopotamab - EMEA/H/C/006081

Treatment of adult patients with locally advanced or metastatic non squamous non-small cell lung cancer (NSCLC)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.06.2024.

3.2.4. Pegfilgrastim - EMEA/H/C/006407

Treatment of neutropenia

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

Action: For adoption

List of Questions adopted on 27.06.2024.

3.2.5. Denosumab - EMEA/H/C/006398

Prevention of skeletal related events with advanced malignancies

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

3.2.6. Denosumab - EMEA/H/C/006157

Prevention of skeletal related events with advanced malignancies

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

3.2.7. Denosumab - EMEA/H/C/006399

Treatment of osteoporosis and bone loss

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

3.2.8. Aflibercept - EMEA/H/C/006339

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.06.2024.

3.2.9. Denosumab - EMEA/H/C/006156

Treatment of osteoporosis and bone loss

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

3.2.10. Aflibercept - EMEA/H/C/006551

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.06.2024.

3.2.11. Ustekinumab - EMEA/H/C/006444

For the treatment of Crohn's disease and ulcerative colitis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.06.2024.

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

3.3.1. Belantamab mafodotin - Orphan - EMEA/H/C/006511

Glaxosmithkline Trading Services Limited; treatment of multiple myeloma

Scope: List of questions

Action: For adoption

3.3.2. Emtricitabine / Rilpivirine / Tenofovir alafenamide - EMEA/H/C/006491

Treatment of HIV-1

Scope: List of questions

Action: For adoption

3.3.3. Aflibercept - EMEA/H/C/006282

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

Scope: List of questions

Action: For adoption

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Treatment of Crohn's Disease and Ulcerative colitis, treatment of plaque psoriasis, arthritis psoriatic

Scope: List of questions

Action: For adoption

3.3.5. Denosumab - EMEA/H/C/006436

Treatment of osteoporosis and bone loss

Scope: List of questions

Action: For adoption

3.3.6. Nintedanib - EMEA/H/C/006486

Treatment of Idiopathic Pulmonary Fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) and systemic sclerosis associated interstitial lung disease (SSc-ILD)

Scope: List of questions

Action: For adoption

3.3.7. ACELLULAR PERTUSSIS VACCINE - EMEA/H/C/006304

Indicated as active booster immunization against pertussis of persons aged 11 years onwards and passive protection against pertussis in early infancy following maternal immunisation during pregnancy

Scope: List of questions

Action: For adoption

3.3.8. Vimseltinib - Orphan - EMEA/H/C/006363

Deciphera Pharmaceuticals (Netherlands) B.V.; Treatment of adult patients with tenosynovial giant cell tumour (TGCT) who are not amenable to surgery

Scope: List of questions

Action: For adoption

3.3.9. Denosumab - EMEA/H/C/006437

Prevention of skeletal related events with advanced malignancies

Scope: List of questions

Action: For adoption

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

3.4.1. Resminostat - Orphan - EMEA/H/C/006259

4Sc AG; treatment of patients with advanced stage mycosis fungoides (MF) and Sézary syndrome (SS)

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

Action: For adoption

List of Questions adopted on 27.06.2024

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

3.5.1. LEQEMBI - Lecanemab - EMEA/H/C/005966

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

Scope: Opinion

Action: For adoption

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

Opinion adopted on 25.07.2024. List of Outstanding Issues adopted on 27.06.2024, 21.03.2024, 09.11.2023. List of Questions adopted on 25.05.2023.

See 2.2

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Avacincaptad pegol - EMEA/H/C/006153

Is indicated for the treatment of adults with geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Scope: Withdrawal of marketing authorisation application

Action: For information

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

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

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

4.1.1. Jakavi - Ruxolitinib - EMEA/H/C/002464/X/0070/G

Novartis Europharm Limited;

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

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

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

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

Action: For adoption

List of Outstanding Issues adopted on 17.10.2024. List of Questions adopted on 25.04.2024.

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

Sanofi Winthrop Industrie;

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

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

Action: For adoption

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

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

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

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

Scope: "Extension application to add a new strength of 25 mg hard capsules, grouped with an extension of indication (C.I.6.a) to include treatment of fibrosing Interstitial Lung Diseases (ILDs) in children and adolescents from 6 to 17 years of age for Ofev, following the assessment of procedure X/0052/G, based on final results from study 1199-0337 (A Double Blind, Randomised, Placebo-controlled Trial to Evaluate the Dose-exposure and Safety of Nintedanib Per os on Top of Standard of Care for 24 Weeks, Followed by Open Label Treatment With Nintedanib of Variable Duration, in Children and Adolescents (6 to 17 Year-old) With Clinically Significant Fibrosing Interstitial Lung Disease), which is supplemented by the currently ongoing prospective Phase III extension trial 1199-0378 (An Open-label Trial of the Long-term Safety and Tolerability of Nintedanib Per os, on Top of Standard of Care, Over at Least 2 Years, in Children and Adolescents With Clinically Significant Fibrosing Interstitial Lung Disease). The main objective of the study 1199-0337 was to evaluate dose-exposure and safety of nintedanib in children and adolescents with fibrosing Interstitial Lung Disease (ILD). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 12.0 of the RMP has also been submitted."

Action: Oral explanation to be held on 12 November 2024 at 16:00

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

See 2.3

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

4.2.1. Aqumeldi - Enalapril maleate - EMEA/H/C/005731/X/0001/G

Proveca Pharma Limited;

Rapporteur: John Joseph Borg, PRAC Rapporteur: Mari Thorn

Scope: "Extension application to add a new strength of 1 mg orodispersible tablet grouped with a type IB variation (C.I.z) to correct the SmPC to remove the recommended dose of epinephrine from Section 4.4."

Request from the applicant for an extension to the clock stop to respond to the list of outstanding issues to be adopted in November 2024.

Action: For adoption

List of Questions adopted on 27.06.2024.

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

4.3.1. Brukinsa - Zanubrutinib - EMEA/H/C/004978/X/0023

BeiGene Ireland Ltd;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Bianca Mulder

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (160 mg film-coated tablets)."

Action: For adoption

4.3.2. Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/X/0140

Moderna Biotech Spain S.L.;

Rapporteur: Jan Mueller-Berghaus

Scope: "Extension application to add a new strength of 25 µg, XBB.1.5, Dispersion for injection."

Action: For adoption

4.3.3. Xofluza - Baloxavir marboxil - EMEA/H/C/004974/X/0022

Roche Registration GmbH;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Sonja Hrabcik

Scope: "Extension application to add a new pharmaceutical form (granules) associated with three new strengths (10, 30 and 40 mg)."

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. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - ATMP - EMEA/H/C/004731/II/0043/G

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Concetta Quintarelli, PRAC Rapporteur: Gabriele Maurer, CHMP Coordinator: Paolo Gasparini

Scope: "A grouped application consisting of:

C.I.6 (Type II): Extension of indication for Breyanzi to include treatment of adult patients with 3rd line + follicular lymphoma (FL) based on final results from the pivotal study JCAR017-FOL-001 (FOL-001, TRANSCEND-FL). This is a phase 2, open-label, single-arm, multicohort, multicentre study to evaluate efficacy and safety of JCAR017 in adult subjects with relapsed or refractory (r/r) follicular Lymphoma (FL) or marginal zone lymphoma (MZL). As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP is being submitted. Furthermore, as part of the application the MAH is requesting a 1-year extension of the market protection

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

Action: For adoption

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

Roche Registration GmbH;

Rapporteur: Thalia Marie Estrup Blicher

Scope: "C.I.6.a: Extension of indication to include paediatric patients (3 months to 18 years of age) for hepatic and cardiac transplants and to extend the indication for renal transplants for paediatric patients starting from 3 months, based on pharmacokinetic data, published literature and the Roche Global Safety Database. As a consequence, sections 4.1, 4.2, 4.8 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly.

Type IB (C.I.z): To update section 4.2 of the SmPC for the CellCept 500 mg tablets formulation in order to be in line with the other three CellCept formulations. And for alignment with the current QRD guidance, the Package Leaflet was updated to cross reference section 2 in section 6 for sodium content.

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

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024, 25.07.2024, 21.03.2024, 14.09.2023.

5.1.3. Columvi - Glofitamab - Orphan - EMEA/H/C/005751/II/0005

Roche Registration GmbH;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Jana Lukacisinova

Scope: "Extension of indication to include in combination with gemcitabine and oxaliplatin the treatment of adult patients with relapse or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are not candidates for autologous stem cell transplant (ASCT) for COLUMVI, based on results of primary and updated analyses from study GO41944 (STARGLO) listed as a Specific Obligation in the Annex II of the Product Information, as well supportive data from the Phase Ib study GO41943. Study GO41944 (STARGLO) is a Phase III, open-label, multicentre, randomized study of glofitamab in combination with GemOx (Glofit-GemOx) vs. rituximab in combination with GemOx (R-GemOx) in patients with R/R DLBCL. 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 Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

5.1.4. Enhertu - Trastuzumab - EMEA/H/C/005124/II/0048

Daiichi Sankyo Europe GmbH;

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Carla Torre

Scope: "Extension of indication to include treatment of adult patients with unresectable or metastatic HER2-low or HER2-ultralow breast cancer (BC) who have received at least one endocrine therapy in the metastatic setting for ENHERTU, based on results from study D9670C00001 (DESTINY-Breast06); this is a phase 3, randomized, multicentre, open-label study of trastuzumab deruxtecan (DS-8201a) compared with investigator's choice chemotherapy in, hormone receptor-positive, HER2-low and HER2-ultralow BC patients whose disease has progressed on endocrine therapy in the metastatic setting. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI, to update the list of local representatives in the Package Leaflet and to update the PI according to the Excipients Guideline."

Action: For adoption

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

Ultragenyx Germany GmbH;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Mari Thorn

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

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024.

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

Seqirus Netherlands B.V.;

Rapporteur: Sol Ruiz, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include treatment of adults and children from 6 months of age and older for FLUCELVAX TETRA based on final results from study V130_14. This is a phase 3, randomized, observer-blind, multicentre study to evaluate the efficacy, immunogenicity, and safety of Seqirus' Cell-Based Quadrivalent Subunit Influenza Virus Vaccine (QIVc) compared to a non-influenza vaccine when administrated in healthy subjects aged 6 months through 47 months. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.3 of the RMP has also been submitted."

Action: For adoption

5.1.7. Imfinzi - Durvalumab - EMEA/H/C/004771/II/0064

AstraZeneca AB;

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

Scope: "Extension of indication to include IMFINZI in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, for the treatment of adults with resectable (tumours ≥ 4 cm and/or node positive) NSCLC and no known EGFR mutations or ALK rearrangements for IMFINZI, based on the interim results from study D9106C00001 (AEGEAN); this is a Phase III, double-blind, placebo-controlled, multi-centre international study of neoadjuvant/adjuvant durvalumab for the treatment of patients with resectable stages II and III non-small cell lung cancer. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 21.03.2024.

5.1.8. Invokana - Canagliflozin - EMEA/H/C/002649/II/0069

Janssen-Cilag International N.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include treatment of paediatric patients with type 2 diabetes mellitus aged 10 years old and older for INVOKANA, based on final results from study JNJ-28431754DIA3018 as well as study JNJ-28431754DIA1055. Study JNJ-28431754DIA3018 is a double-blind, placebo-controlled, 2-arm, parallel-group, multicentre Phase 3 study in participants with T2DM >10 and <18 years of age who had inadequate glycaemic control (ie, HbA1c of >6.5% to <11.0%). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI and update the list of local representatives in the Package Leaflet."

Action: For adoption

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

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024, 25.07.2024.

See 2.3

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

Eli Lilly Nederland B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include, as an adjunct to diet and exercise, the treatment of moderate to severe obstructive sleep apnoea (OSA) in adults with obesity for MOUNJARO based on final results from studies I8F-MC-GPI1 and I8F-MC-GPI2; these are multicentre, randomized, parallel-arm, double-blind, placebo-controlled studies investigating the effects of tirzepatide compared with placebo in adult participants with moderate-to-severe OSA and

obesity. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

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

Stallergenes;

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

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

B.II.e.5.a: Introduction of a new pack-size
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024, 30.05.2024, 14.12.2023.

