24 February 2025
EMA/CHMP/41869/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 24-27 February 2025
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

24 February 2025, 09:00 – 19:30, virtual meeting/room 1C

25 February 2025, 08:30 – 19:30, virtual meeting/room 1C

26 February 2025, 08:30 – 19:30, virtual meeting/room 1C

27 February 2025, 08:30 – 15:00, virtual meeting/room 1C

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 24-27 February 2025. See February 2025 CHMP minutes (to be published post March 2025 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 24-27 February 2025

1.3. Adoption of the minutes

CHMP minutes for 27-30 January 2025.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 17 February 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 24 February 2025 at 14:00

List of Outstanding Issues adopted on 12.12.2024, 19.09.2024. List of Questions adopted on 25.05.2023.

2.1.2. Donanemab - EMEA/H/C/006024

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

Scope: Oral explanation

Action: Oral explanation to be held on 26 February 2025 at 14:00

List of Outstanding Issues adopted on 12.12.2024, 25.04.2024. List of Questions adopted on 14.12.2023.

2.1.3. Atropine - EMEA/H/C/006324

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

Scope: Oral explanation

Action: Oral explanation to be held on 26 February 2025 at 09:00

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

2.2. Re-examination procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 25 February 2025 at 14:00

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

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

See 3.5

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

Merck Sharp & Dohme B.V.;

Scope: Oral explanation

Action: Oral explanation to be held on 26 February 2025 at 16:00

Opinion adopted on 14.11.2024.

See 5.3

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

Orphelia Pharma; treatment of neuroblastoma

Scope: Oral explanation

Action: Oral explanation to be held on 25 February 2025 at 11:00

Hybrid application (Article 10(3) of Directive No 2001/83/EC)

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

Third party intervention

See 3.5

2.3. Post-authorisation procedure oral explanations

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

AstraZeneca AB;

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Oral explanation

Action: Oral explanation to be held on 25 February 2025 at 09:00

Request for Supplementary Information adopted on 12.12.2024.

See 5.1

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

Merck Sharp & Dohme B.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Terhi Lehtinen

Scope: Oral explanation

Action: Oral explanation to be held on 26 February 2025 at 11:00

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

3.1.2. Linvoseltamab - EMEA/H/C/006370

monotherapy for the treatment of adult patients with relapsed or refractory multiple myeloma

Scope: Opinion

Action: For adoption

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

3.1.3. Trabectedin - EMEA/H/C/006433

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

Scope: Opinion

Action: For adoption

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

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 06.12.2024, 11.10.2024. List of Questions adopted on 15.03.2024.

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

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

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

Scope: List of outstanding issues

Action: For adoption

3.2.2. L-Acetylleucine - Orphan - EMEA/H/C/006327

Intrabio Ireland Limited; is indicated in adults and children from birth for chronic treatment of Niemann-Pick Type C (NPC).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2024.

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

treatment of myopia in children aged 3 years and older

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.4. Deutetrabenazine - EMEA/H/C/006371

treatment of tardive dyskinesia

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

3.2.5. Denosumab - EMEA/H/C/006434

treatment of osteoporosis and bone loss

Scope: List of outstanding issues

Request by the applicant for an extension to the clock-stop to respond to the List of outstanding issues.

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.6. Denosumab - EMEA/H/C/006435

prevention of skeletal related events with advanced malignancies

Scope: List of outstanding issues

Request by the applicant for an extension to the clock-stop to respond to the List of outstanding issues.

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.7. Denosumab - EMEA/H/C/006199

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.8. Denosumab - EMEA/H/C/006376

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.9. Inavolisib - EMEA/H/C/006353

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.10. Denosumab - EMEA/H/C/006152

for the treatment of osteoporosis and bone loss.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 27.06.2024.

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

Camurus AB; treatment of acromegaly

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.14. Teprotumumab - EMEA/H/C/006396

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.15. Teriparatide - EMEA/H/C/005687

treatment of osteoporosis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 09.11.2023.

3.2.16. Denosumab - EMEA/H/C/006377

for the treatment of osteoporosis and bone loss

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.09.2024.

3.2.17. Zanidatamab - Orphan - EMEA/H/C/006380

Jazz Pharmaceuticals Ireland Limited; Treatment of biliary tract cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2024.

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

3.3.1. Enzalutamide - EMEA/H/C/006612

treatment of prostate cancer

Scope: List of questions

Action: For adoption

3.3.2. Golimumab - EMEA/H/C/006560

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis and ulcerative colitis

Scope: List of questions

Action: For adoption

3.3.3. 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

Scope: List of questions

Action: For adoption

3.3.4. Elinzanetant - EMEA/H/C/006298

for the treatment of moderate to severe vasomotor symptoms (VMS)

Scope: List of questions

Action: For adoption

3.3.5. Rivaroxaban - EMEA/H/C/006643

prevention of atherothrombotic events

Scope: List of questions

Action: For adoption

3.3.6. Teduglutide - EMEA/H/C/006564

treatment of Short Bowel Syndrome

Scope: List of questions

Action: For adoption

3.3.7. Rilzabrutinib - Orphan - EMEA/H/C/006425

Sanofi B.V.; for the treatment of persistent or chronic immune thrombocytopenia (ITP)

Scope: List of questions

Action: For adoption

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

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

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

Scope: Request by the applicant for an extension to the clock-stop to respond to the list of questions adopted in February 2025

Action: For adoption

3.4.2. Bifikafusp alfa / Onfekafusp alfa - EMEA/H/C/005651

neoadjuvant treatment of adult patients with locally advanced fully resectable melanoma.

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

Action: For adoption

List of Questions adopted on 17.10.2024.

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

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

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

Scope: Opinion

Action: For adoption

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

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

See 2.2

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

Orphelia Pharma; treatment of neuroblastoma

Scope: Opinion

Action: For adoption

Hybrid application (Article 10(3) of Directive No 2001/83/EC)

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

See 2.2

3.6. Initial applications in the decision-making phase

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

Eisai GmbH; treatment of early Alzheimer's disease in apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes.

Scope: CHMP Response to the EC question

Action: For discussion

3.7. Withdrawals of initial marketing authorisation application

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

treatment of neutropenia in paediatric patients

Scope: Withdrawal of initial marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 12.12.2024, 17.10.2024. List of Questions adopted on 30.05.2024.

3.7.2. Rilonacept - Orphan - EMEA/H/C/006537

FGK Representative Service GmbH; treatment of idiopathic pericarditis

Scope: Withdrawal of initial marketing authorisation application

Action: For information

List of Questions adopted on 30.01.2025.

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. 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."

Action: For adoption

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

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

Upjohn EESV;

Rapporteur: Peter Mol, PRAC Rapporteur: Liana Martirosyan

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

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 30.05.2024.

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

Merck Sharp & Dohme B.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Terhi Lehtinen

Scope: "Extension applications to introduce a new pharmaceutical form (granules in sachet) associated with new strengths (20 and 120 mg) grouped with a type II variation (C.I.6.a) to include treatment of paediatric patients from birth up to 18 years old based on the final results from studies P030 and P031.
Study P030 was a Phase 2b, open-label, single-arm study to evaluate PK, efficacy, safety, and tolerability of LET when used for CMV prophylaxis in paediatric participants from birth to <18 years of age who are at risk of developing CS-CMVi following an allogeneic HSCT.
Study P031 was an open-label, single-dose, four-period, seven-treatment, crossover study designed to evaluate the bioavailability of 2 paediatric formulations of MK-8228 (Formulations A and B) administered alone or in soft food (applesauce and vanilla pudding) compared to a currently marketed tablet formulation.

As a consequence, sections 4.1, 4.2, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes."

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

See 2.3

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

Eli Lilly Nederland B.V.;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 25.07.2024.

4.1.5. 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

List of Questions adopted on 14.11.2024.

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

Janssen-Cilag International N.V.;

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

Scope: "Extension application to:
- introduce a new pharmaceutical form (concentrate for solution for infusion), a new strength (200 mg) and a new route of administration (intravenous use)
- add a new strength of 200 mg for solution for injection (in pre-filled syringe / pre-filled pen) for subcutaneous use
This application is grouped with a type II variation (C.I.6.a) to include the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor for Tremfya, based on results of a Phase 2b/3 clinical development programme (CNTO1959UCO3001) consisting of 3 separate

studies, an Induction dose finding Study 1 Phase 2b, an Induction Study 2 Phase 3 and a Phase 3 Maintenance Study. These studies were randomized, double-blind, placebo-controlled, parallel-group, multicentre studies that evaluated the efficacy and safety of guselkumab in participants with moderately to severely active UC. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC of the already approved form 100 mg solution for injection are updated. The Package Leaflet and Labelling are updated in accordance. Version 10.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI."

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 19.09.2024.

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

4.2.1. Adempas - Riociguat - EMEA/H/C/002737/X/0041

Bayer AG;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension application to introduce a new pharmaceutical form associated with a new strength (0.15 mg/ml granules for oral suspension) for the Pulmonary arterial hypertension (PAH) paediatric indication. As a consequence, the film coated tablets presentations are updated to accommodate the new pharmaceutical form. In addition, contact details for local representatives of Belgium, Luxembourg, Greece and Ireland, have also been updated."

Action: For adoption

List of Questions adopted on 17.10.2024.

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. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/X/0039

Vanda Pharmaceuticals Netherlands B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski

Scope: "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."

Action: For adoption

4.3.2. Livmarli - Maralixibat - Orphan - EMEA/H/C/005857/X/0015

Mirum Pharmaceuticals International B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "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."

Action: For adoption

4.3.3. Pyzchiva - Ustekinumab - EMEA/H/C/006183/X/0006

Samsung Bioepis NL B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

Scope: "Extension application to introduce a new strength (45 mg solution for injection in a vial) for partial use in paediatric patients."

