24 March 2025
EMA/CHMP/64819/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

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

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

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

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

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

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

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

1.2. Adoption of agenda

CHMP agenda for 24-27 March 2025

1.3. Adoption of the minutes

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

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. 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: Oral explanation

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

List of Outstanding Issues adopted on 30.01.2025. List of Questions adopted on 22.02.2024.

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

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

Scope: Oral explanation

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

List of Outstanding Issues adopted on 12.12.2024, 19.09.2024. List of Questions adopted on 14.12.2023.

2.1.3. Clascoterone - EMEA/H/C/006138

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

Scope: Oral explanation

Action: Oral explanation to be held on 25 March 2025 at 16:00

List of Outstanding Issues adopted on 12.12.2024, 17.10.2024. List of Questions adopted on 22.02.2024.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.4. Referral procedure oral explanations

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

Orexigen Therapeutics Ireland Limited

Rapporteur: Kristina Dunder, Co-Rapporteur: Daniela Philadelphy

Scope: Oral explanation

Action: Oral explanation to be held on 24 March 2025 at 16:00

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

See 10.1

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Denosumab - EMEA/H/C/006398

prevention of skeletal related events in adults with advanced malignancies involving bone

Scope: Opinion

Action: For adoption

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

3.1.2. Donanemab - EMEA/H/C/006024

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

Scope: Opinion

Action: For adoption

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

3.1.3. Denosumab - EMEA/H/C/006399

treatment of osteoporosis and bone loss

Scope: Opinion

Action: For adoption

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

3.1.4. Ustekinumab - EMEA/H/C/006649

for the treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis

Scope: Opinion

Action: For adoption

3.1.5. Atropine - EMEA/H/C/006324

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

Scope: Opinion

Action: For adoption

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

3.1.6. Ferric citrate coordination complex - EMEA/H/C/006402

treatment of iron deficiency anaemia in adult chronic kidney disease (CKD) patients with elevated serum phosphorus levels

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 30.01.2025. List of Questions adopted on 25.07.2024.

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

3.2.1. Obecabtagene autoleucel - PRIME - Orphan - ATMP - EMEA/H/C/005907

Autolus GmbH; treatment of patients with relapsed or refractory B cell precursor acute lymphoblastic leukaemia (ALL)

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 19.07.2024.

3.2.2. Denosumab - EMEA/H/C/006269

prevention of skeletal related events in adults with advanced malignancies involving bone

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2024.

3.2.3. Denosumab - EMEA/H/C/006268

treatment of osteoporosis and bone loss

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2024.

3.2.4. Denosumab - EMEA/H/C/006526

treatment of osteoporosis and bone loss

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2024.

3.2.5. Aflibercept - EMEA/H/C/006745

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

Scope: List of outstanding issues

Action: For adoption

3.2.6. Emtricitabine / Tenofovir alafenamide - EMEA/H/C/006469

for the treatment of human immunodeficiency virus type 1 (HIV-1)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 17.10.2024.

3.2.7. Sargramostim - EMEA/H/C/006411

treatment for exposure to myelosuppressive doses of radiation

Scope: List of outstanding issues; Request by the applicant for an extension to the clock-stop to respond to the 2nd list of outstanding issued to be adopted in March 2025.

Action: For adoption

List of Outstanding Issues adopted on 12.12.2024. List of Questions adopted on 23.07.2024.

3.2.8. Autologous cartilage-derived articular chondrocytes, in-vitro expanded - ATMP - EMEA/H/C/004594

repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 19.04.2024.

3.2.9. Resmetirom - EMEA/H/C/006220

for the treatment of adults with non-alcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis

Scope: List of outstanding issues; Request by the applicant for an extension to the clock-stop to respond to the list of outstanding issues to be adopted in March 2025

Action: For adoption

List of Questions adopted on 27.06.2024.

3.2.10. Tegomil fumarate - EMEA/H/C/006427

treatment of multiple sclerosis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

3.2.11. Denosumab - EMEA/H/C/006534

prevention of skeletal related events in adults with advanced malignancies involving bone

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 12.12.2024.

3.2.12. Aflibercept - EMEA/H/C/006192

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.07.2024.