5.1.12. Ronapreve - Casirivimab / Imdevimab - EMEA/H/C/005814/II/0017

Roche Registration GmbH;

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Mari Thorn

Scope: "Extension of indication to include treatment of paediatric patients from 2 to less than 12 years old, weighing at least 10kg, who do not require supplemental oxygen and who are at increased risk of progression to severe COVID-19 for Ronapreve, based on final results from study COV-2067; this was a seamless, adaptive, Phase 3, randomized, double-blinded, placebo-controlled, multi-centre study to evaluate the efficacy, safety, and tolerability of casirivimab+imdevimab combination therapy in paediatric and adult outpatients with mild to moderate COVID-19. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.05.2024.

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

Janssen-Cilag International N.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer

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

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024, 30.05.2024.

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

Sanofi Winthrop Industrie;

Rapporteur: Peter Mol, PRAC Rapporteur: Monica Martinez Redondo

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

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024, 25.07.2024.

5.1.15. Saxenda - Liraglutide - EMEA/H/C/003780/II/0042

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include the use of SAXENDA for weight management in

children from the age of 6 years to less than 12 years based on results from study NN8022-4392; this is a 56-week, double-blind, randomised, placebo-controlled study investigating safety and efficacy of liraglutide on weight management in children with obesity aged 6 to <12 years. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 34.0 of the RMP has also been submitted."

Action: For adoption

5.1.16. Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0021/G

Sanofi Pasteur;

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Tiphaine Vaillant

Scope: "Grouped application comprising two type II variations as follows:
C.I.6.a – Extension of indication to include the treatment of children 9 years of age and older for Supemtek, based on final results from study VAP00027; this is a Phase III, non-randomized, open-label, uncontrolled study to demonstrate the non-inferior HAI immune response of RIV4 for the 4 strains in participants aged 9 to 17 years vs participants aged 18 to 49 years; 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 2.0 of the RMP has also been submitted.
C.I.4 - Update of sections 4.8 and 5.1 of the SmPC in order to update paediatric information based on final results from study VAP00026; this is a Phase III, randomized, modified double-blind, active-controlled 2-arm to demonstrate the non-inferior HAI immune response of RIV4 vs licensed IIV4 for the 4 strains based on the egg-derived antigen in all participants. Version 2.0 of the RMP has also been submitted."

Action: For adoption

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

AstraZeneca AB;

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy for TAGRISSO as monotherapy, based on results from study D5160C00048 (LAURA); this is a Phase III, randomised, double-blind, placebo-controlled, multicentre international study of osimertinib as maintenance therapy in patients with locally advanced unresectable EGFR mutation-positive non-small cell lung cancer (stage III) whose disease has not progressed following definitive platinum-based chemoradiation therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 17.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024, 25.07.2024.

5.1.18. Taltz - Ixekizumab - EMEA/H/C/003943/II/0053

Eli Lilly and Co (Ireland) Limited;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include treatment of juvenile idiopathic arthritis for TALTZ, based on week 16 results from study I1F-MC-RHCG; this is a multicentre, open-label, efficacy, safety, tolerability, and pharmacokinetic study (COSPIRIT-JIA) of subcutaneous ixekizumab with adalimumab reference arm, in children from 2 to less than 18 years of age with juvenile idiopathic arthritis subtypes of enthesitis-related arthritis (including juvenile-onset ankylosing spondylitis) and juvenile psoriatic arthritis was performed to evaluate the efficacy and safety of ixekizumab for 16 weeks after treatment initiation. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. Furthermore, the PI is in line with the latest QRD template version 10.4."

Action: For adoption

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

Bristol-Myers Squibb Pharma EEIG;

Lead Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

Scope: "A Worksharing application for OPDIVO and YERVOY, as follows:

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

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

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024.

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

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

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

Rapporteur: Peter Mol, Co-Rapporteur: Finbarr Leacy

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

Update on the procedure

Action: For discussion

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

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

Orexigen Therapeutics Ireland Limited;

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

Action: For adoption

Opinion adopted on 25.07.2024.

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

6.1.1. Human albumin solution - EMEA/H/D/006410

Vitrification of human MII-phase oocytes and embryos for assisted reproductive technology (ART)

Scope: Opinion

Action: For adoption

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

6.1.2. Human albumin solution - EMEA/H/D/006540

Ex vivo heart perfusion

Scope: Day 120 list of questions

Action: For adoption

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006590

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

Scope: Opinion

Action: For adoption

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.2. 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. Erbitux - Cetuximab - EMEA/H/C/000558/II/0099

Merck Europe B.V.

Rapporteur: Filip Josephson, PRAC Rapporteur: Mari Thorn

Scope: "Update of sections 4.2, 4.4 and 4.9 of the SmPC in order to introduce every two-weeks (Q2W) dosing regimen as an alternative to the already approved every week (Q1W) dosing regimen for the indications of metastatic colorectal cancer (CRC) and the recurrent/metastatic squamous cell cancer of the head and neck (SCCHN) in combination with platinum-based chemotherapy, based on pharmacokinetic (PK)-TGI-OS modelling and simulations. The Package Leaflet is updated accordingly. The RMP version 19.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information."

Action: For adoption

Request for Supplementary Information adopted on 27.06.2024.

9.1.2. Vabysmo - Faricimab - EMEA/H/C/005642/II/0014

Roche Registration GmbH

Rapporteur: Jayne Crowe

Scope: "Update of section 4.2 of the SmPC to modify the posology recommendations based on the post-hoc efficacy analysis of Phase III interventional studies TENAYA (GR40306), LUCERNE (GR40844), YOSEMITE (GR40349) and RHINE (GR40398). The Package leaflet is updated accordingly."

Action: For adoption

9.1.3. WS2754 Iscover-EMEA/H/C/000175/WS2754/0156 Plavix-EMEA/H/C/000174/WS2754/0157

Sanofi Winthrop Industrie

Lead Rapporteur: Fátima Ventura

Scope: "Update of sections 4.2 and 5.1 of the SmPC in order to include information on posology enhancement and to update pharmacodynamic information based on post marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the SmPC."

Action: For adoption

9.1.4. Zeposia - Ozanimod - EMEA/H/C/004835/R/0028

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Fátima Ventura, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Renewal of marketing authorisation for unlimited validity

Action: For adoption

9.1.5. Tecentriq - Atezolizumab - EMEA/H/C/004143/II/0087

Roche Registration GmbH

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Carla Torre

Scope: "Update of sections 4.2, 4.8 and 5.1 in order to include information regarding switching treatment between Tecentriq intravenous and subcutaneous (and vice versa) and to update safety information, based on primary results from study MO43576 (IMscin002); this is a phase II, randomised, multicentre, open-label cross-over study to evaluate participants and healthcare professional reported reference for subcutaneous atezolizumab compared with intravenous atezolizumab formulation in participants with non-small cell lung cancer. The RMP version 31.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024.

9.1.6. BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/II/0016

Hipra Human Health S.L., Rapporteur: Daniela Philadelphy

Action: For information

Request for Supplementary Information adopted on 19.09.2024, 25.07.2024.

See 2.3

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

Takeda Pharma A/S

Rapporteur: Maria Luttgen, CHMP Coordinator: <not set in SIAMED>, PRAC Rapporteur: Gabriele Maurer

Scope: Update on the procedure; "A grouped application comprised of 4 Type II Variations, as follows: (C.I.4): Update of sections 4.8 and 5.1 of the SmPC in order to update the safety information, based on pooled safety data from the two phase 3 controlled studies (ADMIRE-CD & ADMIRE-CD II) and to update efficacy information based on final results from study ADMIRE-CD II, listed as an obligation in the Annex II. ADMIRE-CD II (Cx601-0303) is a Phase III randomised double blind, placebo-controlled study to assess efficacy and safety of Cx601, adult allogeneic expanded adipose-derived stem cells (eASC) for the treatment of complex perianal fistula(s) in patients with Crohn's disease. The Annex II is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI, including to section 4.2 of the SmPC and to the Package Leaflet.
3 x (C.I.13): Submission of interim results from studies Darvadstrocel-3003 and Alofisel-5003 (INSPIRE) and final results from study Darvadstrocel-3002 to support the benefit-risk assessment of darvadstrocel based on all new available clinical data.
The RMP version 8.0 has also been submitted."

Action: For information

Request for Supplementary Information adopted on 19.07.2024.

9.1.8. IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/S/0107

Bavarian Nordic A/S

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer

Scope: Annual reassessment for products authorised under exceptional circumstances

Action: For adoption

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

Otsuka Pharmaceutical Netherlands B.V.;

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

Scope: Withdrawal of extension of indication application

Action: For information

Request for Supplementary Information adopted on 14.10.2024, 25.04.2024.

10. Referral procedures

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

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

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

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

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by Proxy

No items

14.1.2. CHMP membership

No items

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

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

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at November 2024 PDCO

Action: For information

Agenda of the PDCO meeting held on 12-15 November 2024

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Action: For adoption

14.3.2. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 28-31 October 2024. Table of conclusions

Action: For information

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

14.3.3. Election of a Vice-Chair of the Vaccines Working Party (VWP)

Chair: Mair Powell

Election of a new vice-chair; nominations received

Action: For election

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

14.7.1. CHMP Work Plan 2025

Draft CHMP work plan for 2025

Action: For discussion

14.8. Planning and reporting

No items

14.9. Others

14.9.1. Revision of variations guidelines

Revision of variations guidelines

Action: For discussion

14.9.2. RWD chapter of the Data Quality Framework

Data Quality Framework for EU medicines regulation: application to Real-World Data – document for public consultation

Action: For adoption

14.9.3. CHMP Learnings

CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

Action: For information

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

Clock-stop extensions and feedback from GIREX

Action: For discussion

Explanatory notes

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

Oral explanations *(section 2)*

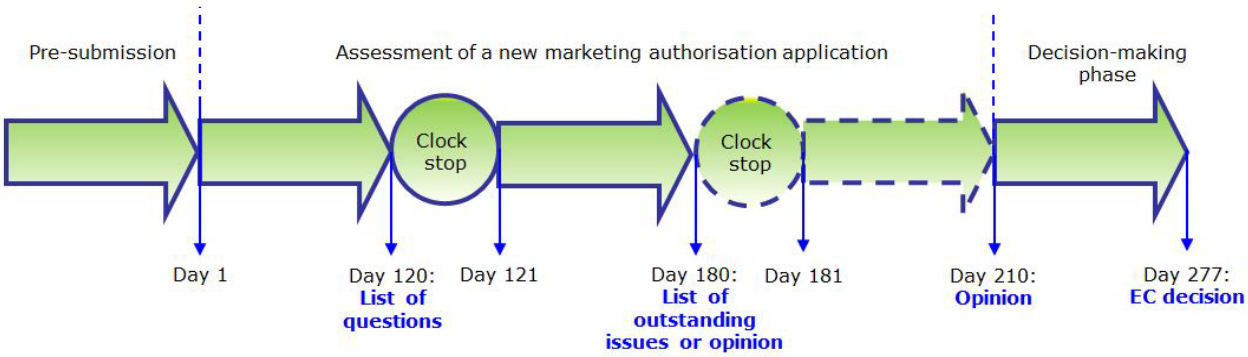
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 November 2024
EMA/CHMP/491548/2024

Annex to 11-14 November 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 November 2024: **For adoption**

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

Final Outcome of Rapporteurship allocation for November 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

Atriance - Nelarabine - EMEA/H/C/000752/S/0068
Sandoz Pharmaceuticals d.d., Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Brineura - Cerliponase alfa - EMEA/H/C/004065/S/0047, Orphan
BioMarin International Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Mari Thorn

IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/S/0107 See 9.1
Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer

Lojuxta - Lomitapide - EMEA/H/C/002578/S/0061
Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Mepsevii - Vestronidase alfa - EMEA/H/C/004438/S/0042, Orphan
Ultragenyx Germany GmbH, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alexandre Moreau,

PRAC Rapporteur: Maria del Pilar Rayon

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

Bemrist Breezhaler - Indacaterol / Mometasone - EMEA/H/C/005516/R/0026
Novartis Europharm Limited, Duplicate of Atectura Breezhaler, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser

Sunosi - Solriamfetol - EMEA/H/C/004893/R/0023
Atnahs Pharma Netherlands B.V., Rapporteur: Janet Koenig, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Julia Pallos
Request for Supplementary Information adopted on 25.07.2024.