Action: For adoption

4.3.4. Spevigo - Spesolimab - EMEA/H/C/005874/X/0011

Boehringer Ingelheim International GmbH;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Zoubida Amimour

Scope: "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."

Action: For adoption

4.3.5. Talzenna - Talazoparib - EMEA/H/C/004674/X/0022

Pfizer Europe MA EEIG;

Rapporteur: Filip Josephson

Scope: "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."

Action: For adoption

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

No items

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

No items

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

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

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

Pfizer Europe Ma EEIG;

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

Scope: "Extension of indication to include active immunization of individuals 18 through 59 years of age for ABRYSVO, based on final results from C3671023 Sub study A; this is a Phase 3 double-blinded, randomised, placebo-controlled study of safety, tolerability and immunogenicity of Abrysvo in participants ≥18 to <60 years of age at high risk of severe RSV disease due to certain chronic medical conditions. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, as part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 12.12.2024, 19.09.2024.

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

AstraZeneca AB;

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension of indication to include CALQUENCE as monotherapy for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy based on final results from study ACE-LY-004 (D8225C00002); this is an open-label, phase 2 study of ACP-196 in subjects with Mantle Cell Lymphoma. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

See 2.3

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

Request for Supplementary Information adopted on 30.01.2025, 14.11.2024.

5.1.4. Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0076

Janssen-Cilag International N.V.;

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

Scope: "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."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

5.1.5. Darzalex - Daratumumab - Orphan - EMEA/H/C/004077/II/0077

Janssen-Cilag International N.V.;

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

Scope: "Extension of indication to include daratumumab for the treatment of adult patients with smouldering multiple myeloma (SMM) at high risk of developing multiple myeloma based on results from studies 54767414SMM3001 (AQUILA) and 54767414SMM2001 (CENTAURUS). SMM3001 (AQUILA) is a Phase 3 Randomized, Multicentre Study of Subcutaneous Daratumumab Versus Active Monitoring in Subjects with High-risk Smouldering Multiple Myeloma. SMM2001 (CENTAURUS) is a Randomized Phase 2 Trial to Evaluate Three Daratumumab Dose Schedules in Smouldering Multiple Myeloma.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the PI in accordance with the latest EMA excipients guideline."

Action: For adoption

5.1.6. Enhertu - Trastuzumab deruxtecan - 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

Request for Supplementary Information adopted on 14.11.2024.

5.1.7. FABHALTA - Iptacopan - Orphan - EMEA/H/C/005764/II/0001

Novartis Europharm Limited;

Rapporteur: Janet Koenig, PRAC Rapporteur: Lina Seibokiene

Scope: "Extension of indication to include, in combination with a renin-angiotensin system (RAS) inhibitor, the treatment of adult patients with complement 3 glomerulopathy (C3G) for FABHALTA, based on interim analysis results from study CLNP023B12301 (APPEAR-C3G)

and supported by additional evidence of efficacy and safety data from Phase II study CLNP023X2202 (X2202) and Phase IIIb study CLNP023B12001B (C3G-REP). APPEAR-C3G is a Phase 3, multicentre, randomized, double-blind, parallel arm, placebo-controlled study to evaluate the efficacy and safety of iptacopan in patients with C3G. The study included a 6-month blinded, placebo-controlled period, followed by a 6-month period in which all patients receive open-label iptacopan (total study duration of 12 months). As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8 and 5.1 of the SmPC are being updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 17.10.2024

5.1.8. 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 14.11.2024, 21.03.2024.

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

Valneva Austria GmbH;

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

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

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

5.1.10. Jaypirca - Pirtobrutinib - EMEA/H/C/005863/II/0002

Eli Lilly Nederland B.V.;

Rapporteur: Alexandre Moreau, Co-Rapporteur: Edward Laane, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor for JAYPIRCA, based on interim results from study LOXO-BTK-20020 (BRUIN CLL-321); this is a phase 3 open-label, randomized study of LOXO-305 versus investigator's choice of idelalisib plus rituximab or bendamustine plus rituximab in BTK inhibitor pretreated CLL/SLL.
As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection."

Request for 1 year of data exclusivity for a new indication (Article 10(5) of Directive 2001/83/EC)

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 27.06.2024.

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

Advanced Accelerator Applications;

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of newly diagnosed, unresectable or metastatic, well-differentiated (G2 and G3), somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) adult patients for LUTATHERA, based on primary analysis results from study CAAA601A22301 (NETTER-2); NETTER-2 study is a Phase III, multicentre, stratified, open-label, randomized, comparator-controlled study comparing treatment with Lutathera plus octreotide LAR 30 mg (Lutathera arm) to treatment with high-dose octreotide LAR 60 mg (control arm). The main purpose of the NETTER-2 study was to determine if treatment in the Lutathera arm prolongs PFS in subjects with newly diagnosed SSTR-positive, G2 and G3 advanced GEP-NET when compared with treatment in the control arm.
As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes in the SmPC. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection."

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

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024.

5.1.12. Mounjaro - Tirzepatide - EMEA/H/C/005620/II/0038

Eli Lilly Nederland B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of symptomatic chronic heart failure with preserved ejection fraction (HFpEF) in adults with obesity for MOUNJARO, based on results from the Phase 3 trial I8F-MC-GPID (SUMMIT). SUMMIT was a randomized, multicentre, international, placebo-controlled, double-blind, parallel-arm study in participants with HFpEF and obesity. The study was designed to evaluate the effect of tirzepatide compared with placebo on both clinical and symptomatic or functional outcomes. As a consequence, sections 4.1, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted."

Action: For adoption

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

AbbVie Deutschland GmbH & Co. KG;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: "Extension of indication to include treatment of giant cell arteritis (GCA) in adult patients for RINVOQ based on final results from study M16-852. This is a phase 3, global, multicentre, randomized, double-blind, PBO-controlled study evaluating the efficacy and safety of upadacitinib in subjects with GCA. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 15.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 17.10.2024

5.1.14. 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

Request for Supplementary Information adopted on 14.11.2024.

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

Janssen-Cilag International N.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Rhea Fitzgerald

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

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 17.10.2024.

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

Sanofi Winthrop Industrie;

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Zoubida Amimour

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

Request for Supplementary Information adopted on 14.11.2024.

5.1.17. Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0017

Beigene Ireland Limited;

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

Scope: "Extension of indication to include, in combination with gemcitabine and cisplatin, the first-line treatment of adult patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) for TEVIMBRA based on final results from study BGB-A317-309 (study 309). Study 309 was a Phase 3 randomised, double-blind, placebo-controlled, Asia-only study that compared the efficacy and safety of tislelizumab combined with gemcitabine plus cisplatin (GC) versus placebo combined with GC as 1L treatment for recurrent or metastatic NPC. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.6 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial and administrative changes to the PI as well as to update the PI in line with the Excipients Guideline."

Action: For adoption

5.1.18. Uplizna - Inebilizumab - EMEA/H/C/005818/II/0012

Horizon Therapeutics Ireland DAC;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of indication to include treatment of adult patients with Immunoglobulin G4-Related Disease (IgG4-RD) for UPLIZNA, based on primary analysis results from study MITIGATE (VIB0551.P3.S2) for all subjects from the completed 52-week randomised-controlled period. This is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adult subjects with IgG4-RD. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to bring it in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

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

Roche Registration GmbH;

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

Scope: "Extension of indication to include treatment of patients aged 3 weeks and above for Xofluza, based on final results from study CP40559 (MiniSTONE-1); this was a global Phase 3, multicentre, single-arm, open-label study to assess the safety, PK, and efficacy of baloxavir marboxil in OwH paediatric patients from birth to < 1 year with influenza-like symptoms. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024.

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

Vertex Pharmaceuticals (Ireland) Limited;

Lead Rapporteur: Peter Mol, PRAC Rapporteur: Martin Huber

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

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024, 30.05.2024, 22.02.2024.

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

5.2.1. Amyvid - Florbetapir (18F) - EMEA/H/C/002422/II/0046

Eli Lilly Nederland B.V.

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication to include monitoring response to therapy for AMYVID, based on supporting literature. As a consequence, sections 4.1 and 4.4 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update section 4.8 of the SmPC to reflect the current clinical trial exposures to align it with the updated RMP."

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

Action: For adoption

Request for Supplementary Information adopted on 25.04.2024, 25.01.2024.

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

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

Merck Sharp & Dohme B.V.;

Scope: "Extension of indication to include in combination with pemetrexed and platinum chemotherapy the first-line treatment of adults with unresectable non-epithelioid 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, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 45.0 of the RMP has also been submitted."

Action: For adoption

Opinion adopted on 14.11.2024.

See 2.2

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

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

Ex vivo heart perfusion

Scope: Opinion

Action: For adoption

List of Questions adopted on 14.11.2024.

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/006648

use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC) tissue, using EnVision FLEX visualization system on Dako Omnis

Scope: Opinion

Action: For adoption

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006668

to detect EGFR mutations in FFPE tissue from adult patients diagnosed with non-small cell lung cancer (NSCLC)

Scope: Opinion

Action: For adoption

6.3.3. In vitro diagnostic medical device - EMEA/H/D/006656

assay to assess the mismatch repair (MMR) proteins (MLH1, PMS2, MSH2, and MSH6) in formalin-fixed, paraffin-embedded (FFPE) colorectal cancer (CRC) tissue using EnVision FLEX visualization system on Dako Omnis automated staining instrument

Scope: Opinion

Action: For adoption

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. Diazoxide choline – H0006576

Treatment of patients ≥ 4 years of age with Prader-Willi syndrome who have hyperphagia

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

Action: For adoption

8.1.2. Brensocatib -H0005820

Treatment of non-cystic fibrosis bronchiectasis in patients 12 years of age and older with two or more exacerbations in the prior 12 months.

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

Action: For adoption

8.1.3. apitegromab - H0005909

Treatment of spinal muscular atrophy as monotherapy or adjunct therapy to SMN up-regulator therapies.

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

Action: For adoption

8.2. Priority Medicines (PRIME)

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. BIMERVAX - SARS-CoV-2, variant JN.1, spike protein, receptor binding domain fusion homodimer - EMEA/H/C/006058/II/0016

Hipra Human Health S.L.,

Rapporteur: Daniela Philadelphy

Scope: Withdrawal of type II variation application

Action: For information

Request for Supplementary Information adopted on 14.11.2024, 19.09.2024, 25.07.2024.

9.1.2. FILSPARI - Sparsentan - EMEA/H/C/005783/II/0002, Orphan

Vifor France

Rapporteur: Vilma Petrikaite, PRAC Rapporteur: Martin Huber

Scope: "Update of sections 4.8, and 5.1 of the SmPC in order to amend the frequency of the adverse drug reactions (ADRs) based on final results from study 021IGAN17001 (PROTECT) listed as a specific obligation in the Annex II; this is a randomized, multicentre, double-blind parallel-group, active control study of the efficacy and safety of sparsentan for the treatment of immunoglobulin A nephropathy. The Package Leaflet is updated accordingly. The RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II and to bring the PI in line with the latest QRD template version 10.4. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025, 17.10.2024.

9.1.3. Fluenz - Influenza vaccine (live attenuated, nasal) - EMEA/H/C/006514/II/0002

AstraZeneca AB

Rapporteur: Christophe Focke

Scope: "Update of section 4.2 of the SmPC, upon request by the CHMP, to include an adequate age range for children that should be vaccinated with a 2-dose schedule, and section 4.4 of the SmPC to include a statement regarding the postponement of vaccinations in individuals with symptoms of an acute infection. In addition, the MAH took the opportunity to implement editorial changes in the SmPC, labelling and Package Leaflet, as well as a rearrangement of existing text for increased clarity."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

9.1.4. Cablivi - Caplacizumab - EMEA/H/C/004426/II/0048, Orphan

Ablynx NV

Rapporteur: Filip Josephson

Scope: Withdrawal of type II variation application

Action: For adoption

Request for Supplementary Information adopted on 17.10.2024, 25.07.2024, 14.03.2024.

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

AstraZeneca AB

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

Scope: "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3."

Action: For adoption

Request for Supplementary Information adopted on 19.09.2024, 21.03.2024.

9.1.6. Champix - Varenicline - EMEA/H/C/000699/II/0085/G

Pfizer Europe MA EEIG

Rapporteur: Thalia Marie Estrup Blicher

Scope: Quality

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

9.1.7. Pemazyre - Pemigatinib – Orphan - EMEA/H/C/005266/R/0019

Incyte Biosciences Distribution B.V.

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

Scope: Renewal of conditional marketing authorization

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

9.1.8. Ontilyv – Opicapone – EMEA/H/C/005782

Bial Portela & Companhia

Rapporteur: Janet Koenig, Co-Rapporteur: Thalia Marie Estrup Blicher

Scope: Expiry of marketing authorisation due to Sunset Clause

Action: For information

9.1.9. Helicobacter Test INFAI - 13C-Urea - EMEA/H/C/000140/II/0028

Infai GmbH

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

Action: For adoption

Opinion adopted on 30.01.2024 Request for Supplementary Information adopted on 17.10.2024, 30.05.2024.

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

10.6.1. Azithromycin containing medicinal products for systemic use – various – EMEA/H/A-31/1532

MAH various (NAPs only)

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Antonio Gómez Outes

Scope: List of outstanding issues/ opinion

Action: For adoption

Need to re-evaluate the benefit-risk ratio of the approved indications considering the current scientific knowledge, the increasing resistance rate, the consumption data suggesting overuse and the different indications in the EU Member States. Furthermore, the appropriate dose and duration of administration for both oral and intravenous formulations need to be discussed as well as the adequacy of safety relevant information, information on pregnancy and breastfeeding and pharmacological properties.
The German National Competent Authority triggered a referral under Article 31 of Directive 2001/83 based on interest of the Union, requesting an opinion to CHMP on the benefit-risk of azithromycin-containing products and whether marketing authorisations of azithromycin-containing products for systemic use should be maintained, varied, suspended, or revoked.

List of outstanding issues adopted on 17.10.2024, 25.04.2024.

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

February 2025 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 February 2025

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at February 2025 PDCO

Action: For information

Agenda of the PDCO meeting held on 25-28 February 2025

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Action: For adoption

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 11-12 February 2025.

Action: For adoption

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 10-13 February 2025. 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.

14.3.4. Election of new Scientific Advice Working Party (SAWP) Chair

Election of new SAWP chair. The first mandate of Scientific Advice Working Party Chair Paolo Foggi will expire on 13 March 2025.

Action: For election

Nomination(s) received

14.3.5. Scientific Advice Group (SAG) mandate renewal and (re)nominations

Update of the renewal of SAG mandate/call for nomination of experts for the 5 therapeutic SAGs (Neurology, Vaccines, Infectious Diseases and Cardiovascular Issues).

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

14.9.1. CHMP Learnings

CHMP: Outi Mäki-Ikola

Collection, discussion and recording of CHMP learnings.

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

Analysis of requests for 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)*

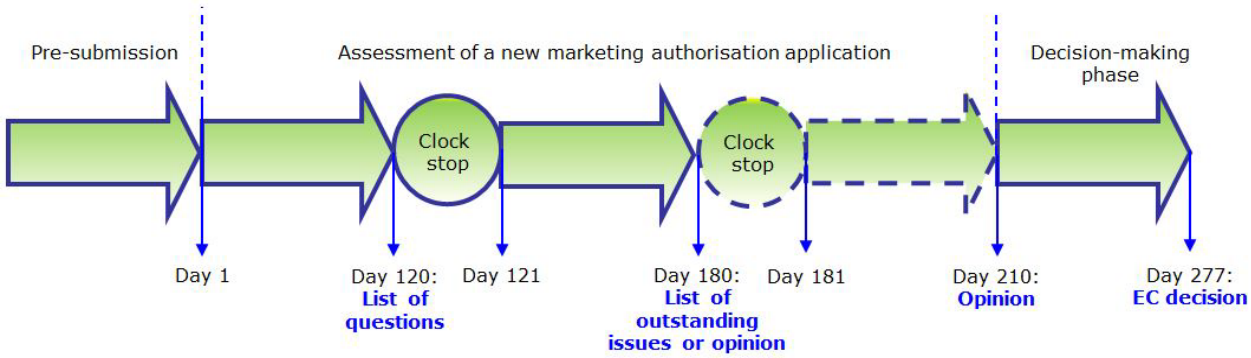
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

24 February 2025
EMA/CHMP/41993/2025

Annex to 24-27 February 2025 CHMP Agenda

Pre-submission and post-authorisations issues

Note: Starting with January 2025, EMA is publishing in Excel format the CHMP agenda annex with the regulatory procedures handled in IRIS. This is a secure online platform for managing product-related scientific and regulatory procedures with EMA. This change follows the transition of the post-authorisation regulatory procedures to IRIS. It is also in the context of the digitalisation of EMA's activities and will help facilitate data analysis.

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for February 2025: **For adoption**

Appointment of Rapporteur / Co-Rapporteur Full Applications

Final Outcome of Rapporteurship allocation for February 2025: **For adoption**

B. POST-AUTHORISATION PROCEDURES OUTCOMES

Annual re-assessment outcomes

B.1.1. Annual reassessment for products authorised under exceptional circumstances

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

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

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

Upstaza - Eladocagene exuparvovec - EMEA/H/C/005352/S/0025, Orphan, ATMP
PTC Therapeutics International Limited, Rapporteur: Joseph DeCourcey, Co-Rapporteur: Maria Luttgen, CHMP Coordinator: Finbarr Leacy, PRAC Rapporteur: Gabriele Maurer
Request for Supplementary Information adopted on 06.12.2024.

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

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

Renewals of Marketing Authorisations requiring 2nd Renewal

LIVOGIVA - Teriparatide -
EMEA/H/C/005087/R/0015
Theramex Ireland Limited, Rapporteur: Christian Gartner, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Tiphaine Vaillant
Request for Supplementary Information adopted on 30.01.2025.

B.2.1. Renewals of Marketing Authorisations for unlimited validity

Apixaban Accord - Apixaban -
EMEA/H/C/005358/R/0012
Accord Healthcare S.L.U., Generic of Eliquis, Rapporteur: Alar Irs, PRAC Rapporteur: Bianca Mulder

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

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
Request for Supplementary Information adopted on 30.01.2025.

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

Renewals of Conditional Marketing Authorisations

Koselugo - Selumetinib -
EMEA/H/C/005244/R/0019, Orphan
AstraZeneca AB, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

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

Bytyqi
Request for Supplementary Information adopted on 30.01.2025.

Lunsumio - Mosunetuzumab - EMEA/H/C/005680/R/0014, Orphan
Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn

Pemazyre - Pemigatinib - EMEA/H/C/005266/R/0019, Orphan — See 9.1
Incyte Biosciences Distribution B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder
Request for Supplementary Information adopted on 12.12.2024.

WAYLIVRA - Volanesorsen - EMEA/H/C/004538/R/0029, Orphan
Akcea Therapeutics Ireland Limited, Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: Martin Huber
Request for Supplementary Information adopted on 30.01.2025.

POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 10-13 February 2025
PRAC:

Signal of colitis

mogamulizumab – POTELIGEO (CAP)

Rapporteur: Peter Mol, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Marie Louise Schougaard Christiansen

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 February 2025 meeting:

EMEA/H/C/PSUSA/00009315/202406
(tobramycin (inhalation powder, capsules))
CAPS:
TOBI Podhaler (EMEA/H/C/002155)
(Tobramycin), Viatris Healthcare Limited, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur:

Liana Martirosyan, "01/07/2021 To: 30/06/2024"

EMEA/H/C/PSUSA/00010379/202407
(nivolumab)
CAPS:
OPDIVO (EMEA/H/C/003985) (Nivolumab), Bristol-Myers Squibb Pharma EEIG, Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Gabriele Maurer, "04/07/2021 To: 03/07/2024"

EMEA/H/C/PSUSA/00010438/202407
(sacubitril / valsartan)
CAPS:
Entresto (EMEA/H/C/004062) (Sacubitril / Valsartan), Novartis Europharm Limited, Rapporteur: Patrick Vrijlandt
Neparvis (EMEA/H/C/004343) (Sacubitril / Valsartan), Novartis Europharm Limited, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Karin Erneholm, "01/08/2023 To: 31/07/2024"

EMEA/H/C/PSUSA/00010516/202406
(opicapone)
CAPS:
Ongentys (EMEA/H/C/002790) (Opicapone), Bial - Portela & Cª, S.A., Rapporteur: Janet Koenig
Ontilyv (EMEA/H/C/005782) (Opicapone), Bial Portela & Companhia S.A., Rapporteur: Janet Koenig, PRAC Rapporteur: Maria del Pilar Rayon, "23/06/2021 To: 23/06/2024"

EMEA/H/C/PSUSA/00010634/202407
(cladribine (multiple sclerosis))
CAPS:
Mavenclad (EMEA/H/C/004230) (Cladribine), Merck Europe B.V., Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Carla Torre, "07/07/2023 To: 07/07/2024"

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

Adtralza - Tralokinumab - EMEA/H/C/005255/II/0023
LEO Pharma A/S, Rapporteur: Jayne Crowe

Advate - Octocog alfa -	Request for supplementary information adopted

EMEA/H/C/000520/II/0124 Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 13.02.2025.	with a specific timetable.
Aptivus - Tipranavir - EMEA/H/C/000631/II/0096/G Boehringer Ingelheim International GmbH, Rapporteur: Jean-Michel Race Request for Supplementary Information adopted on 19.12.2024.	
Briumvi - Ublituximab - EMEA/H/C/005914/II/0023/G Neuraxpharm Pharmaceuticals S.L., Rapporteur: Ewa Balkowiec Iskra Request for Supplementary Information adopted on 20.02.2025.	Request for supplementary information adopted with a specific timetable.
Ceprotin - Human protein C - EMEA/H/C/000334/II/0143/G Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus	
CEVENFACTA - Eptacog beta (activated) - EMEA/H/C/005655/II/0012 Laboratoire Francais du Fractionnement et des Biotechnologies, Rapporteur: Daniela Philadelphy Request for Supplementary Information adopted on 06.02.2025.	Request for supplementary information adopted with a specific timetable.
Champix - Varenicline - EMEA/H/C/000699/II/0085/G Pfizer Europe MA EEIG, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 30.01.2025.	See 9.1
CooperSurgical Inc ART Media - Human albumin solution - EMEA/H/D/002307/II/0012 Coopersurgical Inc., Rapporteur: Kristina Dunder	
Cosentyx - Secukinumab - EMEA/H/C/003729/II/0124 Novartis Europharm Limited, Rapporteur: Outi Mäki-Ikola Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
ELAHERE - Mirvetuximab soravtansine - EMEA/H/C/005036/II/0001/G, Orphan	Positive Opinion adopted by consensus on 13.02.2025.

AbbVie Deutschland GmbH & Co. KG, Rapporteur: Johanna Lähteenvuo Opinion adopted on 13.02.2025.	
Entyvio - Vedolizumab - EMEA/H/C/002782/II/0088/G Takeda Pharma A/S, Rapporteur: Paolo Gasparini	
EVRA - Ethinylestradiol / Norelgestromin - EMEA/H/C/000410/II/0054 Gedeon Richter Plc., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Fintepla - Fenfluramine - EMEA/H/C/003933/II/0029/G, Orphan UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher Request for Supplementary Information adopted on 06.02.2025.	Request for supplementary information adopted with a specific timetable.
Fluad - Influenza vaccine (surface antigen, inactivated, adjuvanted) - EMEA/H/C/006538/II/0001/G Seqirus Netherlands B.V., Rapporteur: Sol Ruiz	
GIVLAARI - Givosiran - EMEA/H/C/004775/II/0022, Orphan Alnylam Netherlands B.V., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
GONAL-f - Follitropin alfa - EMEA/H/C/000071/II/0177/G Merck Europe B.V., Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 20.02.2025.	Request for supplementary information adopted with a specific timetable.
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0163 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0164 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.

Lamzede - Velmanase alfa - EMEA/H/C/003922/II/0040/G, Orphan Chiesi Farmaceutici S.p.A., Rapporteur: Patrick Vrijlandt	
LifeGlobal Media - Human albumin solution - EMEA/H/D/004287/II/0009 Coopersurgical Inc., Rapporteur: Maria Grazia Evandri	
LIVOGIVA - Teriparatide - EMEA/H/C/005087/II/0013/G Theramex Ireland Limited, Rapporteur: Christian Gartner Request for Supplementary Information adopted on 31.10.2024.	
Omvoh - Mirikizumab - EMEA/H/C/005122/II/0010/G Eli Lilly Nederland B.V., Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 23.01.2025.	
Origio - Human albumin solution - EMEA/H/D/000830/II/0021 Coopersurgical Inc., Rapporteur: Jayne Crowe	
Ozempic - Semaglutide - EMEA/H/C/004174/II/0051 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Praluent - Alirocumab - EMEA/H/C/003882/II/0098/G Sanofi Winthrop Industrie, Rapporteur: Patrick Vrijlandt Opinion adopted on 06.02.2025.	Positive Opinion adopted by consensus on 06.02.2025.
Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0213 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Privigen - Human normal immunoglobulin - EMEA/H/C/000831/II/0214 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus	
Refixia - Nonacog beta pegol - EMEA/H/C/004178/II/0040/G Novo Nordisk A/S, Rapporteur: Daniela	Positive Opinion adopted by consensus on 06.02.2025.

Philadelphy Opinion adopted on 06.02.2025.	
Roclanda - Latanoprost / Netarsudil - EMEA/H/C/005107/II/0031/G Santen Oy, Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Semglee - Insulin glargine - EMEA/H/C/004280/II/0053 Biosimilar Collaborations Ireland Limited, Rapporteur: Janet Koenig	
Simulect - Basiliximab - EMEA/H/C/000207/II/0123/G Novartis Europharm Limited, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
Skyclarys - Omaveloxolone - EMEA/H/C/006084/II/0016, Orphan Biogen Netherlands B.V., Rapporteur: Thalia Marie Estrup Blicher Opinion adopted on 06.02.2025.	Positive Opinion adopted by consensus on 06.02.2025.
Sondelbay - Teriparatide - EMEA/H/C/005827/II/0008 Accord Healthcare S.L.U., Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Strensiq - Asfotase alfa - EMEA/H/C/003794/II/0073/G, Orphan Alexion Europe SAS, Rapporteur: Paolo Gasparini Request for Supplementary Information adopted on 06.02.2025.	Request for supplementary information adopted with a specific timetable.
TAKHZYRO - Lanadelumab - EMEA/H/C/004806/II/0043/G, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
Tyenne - Tocilizumab - EMEA/H/C/005781/II/0007 Fresenius Kabi Deutschland GmbH, Rapporteur: Kristina Dunder Opinion adopted on 06.02.2025.	Positive Opinion adopted by consensus on 06.02.2025.
Ultomiris - Ravulizumab - EMEA/H/C/004954/II/0048 Alexion Europe SAS, Rapporteur: Antonio	Positive Opinion adopted by consensus on 13.02.2025.

Gomez-Outes Opinion adopted on 13.02.2025.	
Uzpruvo - Ustekinumab - EMEA/H/C/006101/II/0002/G STADA Arzneimittel AG, Rapporteur: Christian Gartner Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 19.12.2024, 11.07.2024.	Positive Opinion adopted by consensus on 13.02.2025.
Vyloy - Zolbetuximab - EMEA/H/C/005868/II/0006/G, Orphan Astellas Pharma Europe B.V., Rapporteur: Jan Mueller-Berghaus Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
Wegovy - Semaglutide - EMEA/H/C/005422/II/0027 Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
WS2622 **HyQvia-EMEA/H/C/002491/WS2622/0103** **Kiovig-EMEA/H/C/000628/WS2622/0130** Takeda Manufacturing Austria AG, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
WS2727 **Esperoct-EMEA/H/C/004883/WS2727/0025** **NovoEight-EMEA/H/C/002719/WS2727/0044** **NovoSeven-EMEA/H/C/000074/WS2727/0125** **NovoThirteen-EMEA/H/C/002284/WS2727/0032** **Refixia-EMEA/H/C/004178/WS2727/0038** Novo Nordisk A/S, Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 19.12.2024, 05.09.2024.	
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 Request for Supplementary Information adopted on 13.02.2025, 19.12.2024.	Request for supplementary information adopted with a specific timetable.