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Arsenic trioxide Mylan - Arsenic trioxide - EMEA/H/C/005235/R/0012
Mylan Ireland Limited, Generic of TRISENOX, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Tiphaine Vaillant
Request for Supplementary Information adopted on 17.10.2024.

Atectura Breezhaler - Indacaterol / Mometasone - EMEA/H/C/005067/R/0031
Novartis Europharm Limited, Rapporteur: Finbarr Leacy, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser

Fetcroja - Cefiderocol - EMEA/H/C/004829/R/0022
Shionogi B.V., Rapporteur: Filip Josephson, Co-Rapporteur: Jayne Crowe, PRAC Rapporteur: Martin Huber
Request for Supplementary Information adopted on 17.10.2024.

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

on 19.09.2024.	
SARCLISA - Isatuximab - EMEA/H/C/004977/R/0033 Sanofi Winthrop Industrie, Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Monica Martinez Redondo	
Vaxchora - Cholera vaccine, oral, live - EMEA/H/C/003876/R/0024 Bavarian Nordic A/S, Rapporteur: Ingrid Wang, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Jean-Michel Dogné Request for Supplementary Information adopted on 17.10.2024.	
Zeposia - Ozanimod - EMEA/H/C/004835/R/0028 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Fátima Ventura, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Maria del Pilar Rayon	See 9.1

B.2.3. Renewals of Conditional Marketing Authorisations

Deltyba - Delamanid - EMEA/H/C/002552/R/0076, Orphan Otsuka Novel Products GmbH, Rapporteur: Christophe Focke, PRAC Rapporteur: Jo Robays	
Retsevmo - Selpercatinib - EMEA/H/C/005375/R/0035 Eli Lilly Nederland B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Bianca Mulder Request for Supplementary Information adopted on 17.10.2024.	
Tecartus - Brexucabtagene autoleucel - EMEA/H/C/005102/R/0047, Orphan, ATMP Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Rune Kjeken, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder Request for Supplementary Information adopted on 13.09.2024.	

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 28-31 October 2024 PRAC:

Signal of intestinal angioedema

Angiotensin II receptor blockers: amlodipine, valsartan; amlodipine, valsartan, hydrochlorothiazide; azilsartan medoxomil; irbesartan; irbesartan, hydrochlorothiazide; telmisartan, sacubitril, valsartan; telmisartan; telmisartan, amlodipine; telmisartan, hydrochlorothiazide; sacubitril, valsartan; olmesartan; candesartan; eprosartan; losartan; other relevant fixed dose combinations containing angiotensin II receptor blockers – EDARBI, APROVEL, IFIRMASTA, IRBESARTAN TEVA, IRBESARTAN ZENTIVA, KARVEA, COAPROVEL, IFIRMACOMBI, IRBESARTAN HYDROCHLOROTHIAZIDE ZENTIVA, IRBESARTAN/HYDROCHLOROTHIAZIDE TEVA, KARVEZIDE, TWYNSTA, ACTELSAR HCT, KINZALKOMB, MICARDISPLUS, PRITORPLUS, TOLUCOMBI, KINZALMONO, MICARDIS, PRITOR, TELMISARTAN ACTAVIS, TOLURA, ENTRESTO, NEPARVIS, COPALIA, DAFIRO, EXFORGE, COPALIA HCT, DAFIRO HCT, EXFORGE HCT (CAP & NAP)

Rapporteur: multiple, Co-Rapporteur: multiple, PRAC Rapporteur: multiple

PRAC recommendation on a variation
Action: For adoption

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

EMEA/H/C/PSUSA/00001269/202403
(esomeprazole)
CAPS:
Nexium Control (EMEA/H/C/002618) (Esomeprazole), GlaxoSmithKline Dungarvan Ltd, Rapporteur: Vilma Petrikaite
NAPS:
NAP - EU
PRAC Rapporteur: Rugile Pilviniene,
"11/03/2021 To: 10/03/2024"

EMEA/H/C/PSUSA/00002780/202403
(spironolactone)
CAPS:
Qaialdo (EMEA/H/C/005535)
(Spironolactone), Nova Laboratories Ireland Limited, Rapporteur: Frantisek Drafi
NAPS:
NAPs - EU
PRAC Rapporteur: Terhi Lehtinen, "07/03/2021 To: 08/03/2024"

EMEA/H/C/PSUSA/00003098/202403
(vardenafil)
CAPS:
Levitra (EMEA/H/C/000475) (Vardenafil), Bayer AG, Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Maria del Pilar Rayon, "05/03/2019 To: 04/03/2024"

EMEA/H/C/PSUSA/00009075/202403
(belimumab)
CAPS:
Benlysta (EMEA/H/C/002015) (Belimumab), GlaxoSmithKline (Ireland) Limited, Rapporteur: Kristina Dunder, PRAC Rapporteur: Karin Bolin, "09/03/2021 To: 08/03/2024"

EMEA/H/C/PSUSA/00010662/202403
(ocrelizumab)
CAPS:
Ocrevus (EMEA/H/C/004043) (Ocrelizumab), Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer, "28/03/2021 To: 27/03/2024"

EMEA/H/C/PSUSA/00010765/202403
(risankizumab)
CAPS:
Skyrizi (EMEA/H/C/004759) (Risankizumab), AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan, "26/03/2023 To: 25/03/2024"

EMEA/H/C/PSUSA/00010818/202403 (siponimod) CAPS: **Mayzent** (EMEA/H/C/004712) (Siponimod), Novartis Europharm Limited, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Maria del Pilar Rayon, "26/03/2023 To: 25/03/2024"	
EMEA/H/C/PSUSA/00010967/202403 (avacopan) CAPS: **TAVNEOS** (EMEA/H/C/005523) (Avacopan), Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder, PRAC Rapporteur: Liana Martirosyan, "26/03/2023 To: 26/03/2024"	

B.4. EPARs / WPARs

Absimky - Ustekinumab - EMEA/H/C/006585 Accord Healthcare, treatment of active plaque psoriasis, paediatric plaque psoriasis, psoriatic arthritis (PsA) and Crohn's disease. Duplicate, Duplicate of Imuldosa, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Alhemo - Concizumab - EMEA/H/C/005938 Novo Nordisk A/S, 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, 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.
Buprenorphine Neuraxpharm - Buprenorphine - EMEA/H/C/006188 Neuraxpharm Pharmaceuticals S.L., treatment of opioid drug dependence, Hybrid application (Article 10(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Eltrombopag Viatris - Eltrombopag - EMEA/H/C/006417 Viatris Limited, treatment of primary immune thrombocytopenia (ITP), chronic hepatitis C virus (HCV) and acquired severe aplastic anaemia (SAA), Generic, Generic of Revolade, Generic application (Article 10(1) of Directive No	For information only. Comments can be sent to the PL in case necessary.

2001/83/EC)	
Fluad - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/006538 Seqirus Netherlands B.V., Prophylaxis of influenza in adults 50 years of age and older, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Flucelvax - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/006532, Article 28 Seqirus Netherlands B.V., Prophylaxis of influenza in adults and children from 2 years of age., Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Imuldosa - Ustekinumab - EMEA/H/C/006221 Accord Healthcare S.L.U., treatment of plaque psoriasis, paediatric plaque psoriasis, psoriatic arthritis (PsA), Crohn's disease and ulcerative colitis, Similar biological application (Article 10(4) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Izelvay (WD) - Avacincaptad pegol - EMEA/H/C/006153 Astellas Pharma Europe B.V., is indicated for the treatment of adults with geographic atrophy (GA) secondary to age-related macular degeneration (AMD), New active substance (Article 8(3) of Directive No 2001/83/EC) **WPAR**	For information only. Comments can be sent to the PL in case necessary.
Korjuny - Catumaxomab - EMEA/H/C/005697 Lindis Biotech GmbH, indicated for the treatment of malignant ascites, Known active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
Masitinib AB Science - Masitinib - EMEA/H/C/005897, Orphan AB Science, in combination with riluzole for the treatment of adult patients with amyotrophic lateral sclerosis (ALS), New active substance (Article 8(3) of Directive No 2001/83/EC)	For information only. Comments can be sent to the PL in case necessary.
SIILTIBCY - rdESAT-6 / rCFP-10 - EMEA/H/C/006177 Serum Life Science Europe GmbH, Diagnosis of infection with *Mycobacterium tuberculosis*, New active substance (Article 8(3) of Directive No	For information only. Comments can be sent to the PL in case necessary.

2001/83/EC)	
Wainzua - Eplontersen - EMEA/H/C/006295, Orphan AstraZeneca AB, indicated for the treatment of adult patients with polyneuropathy associated with hereditary transthyretin-mediated amyloidosis (ATTRv), 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

Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0010/G Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe	
Besremi - Ropeginterferon alfa-2b - EMEA/H/C/004128/II/0037 AOP Orphan Pharmaceuticals GmbH, Rapporteur: Janet Koenig	
Bexsero – meningococcal group b vaccine (rDNA, component, adsorbed) – EMA/VR/0000228110 Glaxosmithkline Vaccines S.r.l., Rapporteur: Filip Josephson,	
BIMERVAX - SARS-CoV-2, variant XBB.1.16, spike protein, receptor binding domain fusion homodimer / Selvacovatein - EMEA/H/C/006058/II/0016 Hipra Human Health S.L., Rapporteur: Daniela Philadelphy Request for Supplementary Information adopted on 19.09.2024, 25.07.2024.	See 9.1
Briumvi - Ublituximab - EMEA/H/C/005914/II/0017/G Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra Request for Supplementary Information adopted on 10.10.2024.	
Cablivi - Caplacizumab - EMEA/H/C/004426/II/0052, Orphan Ablynx NV, Rapporteur: Filip Josephson	Positive Opinion adopted by consensus on 07.11.2024.

Opinion adopted on 07.11.2024.	
Camcevi – Leuprorelin – EMA/VR/0000226224 Accord Healthcare S.L.U., Rapporteur: Johanna Lähteenvuo,	
Camcevi – Leuprorelin – EMA/VR/0000226228 Accord Healthcare S.L.U., Rapporteur: Johanna Lähteenvuo,	
Ceprotin - Human protein C - EMEA/H/C/000334/II/0141 Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus	
Columvi - Glofitamab - EMEA/H/C/005751/II/0006/G, Orphan Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen	
Dynastat - Parecoxib - EMEA/H/C/000381/II/0093 Pfizer Europe MA EEIG, Duplicate of Xapit (SRD), Rapporteur: Finbarr Leacy Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 12.09.2024.	Positive Opinion adopted by consensus on 31.10.2024.
Elaprase - Idursulfase - EMEA/H/C/000700/II/0119/G Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Patrick Vrijlandt	
Entecavir Viatris - Entecavir - EMEA/H/C/004377/II/0013 Viatris Limited, Generic of Baraclude, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 07.11.2024.	Request for supplementary information adopted with a specific timetable.
IMVANEX - Smallpox vaccine (live modified vaccinia virus Ankara) - EMEA/H/C/002596/II/0106 Bavarian Nordic A/S, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 26.09.2024.	
Insuman - Insulin human - EMEA/H/C/000201/II/0150 Sanofi-Aventis Deutschland GmbH, Rapporteur: Karin Janssen van Doorn Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.

Request for Supplementary Information adopted on 05.09.2024.	
Jubbonti - Denosumab - EMEA/H/C/005964/II/0002/G Sandoz GmbH, Rapporteur: Christian Gartner Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
Kengrexal - Cangrelor - EMEA/H/C/003773/II/0033 Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 25.07.2024.	
LIVOGIVA - Teriparatide - EMEA/H/C/005087/II/0013/G Theramex Ireland Limited, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 31.10.2024.	Request for supplementary information adopted with a specific timetable.
Lutetium (177Lu) chloride Billev - Lutetium (177Lu) chloride - EMEA/H/C/005859/II/0005/G Billev Pharma ApS, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 05.09.2024.	
Metalyse - Tenecteplase - EMEA/H/C/000306/II/0074/G Boehringer Ingelheim International GmbH, Rapporteur: Janet Koenig Opinion adopted on 24.10.2024.	Positive Opinion adopted by consensus on 24.10.2024.
Nimenrix - Meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0136/G Pfizer Europe MA EEIG, Rapporteur: Ingrid Wang Opinion adopted on 24.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 24.10.2024.
Nustendi - Bempedoic acid / Ezetimibe - EMEA/H/C/004959/II/0046 Daiichi Sankyo Europe GmbH, Rapporteur: Patrick Vrijlandt Opinion adopted on 24.10.2024. Request for Supplementary Information adopted on 25.07.2024.	Positive Opinion adopted by consensus on 24.10.2024.
Odomzo - Sonidegib -	

EMEA/H/C/002839/II/0053/G Sun Pharmaceutical Industries Europe B.V., Rapporteur: Peter Mol	
Pergoveris - Follitropin alfa / Lutropin alfa - EMEA/H/C/000714/II/0095/G Merck Europe B.V., Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 03.10.2024.	
Polivy - Polatuzumab vedotin - EMEA/H/C/004870/II/0032/G, Orphan Roche Registration GmbH, Rapporteur: Alexandre Moreau Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
Remsima - Infliximab - EMEA/H/C/002576/II/0143/G Celltrion Healthcare Hungary Kft., Rapporteur: Outi Mäki-Ikola	
Retacrit - Epoetin zeta - EMEA/H/C/000872/II/0119 Pfizer Europe MA EEIG, Rapporteur: Janet Koenig Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 12.09.2024.	Positive Opinion adopted by consensus on 31.10.2024.
Ruxience - Rituximab - EMEA/H/C/004696/II/0015 Pfizer Europe MA EEIG, Rapporteur: Peter Mol Request for Supplementary Information adopted on 23.05.2024, 04.04.2024.	
SomaKit TOC - Edotreotide - EMEA/H/C/004140/II/0028, Orphan Advanced Accelerator Applications, Rapporteur: Antonio Gomez-Outes Request for Supplementary Information adopted on 05.09.2024, 16.05.2024.	
Spectrila - Asparaginase - EMEA/H/C/002661/II/0042/G medac Gesellschaft fur klinische Spezialpraparate mbH, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 31.10.2024.	Request for supplementary information adopted with a specific timetable.
Supemtek - Influenza quadrivalent vaccine (rDNA) - EMEA/H/C/005159/II/0015/G Sanofi Pasteur, Rapporteur: Jan Mueller-	Request for supplementary information adopted with a specific timetable.

Berghaus Request for Supplementary Information adopted on 07.11.2024, 03.10.2024, 06.06.2024, 08.02.2024.	
Surgiflo Haemostatic Matrix Kit - Human thrombin - EMEA/H/D/002301/II/0039/G Ferrosan Medical Devices A/S, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 24.10.2024. Request for Supplementary Information adopted on 19.09.2024.	Positive Opinion adopted by consensus on 24.10.2024.
TRODELVY - Sacituzumab govitecan - EMEA/H/C/005182/II/0035/G Gilead Sciences Ireland UC, Rapporteur: Jan Mueller-Berghaus	
WEZENLA - Ustekinumab - EMEA/H/C/006132/II/0001 Amgen Technology (Ireland) Unlimited Company, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 03.10.2024.	
Wyost - Denosumab - EMEA/H/C/006378/II/0002/G Sandoz GmbH, Duplicate of Jubbonti, Rapporteur: Christian Gartner Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
Ximluci - Ranibizumab - EMEA/H/C/005617/II/0010 STADA Arzneimittel AG, Rapporteur: Jayne Crowe Opinion adopted on 24.10.2024. Request for Supplementary Information adopted on 20.06.2024.	Positive Opinion adopted by consensus on 24.10.2024.
Yargesa - Miglustat - EMEA/H/C/004016/II/0014 Piramal Critical Care B.V., Generic of Zavesca, Rapporteur: Daniela Philadelphy Request for Supplementary Information adopted on 05.09.2024, 21.03.2024.	
Yellox - Bromfenac - EMEA/H/C/001198/II/0036/G Bausch + Lomb Ireland Limited, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 19.09.2024, 30.05.2024, 25.01.2024.	
Zerbaxa - Ceftolozane / Tazobactam -	

EMEA/H/C/003772/II/0046/G Merck Sharp & Dohme B.V., Rapporteur: Ingrid Wang Request for Supplementary Information adopted on 19.09.2024.	
WS2549/G **Hexacima-EMEA/H/C/002702/WS2549/0159/G** **Hexyon-EMEA/H/C/002796/WS2549/0163/G** Sanofi Pasteur Europe, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 07.11.2024.	Request for supplementary information adopted with a specific timetable.
WS2742/G **Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-EMEA/H/W/005362/WS2742/0017/G** **Qdenga-EMEA/H/C/005155/WS2742/0018/G** Takeda GmbH, Lead Rapporteur: Sol Ruiz Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
WS2744/G **GONAL-f-EMEA/H/C/000071/WS2744/0174/G** **Pergoveris-EMEA/H/C/000714/WS2744/0096/G** Merck Europe B.V., Lead Rapporteur: Patrick Vrijlandt Opinion adopted on 24.10.2024.	Positive Opinion adopted by consensus on 24.10.2024.
WS2747/G **Nuwiq-EMEA/H/C/002813/WS2747/0063/G** **Vihuma-EMEA/H/C/004459/WS2747/0045/G** Octapharma AB, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 31.10.2024.	Request for supplementary information adopted with a specific timetable.
WS2748 **Silodosin Recordati-EMEA/H/C/004964/WS2748/0015** **Silodyx-EMEA/H/C/001209/WS2748/0056** **Urorec-EMEA/H/C/001092/WS2748/0059** Recordati Ireland Ltd, Lead Rapporteur: Margareta Bego	
WS2761	

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

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

AQUIPTA - Atogepant - **EMEA/H/C/005871/II/0005** AbbVie Deutschland GmbH & Co. KG, Rapporteur: Janet Koenig, "Update of sections 4.3, 4.4 and 4.8 of the SmPC in order to update the contraindication and warning on hypersensitivity reactions to include anaphylaxis and dyspnoea and to add them to the list of adverse drug reactions (ADRs) with frequency not known, based on a comprehensive safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 19.09.2024.	
Cetrotide - Cetrorelix - **EMEA/H/C/000233/II/0091** Merck Europe B.V., Rapporteur: Janet Koenig, "Type II C.I.4 To update section 6.6 of the SmPC to amend the administered dose of cetrorelix from 'dose of at least 0.23 mg' to 'dose of 0.21 mg' based on the representative dose study conducted to evaluate the administered dose after reconstitution." Opinion adopted on 24.10.2024. Request for Supplementary Information adopted on 05.09.2024, 25.04.2024.	Positive Opinion adopted by consensus on 24.10.2024.
Cimzia - Certolizumab pegol - **EMEA/H/C/001037/II/0110** UCB Pharma S.A., Rapporteur: Kristina Dunder, "Update of sections 4.2 and 4.6 of the SmPC in order to update information on pregnancy based on final results from study UP0085, OTIS Phase I report and post marketing data. UP0085 is a Phase 1b, prospective, longitudinal, interventional, open-label study evaluating the impact of pregnancy on the PK of CZP. OTIS Phase I report presents the formal analysis of	

pregnancy outcome and infant and child follow-up data from the OTIS CZP Pregnancy Registry (RA0023). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4." Request for Supplementary Information adopted on 13.06.2024.	
Dovprela - Pretomanid - EMEA/H/C/005167/II/0022, Orphan Mylan IRE Healthcare Limited, Rapporteur: Filip Josephson, "Update of section 4.2 of the SmPC in order to add clarifications on administration instructions based on post marketing data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement an editorial correction to section 5.1 of the SmPC."	
Drovelis - Drospirenone / Estetrol - EMEA/H/C/005336/II/0026 Gedeon Richter Plc., Rapporteur: Kristina Dunder, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on results from study MIT-Es001-C303. This is a Phase III, Open-label, Single-Arm Study to Evaluate the Safety, Compliance and Pharmacokinetics associated with the use of a Combined Oral Contraceptive Containing 15 mg Estetrol monohydrate and 3 mg Drospirenone in Post-menarchal Female Adolescents for 6 cycles. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 25.07.2024.	
Eylea - Aflibercept - EMEA/H/C/002392/II/0095 Bayer AG, Rapporteur: Jean-Michel Race, "Update of section 4.8 of the SmPC in order to add 'scleritis' to the list of adverse drug reactions (ADRs) with frequency of '0.2 cases per 1 million injections' based on pharmacovigilance data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to add warnings for polysorbate into the SmPC and the Package Leaflet in line with the instructions in the most recent updates to the Appendix of the EC Excipient Guideline." Request for Supplementary Information adopted on 24.10.2024.	Request for supplementary information adopted with a specific timetable.

Galafold - Migalastat - EMEA/H/C/004059/II/0043, Orphan Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, "Update of section 4.8 of the SmPC in order to add 'angioedema' to the list of adverse drug reactions (ADRs) with frequency unknown based on a safety review. The Package Leaflet is updated accordingly. In addition, the MAH has taken the opportunity to update the Product Information (PI) to align with the revised QRD template (version 10.4) and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 31.10.2024.	Request for supplementary information adopted with a specific timetable.
Lydisilka - Drospirenone / Estetrol - EMEA/H/C/005382/II/0026 Estetra SRL, Duplicate of Drovelis, Rapporteur: Kristina Dunder, "Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to update information on paediatric population based on results from study MIT-Es001-C303. This is a Phase III, Open-label, Single-Arm Study to Evaluate the Safety, Compliance and Pharmacokinetics associated with the use of a Combined Oral Contraceptive Containing 15 mg Estetrol monohydrate and 3 mg Drospirenone in Post-menarchal Female Adolescents for 6 cycles. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 25.07.2024.	
MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine - EMEA/H/C/005084/II/0034/G Sanofi Pasteur, Rapporteur: Daniela Philadelphy, "Grouped application comprising two type II variations as follows: C.I.4 - Update of section 5.1 of the SmPC in order to add 5 years persistence of immune response based on final results from study MEQ00066. MEQ00066 was a Phase III, two-stage, randomised, open-label, multi-centre trial to evaluate the immunogenicity and safety of a single dose of MenACYW conjugate vaccine at least 3 years after a prior dose of either MenACYW conjugate vaccine or Menomune. C.I.4 – Update of section 5.1 of the SmPC in order to add immune persistence and booster response data in children based on interim	Positive Opinion adopted by consensus on 24.10.2024.

results from study MEQ00073. MEQ00073 is a Phase IIIb, open-label, multi-centre study to evaluate the immunogenicity and safety of a booster dose of MenQuadfi administered to children and describe 5- and/or 10-year immune persistence of MenQuadfi after primary vaccination. Annex II is also being updated. In addition, the MAH took the opportunity to introduce editorial changes to the PI." Opinion adopted on 24.10.2024. Request for Supplementary Information adopted on 18.07.2024.	
MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine - EMEA/H/C/005084/II/0037 Sanofi Pasteur, Rapporteur: Daniela Philadelphy, "Update of section 4.8 of the SmPC in order to add 'convulsions with or without fever' to the list of adverse drug reactions (ADRs) with frequency not known, based on a safety review. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 24.10.2024.	Request for supplementary information adopted with a specific timetable.
Nexavar - Sorafenib - EMEA/H/C/000690/II/0059, Orphan Bayer AG, Rapporteur: Filip Josephson, "Update of section 5.3 of the SmPC in order to update preclinical safety data on carcinogenicity studies based on final results from studies T4079666 - Carcinogenicity Study in CD-1 Mice (2 Years Administration by Diet) and T8076320 - Carcinogenicity Study in Wistar Rats (2 Years Administration in the Diet with Dose Adjustment). In addition, the MAH took the opportunity to introduce editorial changes to the PI and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 04.07.2024.	
Nplate – Romiplostim – EMA/VR/0000226893 Amgen Europe B.V., Rapporteur: Antonio Gomez-Outes, "Update of sections 4.4 and 4.8 of the SmPC in order to update the warning on thrombotic/thromboembolic complications and update the frequency of 'deep vein thrombosis'	

in the list of adverse drug reactions (ADRs) from 'uncommon' to 'common', based on a comprehensive safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the wording pertaining to bone marrow aspirate and/or biopsy in patients over 60 years of age to be consistent with current standards and international guidelines for immune thrombocytopenia (ITP) diagnosis and management and to introduce minor editorial changes to the PI and update the list of the local representatives in the Package Leaflet."	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0085/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "A grouped application comprised of 3 Type II Variations as follows: C.I.13: Submission of the final non-clinical study report 702-087 - Antibody and Cell-mediated Immune Responses to SARS-CoV-2 rS Vaccines in Baboons. C.I.13: Submission of the final non-clinical study report 702-134 – Immunogenicity of a Primary Series with SARS-CoV-2 Prototype rS or Omicron BA.1 rS Followed by a Booster Immunization with Omicron BA.5 rS or Bivalent Prototype rS + Omicron BA.5 rS in Baboons. C.I.13: Submission of the final non-clinical study report 702-115 – Long-term Immunogenicity and Protective Efficacy of SARS-CoV-2 rS Nanoparticle Vaccines with Matrix-M Adjuvant in Rhesus Macaques." Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0087 Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-311 Part 2 listed as a category 3 study in the RMP. This is a Multi-Part, Phase 3, Randomized, Observer Blinded Study to Evaluate the Safety and Immunogenicity of Omicron Subvariant and Bivalent SARS-CoV-2 rS Vaccines in Adults Previously Vaccinated with other COVID-19 Vaccines."	