WS2789 **Ervebo-EMEA/H/C/004554/WS2789/0039** **Gardasil-** **EMEA/H/C/000703/WS2789/0109** **Gardasil 9-** **EMEA/H/C/003852/WS2789/0078** **HBVAXPRO-** **EMEA/H/C/000373/WS2789/0082** **M-M-RvaxPro-** **EMEA/H/C/000604/WS2789/0130** **ProQuad-** **EMEA/H/C/000622/WS2789/0171** **Vaxneuvance-** **EMEA/H/C/005477/WS2789/0028** Merck Sharp & Dohme B.V., Lead Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 06.02.2025.	Request for supplementary information adopted with a specific timetable.
WS2804/G **Aerius-** **EMEA/H/C/000313/WS2804/0108/G** **Azomyr-** **EMEA/H/C/000310/WS2804/0112/G** **Neoclarityn-** **EMEA/H/C/000314/WS2804/0106/G** Organon N.V., Duplicate of Allex (SRD), Azomyr, Opulis (SRD), Lead Rapporteur: Christophe Focke Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
WS2805/G **Celldemic-** **EMEA/H/C/006052/WS2805/0003/G** **Incellipan-** **EMEA/H/C/006051/WS2805/0003/G** Seqirus Netherlands B.V., Lead Rapporteur: Daniela Philadelphy	

CHMP assessed procedures scope: Non-Clinical and Clinical aspects

Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0012 Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe, "Update of section 5.1 of the SmPC in order to update information based on end-of-season 2 data from clinical study C3671013. This is an ongoing Phase 3, randomized, double-blind, placebo controlled to evaluate safety immunogenicity, and efficacy of Abrysvo in	

prevention of lower respiratory tract disease in adults 60 years of age and older during the first respiratory syncytial virus (RSV) season and the long-term immunogenicity and efficacy of Abrysvo in the second RSV season and across 2 RSV seasons. In addition, the MAH took the opportunity to introduce minor changes to the PI based on the already submitted clinical study report C3671008." Request for Supplementary Information adopted on 21.11.2024.	
Abrysvo - Respiratory syncytial virus vaccine (bivalent, recombinant) - EMEA/H/C/006027/II/0014 Pfizer Europe Ma EEIG, Rapporteur: Jayne Crowe, "Update of section 4.5 of the SmPC in order to add information regarding coadministration of Abrysvo and COVID-19 mRNA vaccines, with or without a high dose influenza vaccine following Phase 1/2 study C5481001 Sub study A - a Study to Evaluate the Safety, Tolerability, and Immunogenicity of Combined Vaccine Candidate(s) Against Infectious Respiratory Illnesses, Including COVID 19 and RSV, in healthy participants ≥65 years of age; the Package Leaflet is updated accordingly." Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 12.12.2024.	Positive Opinion adopted by consensus on 13.02.2025.
Amvuttra - Vutrisiran - EMEA/H/C/005852/II/0014, Orphan Alnylam Netherlands B.V., Rapporteur: Janet Koenig, "Update of section 4.2 of the SmPC in order to add the option for administration by patient and/or caregiver, based on an updated Notified Body Opinion report. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to make editorial changes in the PI." Opinion adopted on 06.02.2025. Request for Supplementary Information adopted on 12.12.2024.	Positive Opinion adopted by consensus on 06.02.2025.
Cablivi - Caplacizumab - EMEA/H/C/004426/II/0048, Orphan Ablynx NV, Rapporteur: Filip Josephson, "Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update efficacy and safety	See 9.1

information on paediatric patients based on results from study OBS17325 - Retrospective Data Collection of Paediatric Patients with Immune Thrombotic Thrombocytopenic Purpura (iTTP) Treated with Caplacizumab. The primary objective of this study was to describe the effectiveness and safety of caplacizumab in paediatric patients with iTTP." Request for Supplementary Information adopted on 17.10.2024, 25.07.2024, 14.03.2024.	
Cerezyme - Imiglucerase - EMEA/H/C/000157/II/0136 Sanofi B.V., Rapporteur: Patrick Vrijlandt, "Update of sections 4.4 and 4.8 of the SmPC in order to add 'Transient hypertension' to the list of adverse drug reactions (ADRs) with frequency not known as well as to reflect the warning on Infusion-associated reactions (IARs), based on a safety review. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Efmody - Hydrocortisone - EMEA/H/C/005105/II/0013 Neurocrine Netherlands B.V., Rapporteur: Patrick Vrijlandt, "Update of sections 4.2, 4.4, 4.5, and 4.8 of the SmPC based on the pooled safety analysis of DIUR-006; this is a phase 3 extension study of efficacy, safety and tolerability of Chronocort in the treatment of congenital adrenal hyperplasia. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI." Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Enhertu - Trastuzumab deruxtecan - EMEA/H/C/005124/II/0054 Daiichi Sankyo Europe GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, "Submission of the final report from study DS8201-A-U201 listed as a Recommendation (REC). This is a phase 2 multicenter, open-label efficacy and safety study of DS-8201a, an Anti-HER2-Antibody Drug Conjugate (ADC) for HER2- positive, unresectable and/or metastatic breast cancer subjects previously treated with T-DM1." Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.

Fexinidazole Winthrop - Fexinidazole - EMEA/H/W/002320/II/0021 Sanofi Winthrop Industrie, Rapporteur: Fátima Ventura, "Submission of the final report from study DNDi-FEX-09-HAT. This is a phase 3b, open-label study assessing effectiveness, safety and compliance with fexinidazole in patients with human African trypanosomiasis due to *T.b. gambiense* at any stage."	
Fintepla - Fenfluramine - EMEA/H/C/003933/II/0024, Orphan UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 4.2 of the SmPC in order to include a table correlating volumes and doses for both Dravet syndrome and Lennox-Gastaut syndrome following the outcome of PSUSA/00010907/202306. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 05.12.2024, 05.09.2024.	Positive Opinion adopted by consensus on 13.02.2025.
Fluenz - Influenza vaccine (live attenuated, nasal) - EMEA/H/C/006514/II/0002 AstraZeneca AB, Rapporteur: Christophe Focke, "Update of section 4.2 of the SmPC, upon request by the CHMP, to include an adequate age range for children that should be vaccinated with a 2-dose schedule, and section 4.4 of the SmPC to include a statement regarding the postponement of vaccinations in individuals with symptoms of an acute infection. In addition, the MAH took the opportunity to implement editorial changes in the SmPC, labelling and Package Leaflet, as well as a rearrangement of existing text for increased clarity." Request for Supplementary Information adopted on 12.12.2024.	See 9.1
HEPLISAV B - Hepatitis B surface antigen (rDNA) - EMEA/H/C/005063/II/0037 Dynavax GmbH, Rapporteur: Filip Josephson, "Update of section 4.9 of the SmPC in order to revise information regarding overdose to indicate "Not Applicable" following review of overall safety data. In addition, the MAH took the opportunity to make some editorial updates to the PI and bring it in line with the latest QRD template."	

Request for Supplementary Information adopted on 16.01.2025.	
Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0088/G Janssen-Cilag International N.V., Rapporteur: Filip Josephson, "A grouped application consisting of: C.I.4: Update of section 5.1 of the SmPC based on results from Study CLL3011 (GLOW study). This is a Randomized, Open-label, Phase 3 Study of the Combination of Ibrutinib plus Venetoclax versus Chlorambucil plus Obinutuzumab for the First-line Treatment of Subjects with Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL). C.I.4: Update of section 5.1 of the SmPC based on results from Study PCYC-1116-CA. This is an Open-label Extension Study in Patients 65 Years or Older with Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) Who Participated in Study PCYC-1115-CA (Ibrutinib versus Chlorambucil)." Request for Supplementary Information adopted on 16.01.2025.	
Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0091 Janssen-Cilag International N.V., Rapporteur: Filip Josephson, "Submission of the final report from study PCYC-1142-CA (CAPTIVATE). This is a Phase 2, international, multicentre study of the combination of ibrutinib plus venetoclax in subjects with treatment-naïve chronic lymphocytic leukaemia (CLL) /small lymphocytic lymphoma (SLL) in order to assess both minimal residual disease (MRD)-guided discontinuation and fixed duration therapy." Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
IMCIVREE - Setmelanotide - EMEA/H/C/005089/II/0034, Orphan Rhythm Pharmaceuticals Netherlands B.V., Rapporteur: Karin Janssen van Doorn, "Update of section 4.8 of the SmPC in order to update the list of adverse drug reactions (ADRs) based on the availability of new safety data. The Package Leaflet is updated accordingly."	
Inrebic - Fedratinib - EMEA/H/C/005026/II/0027, Orphan Bristol-Myers Squibb Pharma EEIG, Rapporteur: Peter Mol, "Update of sections 4.2 and 5.2 of	

the SmPC in order to add administration option based on results from clinical trial FEDR-CP-005. This is a phase 1, open-label, single-centre, 2-part crossover study to evaluate the relative bioavailability of fedratinib when administered as contents of capsules dispersed in a nutritional supplement orally or via nasogastric tube or administered orally as divided doses of intact capsules with a nutritional supplement in healthy adult subjects. The Package Leaflet is being updated accordingly. In addition, the MAH took the opportunity to add editorial changes to the PI."	
JEMPERLI - Dostarlimab - EMEA/H/C/005204/II/0040 GlaxoSmithKline (Ireland) Limited, Rapporteur: Antonio Gomez-Outes, "Update of section 4.8 of the SmPC in order to add 'Guillain-Barre syndrome' to the list of adverse drug reactions (ADRs) in patients treated with dostarlimab in combination with chemotherapy with frequency 'uncommon' based on new safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the PI in accordance with the latest EMA excipients guideline. Also, the MAH has taken the opportunity to update the list of local representatives in the Package Leaflet and introduce editorial changes to the PI." Request for Supplementary Information adopted on 06.02.2025.	Request for supplementary information adopted with a specific timetable.
LYFNUA - Gefapixant - EMEA/H/C/005476/II/0003/G Merck Sharp & Dohme B.V., Rapporteur: Peter Mol, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information and add 'headache' to the list of adverse drug reactions (ADRs) with frequency common, based on final results from studies MK-7264-042 and MK-7264-043; these are multicentre, randomized, double-blind, placebo controlled Phase 3b studies conducted in patients with refractory or unexplained chronic cough. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and introduce minor editorial changes to the PI." Request for Supplementary Information adopted	Request for supplementary information adopted with a specific timetable.

on 20.02.2025, 05.12.2024, 12.09.2024.	
Metalyse - Tenecteplase - EMEA/H/C/000306/II/0075/G Boehringer Ingelheim International GmbH, Rapporteur: Janet Koenig, "A grouped application comprised of 4 Type II Variations, as follows: C.I.4: Update of sections 4.3 and 4.4 of the SmPC in order to update the safety information pertaining to the prevention of bleeding risk related to thrombolytic treatment based on a dataset consisting of literature review including published clinical study outcomes. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.2 and 4.4 of the SmPC in order to update the safety information for patients with body weight < 50 kg based on the dataset consisting of reanalysis of existing clinical data and literature review. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.3 and 4.4 of the SmPC related to the medical recommendations for prior stroke patients based on a dataset consisting of reanalysis of existing clinical data and literature review. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.2 and 4.4 of the SmPC in order to revise the medical recommendation in line with the most current medical knowledge in treatment guidelines. 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, as well as to update the excipient information according to the latest EU Excipients Guideline. Furthermore, the PI is being brought in line with the latest QRD template (version 10.4)."	
Nexavar - Sorafenib - EMEA/H/C/000690/II/0059 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 -	Positive Opinion adopted by consensus on 13.02.2025.

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." Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 07.11.2024, 04.07.2024.	
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." Request for Supplementary Information adopted on 14.11.2024.	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0097/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final clinical study reports from clinical study 2019nCoV-313 Part 1 and Part 2 listed as a category 3 study in the RMP. This is A 2-Part Phase 2/3 Open-Label Study to Evaluate the Safety and Immunogenicity of an XBB.1.5 (Omicron Subvariant) SARS -CoV-2 rS Vaccine Booster Dose in Previously mRNA COVID-19 Vaccinated and Baseline SARS-CoV-2 Seropositive COVID-19 Vaccine Naïve Participants."	
Ontozry - Cenobamate - EMEA/H/C/005377/II/0029 Angelini S.p.A., Rapporteur: Fátima Ventura, "Update of sections 4.2 and 5.2 of the SmPC to include the crushed tablets method of administration and section 4.5 of the SmPC in order to present the existing information on DDI in a tabular format. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement an editorial	

correction of the contact details of the manufacturer ACRAF SPA in Annex II and Package Leaflet." Request for Supplementary Information adopted on 12.12.2024.	
OZAWADE - Pitolisant - EMEA/H/C/005117/II/0012 Bioprojet Pharma, Rapporteur: Peter Mol, "Submission of the study note PH24048. This is an update of the final PopPK model (PH20043) submitted at initial Marketing Authorization Approval integrating the results of study 15-03 (HAROSA III). In addition, the results of re-estimated model parameters and covariates are provided." Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Rezzayo - Rezafungin - EMEA/H/C/005900/II/0007, Orphan Mundipharma GmbH, Rapporteur: Fátima Ventura, " Update of sections 4.8, and 5.1 of the SmPC based on final results of China extension part from study ReSTORE; this is a pivotal Phase 3, multicentre, randomised, double-blind study of the efficacy and safety of rezafungin versus the active control caspofungin IV, followed by optional oral fluconazole step-down, in the treatment of subjects with IC; updated population PK modelling was also presented; the Package Leaflet is updated accordingly."	
RINVOQ - Upadacitinib - EMEA/H/C/004760/II/0055 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, "Update of sections 4.8 and 5.1 of the SmPC in order to include long term efficacy and safety data for ulcerative colitis based on results from study M14-533. This is a phase 3, multicentre, long-term extension study to evaluate the safety and efficacy of upadacitinib in subjects with ulcerative colitis." Request for Supplementary Information adopted on 12.12.2024, 12.09.2024.	
Samsca - Tolvaptan - EMEA/H/C/000980/II/0051 Otsuka Pharmaceutical Netherlands B.V., Rapporteur: Paolo Gasparini, "Update of section 4.5 of the SmPC in order to add drug-drug	Positive Opinion adopted by consensus on 13.02.2025.

interaction information with St John's wort based on literature and to implement the recommendation from EMA on the risk of drug interactions with Hypericum perforatum (St John's Wort) and antiretroviral medicinal products. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 13.02.2025.	
Spikevax - COVID-19 mRNA vaccine - EMEA/H/C/005791/II/0149 Moderna Biotech Spain S.L., Rapporteur: Jan Mueller-Berghaus, "Submission of the final report from study mRNA-1273-P204 listed as a category 3 study in the RMP; this is interventional Phase 2/3, 3-part, dose-escalation, open-label, age de-escalation and randomised, observer-blind, placebo-controlled expansion study to evaluate the safety, reactogenicity, and effectiveness of Spikevax (mRNA-1273) in children 6 months through 11 years of age." Opinion adopted on 06.02.2025.	Positive Opinion adopted by consensus on 06.02.2025.
Vyloy - Zolbetuximab - EMEA/H/C/005868/II/0005, Orphan Astellas Pharma Europe B.V., Rapporteur: Jan Mueller-Berghaus, "Update of section 5.1 of the SmPC in order to update immunogenicity data based on the validation report for the new method (8951-ME-0016) to replace the method originally used to test ADA samples from the pivotal studies SPOTLIGHT and GLOW. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI."	
Xarelto - Rivaroxaban - EMEA/H/C/000944/II/0113 Bayer AG, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add ´splenic rupture´ to the list of adverse drug reactions (ADRs) with frequency 'very rare' based on the data from the clinical trials, post-marketing data sources and literature; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity introduce editorial updates as agreed with QRD group." Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.

Xeljanz - Tofacitinib - EMEA/H/C/004214/II/0068 Pfizer Europe MA EEIG, Rapporteur: Paolo Gasparini, "Update of section 4.6 of the SmPC in order to update information on breast-feeding section based on literature and post-marketing data. In addition, the MAH took the opportunity to introduce editorial changes to the PI and update the list of local representatives in the Package Leaflet." Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
Xenpozyme - Olipudase alfa - EMEA/H/C/004850/II/0013/G, Orphan Sanofi B.V., Rapporteur: Patrick Vrijlandt, "A grouped application consisting of: C.I.4: Update of section 4.2 of the SmPC in order to update the 'Missed Doses' section to facilitate the appropriate clinical management of patients based on pre-existing data from the clinical trials. C.I.4: Update of section 4.2 of the SmPC in order to include a clarification of the infusion rate during the home infusion based on pre-existing data from the clinical trials" Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 12.12.2024.	Positive Opinion adopted by consensus on 13.02.2025.
Zejula - Niraparib - EMEA/H/C/004249/II/0057/G, Orphan GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang, "C.I.4: Update of section 4.5 of the SmPC in order to update information on pharmacokinetic drug-drug interactions based on Physiologically based on results from pharmacokinetic (PBPK) modelling; this is Evaluation of GSK3985771 (Niraparib) Drug-Drug Interaction (DDI) Risk Assessment as a Perpetrator using PBPK Modelling; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and introduce editorial changes to the PI. C.I.4: Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on results from Refined PRIMA Model; this is an amendment to addendum to population pharmacokinetic and exposure-response modelling of niraparib in PRIMA study;	

the Package Leaflet is updated accordingly.”	

B.5.2. CHMP-PRAC assessed procedures

Bavencio - Avelumab - EMEA/H/C/004338/II/0046/G Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Karin Erneholm, “A grouped application consisting of: C.I.4: Update of sections 4.2, 4.4, 4.6 and 4.8 of the SmPC in order to add the immune-mediated adverse reactions sclerosing cholangitis, arthritis, polymyalgia rheumatica, and Sjogren’s syndrome based on post-marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 7.3 has also been submitted. C.I.4: Update of section 4.8 of the SmPC in order to update the immunogenicity information based on results from studies EMR100070-003, B9991003 and 100/B9991001. Study EMR100070-003 is a Phase 2, single-arm, open label, multicentre study to investigate the clinical activity and safety of avelumab in patients with mMCC. T. Study B9991003 is a Phase 3 multinational, multicentre, randomized (1:1), open-label, parallel 2 - arm study of avelumab in combination with axitinib versus sunitinib monotherapy in the 1L treatment of participants with aRCC. Study 100/B9991001 is a Phase 3, multicentre, multinational, randomized, open-label, parallel-arm efficacy and safety study of avelumab plus best supportive care (BSC) versus BSC alone as a maintenance treatment in adult participants with locally advanced or metastatic UC whose disease did not progress after completion of 1L platinum-containing chemotherapy.” Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 31.10.2024.	Positive Opinion adopted by consensus on 13.02.2025.
Columvi - Glofitamab - EMEA/H/C/005751/II/0010, Orphan Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Jana Lukacisinova, “Submission of the updated 2-year follow-up report from study NP30179 listed as a Specific Obligation in the Annex II of the Product Information. This is a multicentre,	