Ocrevus - Ocrelizumab - EMEA/H/C/004043/II/0040/G Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, "A grouped application comprised of three Type II Variations and one Type IA Variation, as follows: 3 Type II (C.I.4): Update of sections 4.4 and 4.8 of the SmPC in order to update clinical safety information based on final results from the three studies: study WA21092 (OPERA I), study WA21093 (OPERA II) and study WA25046 (ORATORIO). Study WA21092 (OPERA I) and study WA21093 (OPERA II) are randomized, double-blind, double-dummy, parallel-group studies to evaluate the efficacy and safety of ocrelizumab in comparison to interferon beta-1a (Rebif) in patients with relapsing multiple sclerosis (RMS), while study WA25046 (ORATORIO) is a phase 3, multicentre, randomized, parallel-group, double blinded, placebo controlled study to evaluate the efficacy and safety of ocrelizumab in adults with primary progressive multiple sclerosis (PPMS). In addition, the MAH took the opportunity to introduce minor editorial change to the Product Information. Type IA (A.6): Change the ATC Code of ocrelizumab from L04AA36 to L04AG08." Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 26.09.2024, 06.06.2024.	Positive Opinion adopted by consensus on 31.10.2024.
Opfolda - Miglustat - EMEA/H/C/005695/II/0010/G Amicus Therapeutics Europe Limited, Rapporteur: Patrick Vrijlandt, "A grouped application comprised of two Type II Variations, as follows: C.I.4: Update of section 5.2 of the SmPC in order to update drug metabolism information based on the final report of the in vitro transporter study 8496647 as well as the population PK study AMC0206. Study 8496647 was for the evaluation of miglustat as a substrate and inhibitor of a panel of human drug transporters. C.I.4: Update of sections 4.6 and 5.3 of the SmPC in order to update reproductive and	Positive Opinion adopted by consensus on 24.10.2024.

developmental toxicology information based on reassessment of non-clinical data. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information." Opinion adopted on 24.10.2024. Request for Supplementary Information adopted on 05.09.2024, 02.05.2024.	
Oxlumo - Lumasiran - EMEA/H/C/005040/II/0021, Orphan Alnylam Netherlands B.V., Rapporteur: Martina Weise, "Update of sections 4.8 and 5.1 of the SmPC in order to include information on the End-of Study safety (patient years of exposure) and efficacy of lumasiran in patients with Primary Hyperoxaluria Type 1 (PH1) based on final results from study ALN-GO1-003 (ILLUMINATE) listed as a category 3 study in the RMP; this is a phase 3 randomized, double-blind placebo-controlled study with an extended dosing period to evaluate the efficacy and safety of lumasiran in children and adults with PH1. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	
Oxlumo - Lumasiran - EMEA/H/C/005040/II/0022, Orphan Alnylam Netherlands B.V., Rapporteur: Martina Weise, "Update of section 4.8 of the SmPC in order to add "hypersensitivity" to the list of adverse drug reactions (ADRs) with frequency "Not known" based on post marketing safety data and literature. In addition, the MAH has taken the opportunity to update the Product Information (PI) to align with the revised QRD template (version 10.4) and to update the list of local representatives in the Package Leaflet."	
Saphnelo - Anifrolumab - EMEA/H/C/004975/II/0020 AstraZeneca AB, Rapporteur: Outi Mäki-Ikola, "Submission of the final report from the NAÏVE study D3461C00023/ESR-20-21053, listed as a category 3 study in the RMP. This study is a phase I, non-randomised, multi-centre, open-label, parallel group study to evaluate the potential impact of anifrolumab administered intravenously (IV) on the effectiveness of immune responses to seasonal influenza vaccination in women or men between the ages of 18 and 70 years with active moderate to	Positive Opinion adopted by consensus on 07.11.2024.

severe manifestations of SLE." Opinion adopted on 07.11.2024. Request for Supplementary Information adopted on 05.09.2024.	
Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0010, Orphan Biogen Netherlands B.V., Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.8 of the SmPC in order to add hypersensitivity, including urticaria and rash, to the list of adverse drug reactions (ADRs) with frequency not known based on post-marketing experience. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce corrections and minor changes to the PI and to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 03.10.2024.	
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0050 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy, "Update of sections 4.8 and 5.1 of the SmPC in order to add information based on data of the final study report M15-997 (LIMMITLESS) listed as a category 3 study in the RMP. This is a multicentre, open label study to assess the safety and efficacy of risankizumab for maintenance in moderate to severe plaque type psoriasis. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."	
Vabysmo - Faricimab - EMEA/H/C/005642/II/0014 Roche Registration GmbH, Rapporteur: Jayne Crowe, "Update of section 4.2 of the SmPC to modify the posology recommendations based on the post-hoc efficacy analysis of Phase III interventional studies TENAYA (GR40306), LUCERNE (GR40844), YOSEMITE (GR40349) and RHINE (GR40398). The Package leaflet is updated accordingly."	See 9.1
Voxzogo - Vosoritide - EMEA/H/C/005475/II/0017, Orphan BioMarin International Limited, Rapporteur: Janet Koenig, "Submission of the BMN-111 PK Modelling report for young children with achondroplasia (ACH). This is a population	Positive Opinion adopted by consensus on 31.10.2024.

pharmacokinetic [P(PK)] analysis by body weight
group (<10kg) to evaluate the PPK model performance of vosoritide in young children with achondroplasia"
Opinion adopted on 31.10.2024.

Xevudy - Sotrovimab - EMEA/H/C/005676/II/0029/G
Glaxosmithkline Trading Services Limited, Rapporteur: Thalia Marie Estrup Blicher, "A grouped application comprised of 5 Type II Variations, as follows:

C.I.4: Update of section 5.1 of the SmPC based on final results from study 218407 (LUNAR); this is a Phase 4 single-arm prospective cohort genomic surveillance study to describe changes in the SARS-CoV-2 spike protein observed in immunocompromised non-hospitalized patients receiving sotrovimab in Great Britain to monitor the emergence of viral variants.

4 x (C.I.13): To submit the final reports from the following studies:

COMET-TAIL Safety Sub study (217114); this is a Phase 3 randomized, multi-centre, open label study to assess the efficacy, safety, and tolerability of monoclonal antibody VIR-7831 (sotrovimab) given intramuscularly versus intravenously for the treatment of mild/moderate coronavirus disease 2019 (COVID-19) in high- risk non-hospitalized patients; Safety Sub study assessing the safety and tolerability of single ascending dose monoclonal antibody VIR-7831.

AGILE (215337); this is a randomized, multicentre, seamless, adaptive, Phase 1/2 platform study to determine the Phase 2a dose of VIR-7832, and evaluate the safety and efficacy of VIR-7831 and VIR-7832 for the treatment of COVID-19.

COSMIC (218128); this is a Phase 1, open-label, randomized, parallel group, single-dose clinical pharmacology study to investigate the relative bioavailability, safety, and tolerability of two different concentrations of sotrovimab administered at different injection sites, in male

or female healthy participants aged 18 to 65 years. And from a clinical pharmacology study evaluating SARS-CoV-2 specific T cells responses in participants receiving 500 mg IV sotrovimab in COMET-ICE (PC-22-0123).” Request for Supplementary Information adopted on 12.09.2024.	
WS2658 **Braftovi-** **EMEA/H/C/004580/WS2658/0039** **Mektovi-** **EMEA/H/C/004579/WS2658/0031** Pierre Fabre Medicament, Lead Rapporteur: Janet Koenig, “Update of sections 5.1 of the SmPC in order to update efficacy and safety information following the outcome of procedures 004579/0000 and R/0024 based on final results from study C4221004 (CMEK162B2301). This was a 2-part, multi-centre, randomized, open label, Phase III study comparing the efficacy and safety of encorafenib plus binimetinib to vemurafenib and encorafenib monotherapy in participants with locally advanced unresectable or metastatic melanoma with BRAF V600 mutation. In addition, the MAH took the opportunity to introduce editorial changes to the PI.” Request for Supplementary Information adopted on 20.06.2024.	
WS2707 **Celldemic-** **EMEA/H/C/006052/WS2707/0001** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2707/0003** Seqirus Netherlands B.V., Lead Rapporteur: Daniela Philadelphy, “Submission of the final report from extension study V89_18E1 (NCT05422326). This is a Phase 2, Randomized, Study to Evaluate Safety and Immunogenicity of One or Two Heterologous Booster Vaccinations with an MF59-adjuvanted, Cell Culture-derived H5N6 Influenza Vaccine in Adults Primed With MF59-adjuvanted, Cell Culture-derived H5N1 Influenza Vaccine or Unprimed. ” Request for Supplementary Information adopted on 25.07.2024.	
WS2739	Positive Opinion adopted by consensus on

M-M-RvaxPro-EMEA/H/C/000604/WS2739/0128 Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.5 and 5.1 of the SmPC in order to update information regarding the concomitant use of M-M-RvaxPro and Varivax with Pneumococcal Conjugate Vaccines (PCVs), based on the final results from study V114-029; this is a phase 3, multicentre, randomised, double-blind, active-comparator-controlled study to evaluate the safety, tolerability, and immunogenicity of a 4-dose regimen of V114 in healthy infants (PNEU-PED). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the product information and update the list of local representatives in the Package Leaflet" Opinion adopted on 24.10.2024.	24.10.2024.
WS2754 **Iscover-EMEA/H/C/000175/WS2754/0156** **Plavix-EMEA/H/C/000174/WS2754/0157** Sanofi Winthrop Industrie, Lead Rapporteur: Fátima Ventura, "Update of sections 4.2 and 5.1 of the SmPC in order to include information on posology enhancement and to update pharmacodynamic information based on post marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the SmPC."	See 9.1

B.5.3. CHMP-PRAC assessed procedures

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

C.I.4: Update of section 4.8 of the SmPC in order to update the immunogenicity information based on results from studies EMR100070-003, B9991003 and 100/B9991001. Study EMR100070-003 is a Phase 2, single-arm, open label, multicentre study to investigate the clinical activity and safety of avelumab in patients with mMCC. T. Study B9991003 is a Phase 3 multinational, multicentre, randomized (1:1), open-label, parallel 2 - arm study of avelumab in combination with axitinib versus sunitinib monotherapy in the 1L treatment of participants with aRCC. Study 100/B9991001 is a Phase 3, multicentre, multinational, randomized, open-label, parallel-arm efficacy and safety study of avelumab plus best supportive care (BSC) versus BSC alone as a maintenance treatment in adult participants with locally advanced or metastatic UC whose disease did not progress after completion of 1L platinum-containing chemotherapy." Request for Supplementary Information adopted on 31.10.2024.	
BESPONSA - Inotuzumab ozogamicin - EMEA/H/C/004119/II/0029, Orphan Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, PRAC Rapporteur: Gabriele Maurer, "Submission of the final report from study B1931030 listed as a category 3 study in the RMP. Phase 4, open-label, randomized study of two Inotuzumab Ozogamicin dose levels in adult patients with relapsed or refractory B-cell acute lymphoblastic leukaemia eligible for hematopoietic stem cell transplantation and who have risk factor(s) for veno-occlusive disease. The RMP version 3.1 has also been submitted." Opinion adopted on 24.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 24.10.2024.
Bimzelx - Bimekizumab - EMEA/H/C/005316/II/0029 UCB Pharma S.A., Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan, "Submission of the final report from study PS0014 (BE BRIGHT) listed as a category 3 study in the RMP. This is a multicentre, open-label extension (OLE) study to assess the long-term safety, tolerability, and efficacy of bimekizumab in adult study participants with moderate to severe plaque PSO who completed	Positive Opinion adopted by consensus on 31.10.2024.

1 of the 3 completed feeder studies. The RMP version 2.2 has also been submitted." Opinion adopted on 31.10.2024.	
Erbitux - Cetuximab - EMEA/H/C/000558/II/0099 Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Mari Thorn, "Update of sections 4.2, 4.4 and 4.9 of the SmPC in order to introduce every two-weeks (Q2W) dosing regimen as an alternative to the already approved every week (Q1W) dosing regimen for the indications of metastatic colorectal cancer (CRC) and the recurrent/metastatic squamous cell cancer of the head and neck (SCCHN) in combination with platinum-based chemotherapy, based on pharmacokinetic (PK)-TGI-OS modelling and simulations. The Package Leaflet is updated accordingly. The RMP version 19.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the Product Information." Request for Supplementary Information adopted on 27.06.2024.	See 9.1
Hepcludex - Bulevirtide - EMEA/H/C/004854/II/0034, Orphan Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, PRAC Rapporteur: Adam Przybylkowski, "Update of section 4.8 of the SmPC in order to update safety information based on final results from study MYR204 listed as a category 3 study in the RMP; this is a multicentre, open-label, randomized Phase 2b clinical study to assess efficacy and safety of bulevirtide in combination with pegylated interferon alfa-2a in patients with chronic hepatitis delta. The RMP version 6.0 has also been adopted." Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 31.10.2024.
HyQvia - Human normal immunoglobulin - EMEA/H/C/002491/II/0102 Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Submission of the final report from study 161505; this is a Phase 3b, open-label, non-controlled, multicentre study to assess the long-term tolerability and safety of immune globulin infusion 10% (human) with	Request for supplementary information adopted with a specific timetable.

recombinant human hyaluronidase (HYQVIA/HyQvia) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP). The RMP version 16.0 has also been submitted." Request for Supplementary Information adopted on 31.10.2024.	
ILARIS - Canakinumab - EMEA/H/C/001109/II/0085 Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 05.09.2024, 11.07.2024.	Positive Opinion adopted by consensus on 31.10.2024.
Kadcyla - Trastuzumab emtansine - EMEA/H/C/002389/II/0071/G Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Karin Erneholm, "A grouped application consisting of: C.I.4 (Type II): Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on interim results from study BO27938 (KATHERINE) listed as a PAES in the Annex II and as a category 3 study in the RMP. This is a Randomized, Multicentre, Open Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients with HER2-Positive Primary Breast Cancer who have Residual Tumour Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy. The Package Leaflet is updated in accordance. The RMP version 16.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI. Furthermore, the MAH took the opportunity to update Annex II-D and to implement editorial changes to the Labelling section." Request for Supplementary Information adopted on 31.10.2024.	Request for supplementary information adopted with a specific timetable.
Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/II/0056, Orphan	Positive Opinion adopted by consensus on 31.10.2024.

Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber, "Update of sections 4.8 and 5.1 of the SmPC in order to update safety and efficacy data based on final results from study VX19-445-107 (Study 107); this is a Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of ELX/TEZ/IVA Combination Therapy in Subjects With Cystic Fibrosis Who Are 6 Years of Age and Older. The RMP version 9.2 has also been submitted." Opinion adopted on 31.10.2024.	
Kalydeco - Ivacaftor - EMEA/H/C/002494/II/0126 Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Monica Martinez Redondo, "Submission of the final report from study VX15-770-126 (study 126) listed as a category 3 study in the RMP; this is a phase 3, 2-arm, multicentre open-label study to evaluate the safety and pharmacodynamics of long-term ivacaftor treatment in subjects with cystic fibrosis who are less than 24 months of age at treatment initiation and have an approved ivacaftor-responsive mutation. The RMP version 16.0 has also been submitted." Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 13.06.2024.	Positive Opinion adopted by consensus on 31.10.2024.
Ocrevus - Ocrelizumab - EMEA/H/C/004043/II/0041 Roche Registration GmbH, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.6 and 5.3 of the SmPC in order to amend the recommendations for breast-feeding during ocrelizumab therapy, based on newly available clinical data. The Package Leaflet is updated accordingly. The RMP version 10.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Request for Supplementary Information adopted on 31.10.2024, 11.07.2024.	Request for supplementary information adopted with a specific timetable.
Pyzchiva - Ustekinumab - EMEA/H/C/006183/II/0005/G Samsung Bioepis NL B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald	

Rystiggo - Rozanolixizumab - EMEA/H/C/005824/II/0006, Orphan UCB Pharma, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Maria del Pilar Rayon, "Update of sections 4.8 and 5.1 of the SmPC based on final results from study MG0007 listed as a specific a category 3 study in the RMP; this is a randomized, open-label extension study to evaluate the long-term safety, tolerability, and efficacy of repeated 6-week treatment cycles of rozanolixizumab based on myasthenia gravis worsening in adult study participants with generalized myasthenia gravis. The RMP version 1.2 is adopted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4 and to update the PI in accordance with the latest EMA excipients guideline." Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0052, Orphan Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of section 4.2 of the SmPC in order to update the posology recommendations by removing the current recommendation of a maximum of four implants per year, based on a literature review and analysis of safety data. The Package Leaflet is updated accordingly. The RMP version 9.8 has also been submitted. In addition, the MAH took the opportunity to introduce a minor editorial change to the Product Information." Request for Supplementary Information adopted on 30.05.2024.	
SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0053, Orphan Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Submission of an updated RMP version 9.12 to include changes made to the pharmacokinetic study CUV052 including the inclusion of adolescent patients in the protocol. CUV052 is an interventional study to evaluate the pharmacokinetics of afamelanotide in patients with Erythropoietic Protoporphyria (EPP)." Request for Supplementary Information adopted on 31.10.2024.	Request for supplementary information adopted with a specific timetable.

TAVNEOS - Avacopan - EMEA/H/C/005523/II/0015, Orphan Vifor Fresenius Medical Care Renal Pharma France, Rapporteur: Kristina Dunder, PRAC Rapporteur: Liana Martirosyan, "Update of sections 4.5 and 5.2 of the SmPC based on final results from study CL020_168; this is an open-label, phase 1 study to evaluate the effect of repeated oral doses of avacopan on the pharmacokinetics of a single dose of simvastatin in healthy volunteers; the Package Leaflet is updated accordingly. The updated RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC." Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 31.10.2024.
Tecentriq - Atezolizumab - EMEA/H/C/004143/II/0087 Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Carla Torre, "Update of sections 4.2, 4.8 and 5.1 in order to include information regarding switching treatment between Tecentriq intravenous and subcutaneous (and vice versa) and to update safety information, based on primary results from study MO43576 (IMscin002); this is a phase II, randomised, multicentre, open-label cross-over study to evaluate participants and healthcare professional reported reference for subcutaneous atezolizumab compared with intravenous atezolizumab formulation in participants with non-small cell lung cancer. The RMP version 31.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI." Request for Supplementary Information adopted on 19.09.2024.	See 9.1
Truqap - Capivasertib - EMEA/H/C/006017/II/0001 AstraZeneca AB, Rapporteur: Janet Koenig, PRAC Rapporteur: Sonja Hrabcik, "Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to update the posology recommendation and the warning regarding Diabetic Ketoacidosis (DKA) and add it to the list of adverse drug reactions (ADRs) with frequency uncommon based on a safety review. The Package Leaflet is updated accordingly. The RMP version 2 has	

also been submitted. In addition, the MAH took the opportunity to remove post authorisation measures which were added to Annex II in error, to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4."	
VPRIV - Velaglucerase alfa - EMEA/H/C/001249/II/0063 Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Update of section 4.2 of the SmPC in order to add information to support at-home self-administration of VPRIV by a trained patient and/or a caregiver based on post-marketing data and literature. The Package Leaflet and Annex IID are updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and Package Leaflet and to update the contact details of the local representatives in the Package Leaflet. The updated RMP version 13.4 was agreed during the procedure." Request for Supplementary Information adopted on 25.07.2024, 25.04.2024, 14.12.2023.	
Vyvgart - Efgartigimod alfa - EMEA/H/C/005849/II/0022/G, Orphan Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald Request for Supplementary Information adopted on 31.10.2024.	Request for supplementary information adopted with a specific timetable.
WEZENLA - Ustekinumab - EMEA/H/C/006132/II/0003/G Amgen Technology (Ireland) Unlimited Company, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Rhea Fitzgerald Request for Supplementary Information adopted on 31.10.2024.	Request for supplementary information adopted with a specific timetable.
Xenpozyme - Olipudase alfa - EMEA/H/C/004850/II/0012/G, Orphan Sanofi B.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber, "A grouped application consisting of: C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study DFI12712 ASCEND, listed as a category 3 study in the RMP; this is a Phase 2/3, multicentre, randomised, double-blinded, placebo-controlled, repeat-dose study to evaluate the efficacy,	Request for supplementary information adopted with a specific timetable.

safety, pharmacodynamics and pharmacokinetics of olipudase alfa in patients with AMSD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the SmPC. C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to update safety information based on final results from study LTS13632 listed as a category 3 study in the RMP; this is a long-term study the ongoing safety and efficacy of olipudase alfa in patients with ASMD. The Package Leaflet is updated accordingly. The RMP version 3.0 has also been submitted." Request for Supplementary Information adopted on 31.10.2024.	
WS2695 **Dengue Tetravalent Vaccine (Live, Attenuated) Takeda-** **EMEA/H/W/005362/WS2695/0015** **Qdenga-** **EMEA/H/C/005155/WS2695/0016** Takeda GmbH, Lead Rapporteur: Sol Ruiz, Lead PRAC Rapporteur: Liana Martirosyan, "Update of section 4.4 and 4.8 of the SmPC in order to add anaphylactic reaction to the list of adverse drug reactions (ADRs) with frequency not known, based on post-authorization experience. The Package Leaflet is updated accordingly. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to introduce minor editorial changes to the PI." Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 11.07.2024.	Positive Opinion adopted by consensus on 31.10.2024.

B.5.4. PRAC assessed procedures

PRAC Led **Fintepla - Fenfluramine -** **EMEA/H/C/003933/II/0025, Orphan** UCB Pharma SA, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of section 4.8 of the SmPC in order to propose a combined Adverse Drug Reaction	Request for supplementary information adopted with a specific timetable.

table for Dravet Syndrome and Lennox-Gastaut syndrome following PSUSA procedure EMEA/H/C/PSUSA/00010907/202306. The package leaflet is updated accordingly." Request for Supplementary Information adopted on 31.10.2024, 05.09.2024.	
PRAC Led **Gilenya - Fingolimod - EMEA/H/C/002202/II/0090/G** Novartis Europharm Limited, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP liaison: Alexandre Moreau, "Grouped application comprising two variations as follows: Type II (C.I.3.b) - Update of sections 4.3 and 4.4 of the SmPC in order to add history of progressive multifocal leukoencephalopathy (PML) as a new contraindication and to amend an existing warning on PML and to update the educational material to improve the general readability of these documents and better address key messages and recommendations for healthcare professionals following the assessment of procedure PSUSA/00001393/202302. The Package Leaflet and Annex II are updated accordingly. The RMP version 20.0 has also been submitted. Type IA (A.6) - To change the ATC Code of Fingolimod from L04AA27 to L04AE01." Request for Supplementary Information adopted on 13.06.2024.	
PRAC Led **Humira - Adalimumab - EMEA/H/C/000481/II/0219** AbbVie Deutschland GmbH & Co. KG, PRAC Rapporteur: Karin Bolin, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study P10-262 listed as a category 3 study in the RMP. This is a long-term, multi-centre, longitudinal, post-marketing observational registry to assess long-term safety and effectiveness of Humira (adalimumab) in children with moderately to severely active polyarticular or polyarticular-course juvenile idiopathic arthritis (JIA). The RMP version 16.1 has also been submitted." Request for Supplementary Information adopted on 31.10.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Kaftrio - Ivacaftor / Tezacaftor /**	Request for supplementary information adopted with a specific timetable.