open-label Phase I/II study to evaluate the safety, efficacy, tolerability, and pharmacokinetics of escalating doses of glofitamab in patients with relapsed/refractory B-cell Non-Hodgkin's Lymphoma (NHL). The Annex II and the RMP version 4.0 are updated accordingly. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation."	
FILSPARI - Sparsentan - EMEA/H/C/005783/II/0002, Orphan Vifor France, Rapporteur: Vilma Petrikaite, PRAC Rapporteur: Martin Huber, "Update of sections 4.8, and 5.1 of the SmPC in order to amend the frequency of the adverse drug reactions (ADRs) based on final results from study 021IGAN17001 (PROTECT) listed as a specific obligation in the Annex II; this is a randomized, multicentre, double-blind parallel-group, active control study of the efficacy and safety of sparsentan for the treatment of immunoglobulin A nephropathy. The Package Leaflet is updated accordingly. The RMP version 1.0 has also been submitted. In addition, the MAH took the opportunity to update Annex II and to bring the PI in line with the latest QRD template version 10.4. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation." Request for Supplementary Information adopted on 30.01.2025, 17.10.2024.	See 9.1
HyQvia - Human normal immunoglobulin - EMEA/H/C/002491/II/0102 Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Submission of the final report from study 161505; this is a Phase 3b, open-label, non-controlled, multicentre study to assess the long-term tolerability and safety of immune globulin infusion 10% (human) with recombinant human hyaluronidase (HYQVIA/HyQvia) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP). The RMP version 16.0 has also been submitted." Request for Supplementary Information adopted 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 16.01.2025, 31.10.2024.	
Kayfanda - Odevixibat - EMEA/H/C/006462/II/0001/G Ipsen Pharma, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski, "A grouped application consisting of: C.I.4: Update of sections 4.4, 4.8, and 5.1 of the SmPC based on results from Study A4250-015 listed as a category 3 study in the RMP; this is a Phase 3, multicentre, open-label extension study to evaluate the long-term safety and efficacy of odevixibat in patients with ALGS. The Package Leaflet is updated accordingly. The RMP version 6.2 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI. C.I.13: Submission of the 72-week report from study A4250-008. This is a Phase 3, multicentre, open-label extension study to investigate the long-term efficacy and safety of odevixibat in patients with Progressive Familial	Request for supplementary information adopted with a specific timetable.

Intrahepatic Cholestasis Types 1 and 2 (PEDFIC 2)." Request for Supplementary Information adopted on 13.02.2025.	
Litfulo - Ritlecitinib - EMEA/H/C/006025/II/0007 Pfizer Europe MA EEIG, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "Update of section 4.8 of the SmPC in order to update the safety information based on interim results from study B7981032 listed as a category 3 study in the RMP; this is a phase 3 open-label, multi-centre, long-term study investigating the safety and efficacy of ritlecitinib in adult and adolescent participants with alopecia areata. The RMP version 2 is acceptable." Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
MVABEA - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005343/II/0021 Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy based on final results from study VAC52150EBL3010 listed as a category 3 study in the RMP as well as study VAC52150EBL3008 and two post-authorization vaccination campaigns. Study VAC52150EBL3010 is a phase 3 open-label randomized clinical trial to evaluate the safety, reactogenicity and immunogenicity of a 2-dose Ebola vaccine regimen of Ad26.ZEBOV followed by MVA-BN-Filo in healthy pregnant women. The Package Leaflet is updated accordingly. The RMP version 3.3 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI." Request for Supplementary Information adopted on 27.06.2024.	
Nuvaxovid - Covid-19 Vaccine (recombinant, adjuvanted) - EMEA/H/C/005808/II/0096/G Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Gabriele Maurer Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
Ocrevus - Ocrelizumab - EMEA/H/C/004043/II/0041	Positive Opinion adopted by consensus on

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. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. The RMP has been updated to version 10.0." Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 16.01.2025, 31.10.2024, 11.07.2024.	13.02.2025.
Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0044 AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Bianca Mulder, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on the final results from study 18-513 (ANNEXA-I), listed as a specific obligation in the Annex II; this is a phase 4 randomised controlled trial to investigate the efficacy and safety of andexanet alfa versus usual care in patients with acute intracranial haemorrhage taking apixaban, rivaroxaban or edoxaban. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. The Annex II and Package Leaflet are updated accordingly. The updated RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template version 10.3." Request for Supplementary Information adopted on 19.09.2024, 21.03.2024.	See 9.1
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 14.11.2024, 30.05.2024.	
TAKHZYRO - Lanadelumab - EMEA/H/C/004806/II/0040, Orphan Takeda Pharmaceuticals International AG Ireland Branch, Rapporteur: Kristina Dunder, PRAC Rapporteur: Terhi Lehtinen, "Update of section 4.4 of the SmPC in order to remove the information related to non-availability of clinical data on the use of lanadelumab in HAE patients with normal C1-INH activity, based on results from studies CASPIAN (SHP643-303) and CASPIAN OLE (TAK-743-3001). CASPIAN (SHP643-303) is a Phase 3, multicentre, randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of lanadelumab for prevention against acute attacks of NONHISTAMINERGIC ANGIOEDEMA with Normal C1 Inhibitor (C1-INH); and CASPIAN OLE (TAK-743-3001) is an open-label study to evaluate the long term safety and efficacy of lanadelumab for prevention against acute attacks of Nonhistaminergic Angioedema with Normal C1-Inhibitor (C1-INH). The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC and the Package Leaflet." Request for Supplementary Information adopted on 17.10.2024, 11.04.2024.	
Vyvgart - Efgartigimod alfa - EMEA/H/C/005849/II/0022/G, Orphan Argenx, Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 31.10.2024.	Positive Opinion adopted by consensus on 13.02.2025.
Yondelis - Trabectedin - EMEA/H/C/000773/II/0070 Pharma Mar, S.A., Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Update of sections 4.4 and 4.6 of the SmPC in order to update the contraceptive precautions when receiving Yondelis, in line with EMA recommendations. The Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted. In	Positive Opinion adopted by consensus on 13.02.2025.

addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4." Opinion adopted on 13.02.2025.	
Zabdeno - Ebola vaccine (rDNA, replication-incompetent) - EMEA/H/C/005337/II/0019 Janssen-Cilag International N.V., Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné, "Update of sections 4.6 and 5.1 of the SmPC in order to update information on pregnancy based on final results from study VAC52150EBL3010 listed as a category 3 study in the RMP as well as study VAC52150EBL3008 and two post-authorisation vaccination campaigns. Study VAC52150EBL3010 is a phase 3 open-label randomized clinical trial to evaluate the safety, reactogenicity and immunogenicity of a 2-dose Ebola vaccine regimen of Ad26.ZEBOV followed by MVA-BN-Filo in healthy pregnant women. The Package Leaflet is updated accordingly. The RMP version 3.3 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.	
WS2798 **Nilemdo-** **EMEA/H/C/004958/WS2798/0045** **Nustendi-** **EMEA/H/C/004959/WS2798/0050** Daiichi Sankyo Europe GmbH, Lead Rapporteur: Patrick Vrijlandt, Lead PRAC Rapporteur: Kimmo Jaakkola, "Update of sections 4.2, 4.4, and 5.2 of the SmPC in order to amend information concerning renal impairment based on the final results from Study 1002-071 listed as a category 3 study in the RMP; this is a phase 1, open-label, single-dose study to evaluate the pharmacokinetics of bempedoic acid in healthy subjects with normal renal function and subjects with end-stage renal disease receiving HD; the Package Leaflet is updated accordingly. The RMP version 7.0 has also been submitted." Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.

PRAC assessed procedures

PRAC Led **Cinryze - C1 ESTERASE INHIBITOR (HUMAN) - EMEA/H/C/001207/II/0104** Takeda Manufacturing Austria AG, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Update of sections 4.6, 5.1 and 5.3 of the SmPC based on final results from the Icatibant Outcome Survey (IOS), listed as an imposed PASS in the Annex II. This is a prospective, observational disease registry. The Package Leaflet is updated accordingly. The RMP version 11.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the product information in line with the latest QRD template version 10.4 and to update Annex II of the PI." Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Cosentyx - Secukinumab - EMEA/H/C/003729/II/0127** Novartis Europharm Limited, PRAC Rapporteur: Monica Martinez Redondo, PRAC-CHMP liaison: Antonio Gomez-Outes, "Update of section 4.4 of the SmPC to include recommendations on clinical management of cases of tuberculosis following the PSUSA (PSUSA/00010341/202312) procedure following which cumulative requests were requested to assess the safety topics of tuberculosis and hepatitis C virus with secukinumab. The Package Leaflet is updated accordingly." Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
PRAC Led **Fasenra - Benralizumab - EMEA/H/C/004433/II/0054** AstraZeneca AB, PRAC Rapporteur: David Olsen, PRAC-CHMP liaison: Ingrid Wang, "Submission of the final report from study D3250R00042 listed as a category 3 study in the RMP. This is a noninterventional, descriptive post authorisation safety study of the incidence of malignancy in severe asthma patients receiving benralizumab and other therapies. The RMP version 7.1 has also been submitted." Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.

PRAC Led **Fintepla - Fenfluramine - EMEA/H/C/003933/II/0025, Orphan** UCB Pharma SA, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Update of section 4.8 of the SmPC in order to propose a combined Adverse Drug Reaction table for Dravet Syndrome and Lennox-Gastaut syndrome following PSUSA procedure EMEA/H/C/PSUSA/00010907/202306. The package leaflet is updated accordingly." Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 31.10.2024, 05.09.2024.	Positive Opinion adopted by consensus on 13.02.2025.
PRAC Led **Firazyr - Icatibant - EMEA/H/C/000899/II/0061** Takeda Pharmaceuticals International AG Ireland Branch, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Update of section 4.6 based on final results from the Icatibant Outcome Survey (IOS) registry listed as a category 3 study in the RMP; this is a prospective, observational disease registry. The RMP version 8 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI and to bring the PI in line with the latest QRD template version 10.4." Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
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 16.2 has also been approved." Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 31.10.2024.	Positive Opinion adopted by consensus on 13.02.2025.