Elexacaftor - EMEA/H/C/005269/II/0055, Orphan Vertex Pharmaceuticals (Ireland) Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of section 4.6 of the SmPC in order to amend the existing wording on exposure during pregnancy following PSUR procedure (EMEA/H/C/PSUSA/00010868/202310)." Request for Supplementary Information adopted on 31.10.2024.	
PRAC Led **Lenvima - Lenvatinib - EMEA/H/C/003727/II/0056** Eisai GmbH, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "To submit the final report from study E7080-M000-508 (STELLAR), listed as a category 3 PASS in the RMP; this is a multicentre non-interventional, observational Phase 4 study to evaluate the safety and tolerability of lenvatinib in patients with advanced or unresectable HCC. An updated RMP version 17.0 has also been submitted." Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 03.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
PRAC Led **Mysimba - Naltrexone hydrochloride / Bupropion hydrochloride - EMEA/H/C/003687/II/0063** Orexigen Therapeutics Ireland Limited, Re-examination 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." Opinion adopted on 25.07.2024. Request for Supplementary Information adopted on 16.05.2024, 09.02.2024, 31.08.2023.	See 5.3
PRAC Led **Orgovyx - Relugolix - EMEA/H/C/005353/II/0024** Accord Healthcare S.L.U, PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Boje Kvorning Pires Ehmsen, "Update of section 4.8	Positive Opinion adopted by consensus on 31.10.2024.

of the SmPC in order to amend the frequency of an existing adverse drug reactions (ADRs) 'Myocardial infarction' from 'rare' to 'uncommon' following PSUSA 00010994/202401 procedure and based on the current available clinical trial data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to add editorial changes." Opinion adopted on 31.10.2024.	
PRAC Led **Signifor - Pasireotide - EMEA/H/C/002052/II/0070, Orphan** Recordati Rare Diseases, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study CSOM230B2410 listed as a category 3 PASS in the RMP. This is a non-interventional, multinational, multi-centre post-marketing study to further document the safety and efficacy of pasireotide s.c. administered in routine clinical practice in patients with Cushing's disease. The RMP version 8.0 has also been submitted." Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
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 9.3 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)." Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 13.06.2024, 08.02.2024.	Positive Opinion adopted by consensus on 31.10.2024.
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,	Positive Opinion adopted by consensus on 31.10.2024.

multi-centre, 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." Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 03.10.2024, 13.06.2024, 11.04.2024.	
PRAC Led **Zejula - Niraparib - EMEA/H/C/004249/II/0055, Orphan** GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Christian Gartner, "Submission of an updated RMP version 8.0 in order to remove the category 3 PASS 3000-04-002/ GSK 214708; this is an integrated meta-analysis of MDS/AML and other SPM incidence in patients with ovarian cancer who have been treated with niraparib." Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
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** ViiV Healthcare B.V., Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "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	Positive Opinion adopted by consensus on 31.10.2024.

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 utilization; 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. In addition, the MAH took the opportunity to implement editorial changes to sections 4.4 and 4.5 of the SmPC. The package leaflet is updated accordingly. The RMP version 19.0 (Tivicay), version 23.1 (Triumeq), version 5.0 (Dovato) and version 8.0 (Juluca) have also been submitted. " Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 03.10.2024, 16.05.2024, 08.02.2024.	
PRAC Led **WS2696** **Adrovance-** **EMEA/H/C/000759/WS2696/0055** **FOSAVANCE-** **EMEA/H/C/000619/WS2696/0058** **VANTAVO-** **EMEA/H/C/001180/WS2696/0045** Organon N.V., Lead PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Christian Gartner, "Submission of an updated RMP version 8.1 following the assessment outcome from procedure WS/2467 to reclassify the risk of atypical femoral fracture from "important potential risk" to "important identified risk" and to extend the risk of "atypical femoral fracture" to "atypical fractures of long bones". Further, the MAH took the opportunity to update the information in the RMP regarding important identified risks and missing information." Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 31.10.2024.

B.5.5. CHMP-CAT assessed procedures

Ebvallo - Tabelecleucel - EMEA/H/C/004577/II/0011/G, Orphan, ATMP Pierre Fabre Medicament, Rapporteur: Egbert	

Flory, CHMP Coordinator: Jan Mueller-Berghaus Request for Supplementary Information adopted on 13.09.2024.	
Hemgenix - Etranacogene dezaparvovec - EMEA/H/C/004827/II/0018, Orphan, ATMP CSL Behring GmbH, Rapporteur: Silke Dorner, CHMP Coordinator: Daniela Philadelphy, "Update of sections 4.4 and 5.1 of the SmPC in order to reflect a modified 9-point anti-AAV5 Neutralising Antibody (NAb) assay. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet and bring the PI in line with the QRD version 10.4."	
Libmeldy - Atidarsagene autotemcel - EMEA/H/C/005321/II/0031/G, Orphan, ATMP Orchard Therapeutics (Netherlands) B.V., Rapporteur: Emmely de Vries, CHMP Coordinator: Peter Mol	

B.5.6. CHMP-PRAC-CAT assessed procedures

ROCTAVIAN - Valoctocogene roxaparvovec - EMEA/H/C/005830/II/0014, Orphan, ATMP BioMarin International Limited, Rapporteur: Violaine Closson Carella, CHMP Coordinator: Jean-Michel Race, PRAC Rapporteur: Bianca Mulder, "Update of the Annex II in order to propose changes to the current marketing authorisation obligations for ROCTAVIAN. The RMP version 1.3 has also been submitted."	

B.5.7. PRAC assessed ATMP procedures

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

WS2712/G **Bretaris Genuair-EMEA/H/C/002706/WS2712/0055/G** **Eklira Genuair-EMEA/H/C/002211/WS2712/0055/G** Covis Pharma Europe B.V., Lead Rapporteur: Ewa Balkowiec Iskra Opinion adopted on 31.10.2024. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 31.10.2024.

on 05.09.2024.	
WS2720/G **Brimica Genuair-** **EMEA/H/C/003969/WS2720/0043/G** **Duaklir Genuair-** **EMEA/H/C/003745/WS2720/0042/G** Covis Pharma Europe B.V., Lead Rapporteur: Ewa Balkowiec Iskra Opinion adopted on 31.10.2024. Request for Supplementary Information adopted on 05.09.2024.	Positive Opinion adopted by consensus on 31.10.2024.
WS2751/G **Dovato-** **EMEA/H/C/004909/WS2751/0051/G** **Juluca-** **EMEA/H/C/004427/WS2751/0060/G** **Tivicay-** **EMEA/H/C/002753/WS2751/0094/G** **Triumeq-** **EMEA/H/C/002754/WS2751/0123/G** ViiV Healthcare B.V., Lead Rapporteur: Filip Josephson Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
WS2755 **Hexacima-** **EMEA/H/C/002702/WS2755/0161** **Hexyon-** **EMEA/H/C/002796/WS2755/0165** Sanofi Pasteur Europe, Duplicate of Hexacima, Lead Rapporteur: Jan Mueller-Berghaus	
WS2765/G **Aflunov-** **EMEA/H/C/002094/WS2765/0087/G** **Foclivia-** **EMEA/H/C/001208/WS2765/0090/G** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2765/0006/G** Seqirus S.r.l., Informed Consent of Aflunov, Lead Rapporteur: Maria Grazia Evandri Request for Supplementary Information adopted on 31.10.2024.	Request for supplementary information adopted with a specific timetable.
WS2772 **Jubbonti-** **EMEA/H/C/005964/WS2772/0004** **Wyost-EMEA/H/C/006378/WS2772/0003** Sandoz GmbH, Lead Rapporteur: Christian Gartner	

WS2775/G **Aflunov-** **EMEA/H/C/002094/WS2775/0088/G** **Foclivia-** **EMEA/H/C/001208/WS2775/0091/G** Seqirus S.r.l, Lead Rapporteur: Maria Grazia Evandri Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
WS2779 **Aflunov-** **EMEA/H/C/002094/WS2779/0089** **Foclivia-** **EMEA/H/C/001208/WS2779/0092** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2779/0007** Seqirus S.r.l, Lead Rapporteur: Maria Grazia Evandri Opinion adopted on 31.10.2024.	Positive Opinion adopted by consensus on 31.10.2024.
WS2785 **Aflunov-** **EMEA/H/C/002094/WS2785/0090** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2785/0008** Seqirus S.r.l, Lead Rapporteur: Maria Grazia Evandri	

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

Enzalutamide - EMEA/H/C/006612 treatment of prostate cancer
Golimumab - EMEA/H/C/006560 treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis and ulcerative colitis
Insulin icodec / Semaglutide - EMEA/H/C/006279 , treatment of adults with type 2 diabetes mellitus insufficiently controlled on basal insulin or glucagon-like peptide 1 (GLP-1) receptor agonists

Elinzanetant - EMEA/H/C/006298
for the treatment of moderate to severe vasomotor symptoms (VMS)

Rivaroxaban - EMEA/H/C/006643
prevention of atherothrombotic events

Teduglutide - EMEA/H/C/006564
treatment of Short Bowel Syndrome

Rilzabrutinib - EMEA/H/C/006425, Orphan
Sanofi B.V., for the treatment of persistent or chronic immune thrombocytopenia (ITP)

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

Hetlioz - Tasimelteon - EMEA/H/C/003870/X/0039, Orphan
Vanda Pharmaceuticals Netherlands B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski, "Extension application to introduce a new pharmaceutical form associated with new strength (4 mg/ml oral solution). The new formulation is indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in paediatric patients 3 to 15 years of age. The RMP (version 5.0) is updated in accordance."

Livmarli - Maralixibat - EMEA/H/C/005857/X/0015, Orphan
Mirum Pharmaceuticals International B.V., Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Extension application to introduce a new pharmaceutical form (tablet) associated with new strengths 10 mg, 15mg, 20 mg and 30 mg.
The RMP (version 5.0) is updated in accordance."

Pyzchiva - Ustekinumab - EMEA/H/C/006183/X/0006
Samsung Bioepis NL B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald, "Extension application to introduce a new strength (45 mg solution for injection in a vial) for partial use in paediatric patients."

Spevigo - Spesolimab - EMEA/H/C/005874/X/0011
Boehringer Ingelheim International GmbH, Rapporteur: Kristina Dunder, PRAC Rapporteur: Tiphaine Vaillant, "Extension application to add

a new strength of 300 mg (150 mg/ml) for solution for injection in a pre-filled syringe. The RMP (version 3.0) is updated in accordance. In addition, the applicant has updated SmPC (Annex I) and Package Leaflet (Annex IIIB) for both 450 mg concentrate for solution for infusion and 150 mg and 300 mg solution for injection in line with the new excipient guideline."

Talzenna - Talazoparib - EMEA/H/C/004674/X/0022
Pfizer Europe MA EEIG, Rapporteur: Filip Josephson, "Extension application to add new strengths of 0.35 mg and 0.5 mg hard capsules. Furthermore, the PI is being brought in line with the QRD template version 10.4."

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

Bylvay - Odevixibat - EMEA/H/C/004691/S/0023, Orphan
Ipsen Pharma, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski

Myalepta - Metreleptin - EMEA/H/C/004218/S/0039, Orphan
Chiesi Farmaceutici S.p.A., Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Adam Przybylkowski

Zokinvy - Lonafarnib - EMEA/H/C/005271/S/0012, Orphan
EigerBio Europe Limited, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski

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

BYANNLI - Paliperidone - EMEA/H/C/005486/R/0008
Janssen-Cilag International N.V., Informed Consent of Xeplion, Rapporteur: Kristina Dunder, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Karin Bolin

Fingolimod Accord - Fingolimod - EMEA/H/C/005191/R/0011

Accord Healthcare S.L.U., Generic of Gilenya, Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Tiphaine Vaillant

Gencebok - Caffeine citrate - EMEA/H/C/005435/R/0012
Gennisium Pharma, Rapporteur: Alar Irs, PRAC Rapporteur: Sonja Hrabcik

Insulin aspart Sanofi - Insulin aspart - EMEA/H/C/005033/R/0020
Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Robert Porszasz, PRAC Rapporteur: Mari Thorn

LIVOGIVA - Teriparatide - EMEA/H/C/005087/R/0015
Theramex Ireland Limited, Rapporteur: Christian Gartner, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Tiphaine Vaillant

MVABEA - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343/R/0023
Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Jean-Michel Dogné

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

Xenleta - Lefamulin - EMEA/H/C/005048/R/0010
Nabriva Therapeutics Ireland DAC, Rapporteur: Jayne Crowe, Co-Rapporteur: Ingrid Wang, PRAC Rapporteur: Eva Jirsová

Zabdeno - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337/R/0022
Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Jean-Michel Dogné

Zercepac - Trastuzumab - EMEA/H/C/005209/R/0039
Accord Healthcare S.L.U., Rapporteur: Sol Ruiz, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Gabriele Maurer

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

Amvuttra - Vutrisiran - EMEA/H/C/005852/II/0015, Orphan Alnylam Netherlands B.V., Rapporteur: Janet Koenig, Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Liana Martirosyan, "Extension of indication to include treatment of wild-type or hereditary transthyretin-mediated amyloidosis in adult patients with cardiomyopathy (ATTR-CM), based on primary analysis results from study HELIOS-B (ALN-TTRSC02-003); a Phase 3, Randomized, Double-blind, Placebo-controlled, Multicentre Study to Evaluate the Efficacy and Safety of Vutrisiran in Patients With Transthyretin Amyloidosis With Cardiomyopathy (ATTR Amyloidosis With Cardiomyopathy). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. An updated version 1.3 of the RMP has also been submitted. As part of the application the MAH applied for +1 year of additional market protection." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
Calquence - Acalabrutinib - EMEA/H/C/005299/II/0028 AstraZeneca AB, Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi, "Extension of indication to include CALQUENCE in combination with venetoclax with or without obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL), based on interim results from study AMPLIFY (D8221C00001). This is a Randomized, Multicentre, Open-Label, Phase 3 Study to Compare the Efficacy and Safety of Acalabrutinib in Combination with Venetoclax with and without Obinutuzumab Compared to Investigator's Choice of Chemoimmunotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukaemia Without del(17p) or TP53 Mutation	

(AMPLIFY). As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8 of the RMP has also been submitted."

Cystadrops - Mercaptamine - EMEA/H/C/003769/II/0032, Orphan

Recordati Rare Diseases, Rapporteur: Kristina Dunder, PRAC Rapporteur: Maria del Pilar Rayon, "Extension of indication to include treatment of children from 6 months of age for CYSTADROPS, based on final results from study CYT-C2-001. This is an Open-label, Single-arm, Multicentre Study to Assess the Safety of Cystadrops in Paediatric Cystinosis Patients from 6 Months to Less Than 2 Years Old. 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 2.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II of the PI and the list of local representatives in the Package Leaflet."

Dapivirine Vaginal Ring 25 mg - Dapivirine - EMEA/H/W/002168/II/0027

International Partnership for Microbicides Belgium AISBL, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jan Neuhauser, "Extension of indication to include reducing the risk of HIV-1 infection via vaginal intercourse in HIV-uninfected women 16 years and older for Dapivirine Vaginal Ring 25 mg, based on final results from study MTN-034 (REACH) listed as a category 3 study in the RMP; this is a Phase 2a crossover trial evaluating the safety of and adherence to a vaginal matrix ring containing dapivirine and oral emtricitabine/tenofovir disoproxil fumarate in an adolescent and young adult female population. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 1.5 of the RMP has also been submitted."

Darzalex - Daratumumab - EMEA/H/C/004077/II/0076, Orphan

Janssen-Cilag International N.V., Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Carla Torre, "Extension of indication for Darzalex in combination with bortezomib, lenalidomide and dexamethasone for the

treatment of newly diagnosed multiple myeloma, to include also adult patients who are not eligible for stem cell transplant (SCT), based on the results of the final PFS analysis from Study CEPHEUS (54767414MMY3019), a randomised, open-label, active-controlled, multicentre phase 3 study in adult participants, comparing the clinical outcome of D-VRd with VRd in participants with untreated multiple myeloma for whom stem cell transplant is not planned as initial therapy, in terms of the primary endpoint of MRD negativity rate in participants with CR or better rate and major secondary endpoints of CR or better rate, PFS and sustained MRD negativity. As a consequence, SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 are updated and the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the contact details of the local representatives in the Package Leaflet. An updated RMP version 11.1 has also been submitted.”	
Hetlioz - Tasimelteon - EMEA/H/C/003870/II/0040, Orphan Vanda Pharmaceuticals Netherlands B.V., Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski, “Extension of indication to include the treatment of nighttime sleep disturbances in adults with Smith Magenis Syndrome (SMS) for HETLIOZ, based on results from study VP-VEC-162-2401. This is a double-blind, randomized, two-period crossover study evaluating the effects of tasimelteon vs. placebo on sleep disturbances of individuals with Smith-Magenis Syndrome (SMS). As a consequence, sections 4.1, 4.5, 5.1, 5.2 and 5.3 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. The RMP version 5.0 has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.” Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)	
Imfinzi - Durvalumab - EMEA/H/C/004771/II/0073 AstraZeneca AB, Rapporteur: Boje Kvorning	

Pires Ehmsen, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: David Olsen, "Extension of indication to include IMFINZI in combination with cisplatin-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, for the treatment of adults with muscle invasive bladder cancer (MIBC), based on an ongoing pivotal study D933RC00001 (NIAGARA); this is a phase 3, randomized, open-label, multi-centre, global study to determine the efficacy and safety of durvalumab in combination with gemcitabine+cisplatin for neoadjuvant treatment followed by durvalumab alone for adjuvant treatment in patients with muscle-invasive bladder cancer. As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. The RMP version 13 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and update the PI according to the Excipients Guideline."	
Jivi - Damoctocog alfa pegol - EMEA/H/C/004054/II/0034 Bayer AG, Rapporteur: Boje Kvorning Pires Ehmsen Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Bianca Mulder, "Extension of indication to include treatment and prophylaxis of bleeding in previously treated patients ≥7 years of age with haemophilia A for JIVI, based on integrated analysis results from Part A of the Alfa-PROTECT study (21824) and PROTECT Kids main study (15912). Alfa-PROTECT is a Phase 3, single-group treatment, open-label study to evaluate the safety of BAY 94-9027 infusions for prophylaxis and treatment of bleeding in previously treated children aged 7 to <12 years with severe haemophilia A. PROTECT Kids is a multi-centre, Phase 3, non-controlled, open-label trial to evaluate the pharmacokinetics, safety, and efficacy of BAY 94-9027 for prophylaxis and treatment of bleeding in previously treated children (age <12 years) with severe haemophilia A. 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 3.1 of the RMP has also been submitted. In addition, the	

Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

NUBEQA - Darolutamide - EMEA/H/C/004790/II/0024

Bayer AG, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Jan Neuhauser, "Extension of indication to include in combination with androgen deprivation therapy (ADT) the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) for NUBEQA, based on final results from study 21140 (ARANOTE); this is a randomized, double-blind, placebo-controlled Phase 3 study of darolutamide to demonstrate the superiority of darolutamide in addition to ADT over placebo plus ADT in patients with mHSPC. 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 5.1 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 and update the Package Leaflet to more patient friendly wording based on patient council feedback."

Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0016

Beigene Ireland Limited, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "Extension of indication to include first-line treatment of adult patients with extensive-stage Small Cell Lung Cancer (SCLC) for Tevimbra in combination with etoposide and platinum chemotherapy based on final results from study BGB-A317-312; a phase 3, randomized, double-blind, placebo-controlled study of platinum plus etoposide with or without tislelizumab in patients with untreated extensive-stage small cell lung cancer. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The MAH also took the opportunity to make editorial changes to the SmPC, Annex II and Package Leaflet.
The supportive studies BGB-A317-309 and BGB-A317-315 are provided for the purpose of updating the safety data package as well as

updated data (latest CSR versions with new data cut-off) from the monotherapy pool (tislelizumab used at 200mg Q3W) consisting of the studies 001, 102, 203, 204, 208, 209, 301, 302, and 303 and from the combination with chemotherapy pool consisting of the studies 205, 206, 304, 305, 306, 307 and 312. Version 2.4 of the RMP has also been submitted."

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

AJOVY - Fremanezumab -
EMEA/H/C/004833/II/0052
TEVA GmbH, Rapporteur: Jan Mueller-Berghaus

Aptivus - Tipranavir -
EMEA/H/C/000631/II/0096/G
Boehringer Ingelheim International GmbH, Rapporteur: Jean-Michel Race

Herzuma - Trastuzumab -
EMEA/H/C/002575/II/0067/G
Celltrion Healthcare Hungary Kft., Rapporteur: Jan Mueller-Berghaus

KIMMTRAK - Tebentafusp -
EMEA/H/C/004929/II/0009/G, Orphan
Immunocore Ireland Limited, Rapporteur: Boje Kvorning Pires Ehmsen

Omlyclo - Omalizumab -
EMEA/H/C/005958/II/0004/G
Celltrion Healthcare Hungary Kft., Rapporteur: Finbarr Leacy, PRAC Rapporteur: Mari Thorn

RoActemra - Tocilizumab -
EMEA/H/C/000955/II/0124/G
Roche Registration GmbH, Rapporteur: Jan Mueller-Berghaus

Spikevax - COVID-19 mRNA vaccine -
EMEA/H/C/005791/II/0146
Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus

WS2770/G
Filgrastim Hexal-
EMEA/H/C/000918/WS2770/0079/G
Zarzio-
EMEA/H/C/000917/WS2770/0080/G
Sandoz GmbH, Lead Rapporteur: Peter Mol

WS2780

Riltrava Aerosphere-
EMEA/H/C/005311/WS2780/0017
Trixeo Aerosphere-
EMEA/H/C/004983/WS2780/0024
AstraZeneca AB, Lead Rapporteur: Finbarr Leacy, Lead PRAC Rapporteur: Jan Neuhauser

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

Omjjara - Momelotinib -
EMEA/H/C/005768/II/0004/G, Orphan
Glaxosmithkline Trading Services Limited, Rapporteur: Christophe Focke, "A grouped application comprised of one Type II, one Type IB and one Type IA Variation, as follows:

Type II (C.I.4): Update of section 4.8 of the SmPC in order to add 'rash' to the list of adverse drug reactions (ADRs) with frequency 'common' based on a safety review of clinical studies and post- marketing safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to add editorial changes to the PI and update the list of local representatives in the Package Leaflet.

Type IB (C.I.z): Update of section 5.2 of SmPC in order to include minor updates to the absorption and biotransformation subsections of the PI based on data from the already submitted study GS-US-352-0102.

Type IA (A.6): Include the ATC Code L01EJ04 in Section 5.1 of the Summary of Product Characteristics (SmPC)."

Strensiq - Asfotase alfa -
EMEA/H/C/003794/II/0070, Orphan
Alexion Europe SAS, Rapporteur: Paolo Gasparini, "Update of section 5.1 of the SmPC in order to reflect data on effectiveness of asfotase alfa in treating adults with paediatric-onset with hypophosphatasia (HPP) based on real world evidence [RWE], and publications from the Global HPP Registry (ALXN-HPP-501), an observational study [EmPATHY] and UK managed access agreement study another observational prospective study. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD

template version 10.4 and add editorial changes to the Labelling."

B.6.10. CHMP-PRAC assessed procedures

B.6.11. PRAC assessed procedures

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

WS2737
Olanzapine Glenmark-
EMEA/H/C/001085/WS2737/0044
Olanzapine Glenmark Europe-
EMEA/H/C/001086/WS2737/0041
Olazax-EMEA/H/C/001087/WS2737/0036
Olazax Disperzi-
EMEA/H/C/001088/WS2737/0038
Glenmark Arzneimittel GmbH, Generic of Olansek (SRD), Zyprexa, Zyprexa Velotab, Lead Rapporteur: Alexandre Moreau

WS2763/G
Trimbow-
EMEA/H/C/004257/WS2763/0043/G
Trydonis-
EMEA/H/C/004702/WS2763/0040/G
Chiesi Farmaceutici S.p.A., Lead Rapporteur: Janet Koenig

WS2776/G
Copalia-
EMEA/H/C/000774/WS2776/0136/G
Dafiro-
EMEA/H/C/000776/WS2776/0140/G
Exforge-
EMEA/H/C/000716/WS2776/0135/G
Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher

WS2786
BiResp Spiromax-
EMEA/H/C/003890/WS2786/0045
DuoResp Spiromax-

EMEA/H/C/002348/WS2786/0045
Teva Pharma B.V., Lead Rapporteur: John Joseph Borg

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

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

B.7.2. Monthly Line listing for Type I variations

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

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

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

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

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers

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

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

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

G. ANNEX G

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

Information related to Scientific Advice cannot be released at the present time as these contain

commercially confidential information.

G.2. PRIME

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

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