PRAC Led **Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor -** **EMEA/H/C/005269/II/0052/G, Orphan** Vertex Pharmaceuticals (Ireland) Limited, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Janet Koenig, "Grouped application comprising two type II variations as follows: - Type II (C.I.3.b) • Update of sections 4.4 and 4.8 of the SmPC in order to update information on existing statements related to rash events in adults and add information regarding the paediatric population. • Update of section 4.8 to add hypersensitivity to the list of adverse drug reactions with frequency "not known". - Type II (C.I.z) – Update of section 4.6 based on post-marketing breast-feeding case reports. Clarification is provided that the medicinal product has been detected in breastfed newborns/infants of treated women. The Package Leaflet is updated accordingly." Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 16.01.2025, 05.09.2024.	Positive Opinion adopted by consensus on 13.02.2025.
PRAC Led **OPDIVO - Nivolumab -** **EMEA/H/C/003985/II/0149** Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Gabriele Maurer, PRAC-CHMP liaison: Jan Mueller-Berghaus, "Submission of the final clinical study report (CSR) for the PASS study CA209234 listed as a category 3 study in the RMP. This is an observational, multicentre, prospective study in patients treated with nivolumab for melanoma and lung cancer in order assess the safety experience, survival, adverse event management, and outcomes of adverse events associated with nivolumab (monotherapy or with ipilimumab) in routine oncology care facilities. The RMP version 42.0 has also been submitted." Request for Supplementary Information adopted on 13.02.2025.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Revlimid - Lenalidomide -** **EMEA/H/C/000717/II/0130** Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Tiphaine Vaillant, PRAC-CHMP	Request for supplementary information adopted with a specific timetable.

liaison: Alexandre Moreau, "Submission of the final report from study CC-5013-MCL-005 listed as a category 3 study in the RMP. This is a non-interventional, post-authorization safety study of patients with relapsed or refractory mantle cell lymphoma to further investigate and characterize the association of lenalidomide with tumour flare reaction and high tumour burden. The RMP version 42.0 has also been submitted." Request for Supplementary Information adopted on 13.02.2025.	
PRAC Led **WS2802** **Entresto-** **EMEA/H/C/004062/WS2802/0070** **Neparvis-** **EMEA/H/C/004343/WS2802/0067** Novartis Europharm Limited, Lead PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report for study CLCZ696B2014 listed as a category 3 study in the RMP; this is a non-interventional post-authorization multi-database safety study to characterize the risk of angioedema and other specific safety events of interest in association with use of Entresto (sacubitril/valsartan) in adult patients with heart failure. The RMP version 9.0 for Entresto and Neparvis has also been submitted." Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
PRAC Led **WS2803** **Entresto-** **EMEA/H/C/004062/WS2803/0071** **Neparvis-** **EMEA/H/C/004343/WS2803/0068** Novartis Europharm Limited, Lead PRAC Rapporteur: Karin Erneholm, PRAC-CHMP liaison: Thalia Marie Estrup Blicher, "Submission of the final report for study CLCZ696B2015 listed as a category 3 study in the RMP for Entresto and Neparvis; this is a non-interventional post-authorization multi-database safety study to assess the risk of myotoxicity, hepatotoxicity and acute pancreatitis in statin-exposed heart failure patients with or without concomitant use of sacubitril/valsartan. The RMP version 9.0 for Entresto and Neparvis has also been submitted."	Positive Opinion adopted by consensus on 13.02.2025.

Opinion adopted on 13.02.2025.	
PRAC Led **WS2819** **Ozempic-** **EMEA/H/C/004174/WS2819/0053** **Wegovy-** **EMEA/H/C/005422/WS2819/0029** Novo Nordisk A/S, Lead PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "To align the RMPs to the version approved for Rybelsys on 3 October 2024." Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.

B.5.3. CHMP-CAT assessed procedures

Abecma - Idecabtagene vicleucel - EMEA/H/C/004662/II/0058/G, Orphan, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang
Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0055/G, ATMP Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini
CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0037, Orphan, ATMP Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus
Casgevy - Exagamglogene autotemcel - EMEA/H/C/005763/II/0009/G, Orphan, ATMP Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghau Request for Supplementary Information adopted on 06.12.2024.
Casgevy - Exagamglogene autotemcel - EMEA/H/C/005763/II/0012/G, Orphan, ATMP Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus
Kymriah - Tisagenlecleucel -

EMEA/H/C/004090/II/0086/G, Orphan, ATMP

Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, "A grouped application consisting of:
C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on cytokine release syndrome based on literature.
C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on neurological adverse reaction based on literature. The Package Leaflet is updated accordingly.
C.I.4: Update of section 4.4 of the SmPC in order to amend existing warnings on hypersensitivity reactions based on post marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the PI."
Request for Supplementary Information adopted on 06.12.2024, 11.10.2024.

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
Request for Supplementary Information adopted on 08.11.2024.

Yescarta - Axicabtagene ciloleucel - EMEA/H/C/004480/II/0085, Orphan, ATMP

Kite Pharma EU B.V., Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, "Submission of the final report from study KT-US-482-0147 (ZUMA-26). This is a Prospective, Noninterventional, Clinical Efficacy Study Investigating and Analyzing the Impact of Tumor Cd19 Antigen Expression and Density on Response to Axicabtagene Ciloleucel Treatment ."

WS2736
Tecartus-
EMEA/H/C/005102/WS2736/0048
Yescarta-
EMEA/H/C/004480/WS2736/0080

Kite Pharma EU B.V., Lead Rapporteur: Jan

Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus Request for Supplementary Information adopted on 06.12.2024, 13.09.2024.	

CHMP-PRAC-CAT assessed procedures

CARVYKTI - Ciltacabtagene autoleucel - EMEA/H/C/005095/II/0036, Orphan, ATMP Janssen-Cilag International NV, Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Jo Robays, "Update of sections 4.8, and 5.1 of the SmPC in order to update the list of adverse drug reactions (ADRs), and update clinical efficacy and safety information based on second interim analysis from study 68284528MMY3002 (CARTITUDE-4); this is a phase 3 randomized study comparing ciltacabtagene autoleucel, a chimeric antigen receptor T cell (CAR-T) therapy directed against BCMA, versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in subjects with relapsed and lenalidomide-refractory multiple myeloma; The RMP version 5.3 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet."	
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." Request for Supplementary Information adopted on 08.11.2024.	

B.5.4. PRAC assessed ATMP procedures

Unclassified procedures and worksharing procedures of type I variations

WS2763/G Trimbow-	Positive Opinion adopted by consensus on 13.02.2025.

EMEA/H/C/004257/WS2763/0043/G **Trydonis-** **EMEA/H/C/004702/WS2763/0040/G** Chiesi Farmaceutici S.p.A., Lead Rapporteur: Janet Koenig Opinion adopted on 13.02.2025. Request for Supplementary Information adopted on 12.12.2024.	
WS2774/G **Dapagliflozin Viatris-** **EMEA/H/C/006006/WS2774/0005/G** Viatris Limited, Generic of Forxiga, Lead Rapporteur: Tomas Radimersky Opinion adopted on 20.02.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 20.02.2025.
WS2791/G **Aflunov-** **EMEA/H/C/002094/WS2791/0091/G** **Foclivia-** **EMEA/H/C/001208/WS2791/0095/G** **Zoonotic Influenza Vaccine Seqirus-** **EMEA/H/C/006375/WS2791/0009/G** Seqirus S.r.l, Lead Rapporteur: Maria Grazia Evandri Request for Supplementary Information adopted on 06.02.2025, 19.12.2024.	Request for supplementary information adopted with a specific timetable.
WS2807 **Ebymect-** **EMEA/H/C/004162/WS2807/0068** **Xigduo-EMEA/H/C/002672/WS2807/0078** AstraZeneca AB, Lead Rapporteur: Kristina Dunder Opinion adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.02.2025.
WS2810/G **Copalia-** **EMEA/H/C/000774/WS2810/0138/G** **Copalia HCT-** **EMEA/H/C/001159/WS2810/0116/G** **Dafiro-** **EMEA/H/C/000776/WS2810/0142/G** **Dafiro HCT-** **EMEA/H/C/001160/WS2810/0118/G** **Exforge-** **EMEA/H/C/000716/WS2810/0137/G** **Exforge HCT-** **EMEA/H/C/001068/WS2810/0115/G** Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher	

Opinion adopted on 20.02.2025.	
WS2810/G **Copalia-** **EMEA/H/C/000774/WS2810/0138/G** **Copalia HCT-** **EMEA/H/C/001159/WS2810/0116/G** **Dafiro-** **EMEA/H/C/000776/WS2810/0142/G** **Dafiro HCT-** **EMEA/H/C/001160/WS2810/0118/G** **Exforge-** **EMEA/H/C/000716/WS2810/0137/G** **Exforge HCT-** **EMEA/H/C/001068/WS2810/0115/G** Novartis Europharm Limited, Lead Rapporteur: Thalia Marie Estrup Blicher	
WS2820 **Blitzima-** **EMEA/H/C/004723/WS2820/0081** **Truxima-** **EMEA/H/C/004112/WS2820/0084** Celltrion Healthcare Hungary Kft., Lead Rapporteur: Sol Ruiz Opinion adopted on 06.02.2025.	Positive Opinion adopted by consensus on 06.02.2025.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

The information on Marketing authorisation applications under review including a summary of the therapeutic indication applied for by the applicant, will continue be published on the EMA website (under this page). As of February, The EMA will also start publishing on the same EMA webpage information on the start of the procedures for extension applications and for Type II variation that propose an extension of the authorised indication, which have been submitted and started in IRIS in 2025. This information will be published the week following the CHMP plenary.

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

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

ANNEX G

F.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.

PRIME

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