3.2.13. Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded - PRIME - Orphan - ATMP - EMEA/H/C/005772

Cordex Biologics International Limited; treatment of adult patients with haematological malignancies

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 11.10.2024.

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

3.3.1. Clesrovimab - EMEA/H/C/006497

prevention of respiratory syncytial virus (RSV)

Scope: List of questions

Action: For adoption

3.3.2. Denosumab - EMEA/H/C/006239

prevention of skeletal related events in adults with advanced malignancies involving bone

Scope: List of questions

Action: For adoption

3.3.3. Doxecitine / Doxribtimine - PRIME - Orphan - EMEA/H/C/005119

UCB Pharma; indicated for the treatment of paediatric and adult patients with thymidine kinase 2 deficiency (TK2d) with an age of symptom onset on or before 12 years

Scope: List of questions

Action: For adoption

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

3.4.1. Belumosudil - Orphan - EMEA/H/C/006421

Sanofi Winthrop Industrie; Treatment of chronic graft-versus host disease (cGVHD) disease (cGVHD) after failure of at least two prior lines of systemic therapy.

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

Action: For adoption

List of Questions adopted on 30.01.2025.

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

3.5.1. Aplidin - plitidepsin - Orphan - EMEA/H/C/004354

Pharma Mar, S.A.; treatment of multiple myeloma

Scope: Request to restart the 2018 re-examination procedure relating to the initial marketing authorisation application for Aplidin following the adoption of Commission Implementing Decision C(2024) 4469 final of 28 June 2024 which revoked Commission Implementing Decision C(2018) 4831 final of 17 July 2018 refusing marketing authorisation for 'Aplidin – plitidepsin'. That decision was revoked following the judgment of 14 March 2024 in D & A Pharma v Commission and EMA, C 291/22 P.

Appointment of re-examination rapporteurs.

Action: For adoption

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

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

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

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

Scope: Withdrawal of initial marketing authorisation application

Action: For information

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

3.7.2. Aflibercept - EMEA/H/C/006551

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

Scope: Withdrawal of initial marketing authorisation application

Action: For information

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

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

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

Pfizer Europe MA EEIG;

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

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

Action: For adoption

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

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

Roche Registration GmbH;

Rapporteur: Fátima Ventura

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

Leaflets of both formulations."

Action: For adoption

List of Outstanding Issues adopted on 30.01.2025. List of Questions adopted on 19.09.2024.

4.1.3. OPDIVO - Nivolumab - EMEA/H/C/003985/X/0144

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (600 mg) and a new route of administration (subcutaneous use). Version 40.0 of the RMP has also been submitted."

Action: For adoption

List of Outstanding Issues adopted on 30.01.2025. List of Questions adopted on 17.10.2024.

4.1.4. REZOLSTA - Darunavir / Cobicistat - EMEA/H/C/002819/X/0054/G

Janssen-Cilag International N.V.;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension application to introduce a new strength (675 mg/150 mg film-coated tablets) grouped with an extension of indication (C.I.6.a) to include, treatment of HIV-1 infected paediatric patients (aged 6 years and older with body weight at least 25 kg) for REZOLSTA, based on the 48-week ad hoc interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicentre, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of cobicistat-boosted darunavir in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1,4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.3, 6.5 and 8 of the SmPC and Annex II are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4."

Action: For adoption

List of Questions adopted on 17.10.2024.

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

Roche Registration GmbH;

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

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

Action: For adoption

List of Questions adopted on 14.11.2024.

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

Viatris Limited;

Rapporteur: Tomas Radimersky, PRAC Rapporteur: Maria del Pilar Rayon

Scope: "Extension application to add a new strength of 160 mg for solution for film-coated tablets.
The RMP (version 1.0) is updated in accordance."

Action: For adoption

4.3.2. Livmarli - Maralixibat - Orphan - EMEA/H/C/005857/X/0016

Mirum Pharmaceuticals International B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to add a new strength (19 mg/ml oral solution). In addition, the MAH took the opportunity to implement editorial changes in sections 4.2 and 4.8. of the SmPC and Point 4 of PL of Livmarli, 9.5 mg/ml oral solution."

Action: For adoption

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

Agios Netherlands B.V.;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adam Przybylkowski

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

Action: For adoption

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

4.4.1. 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."

Request by the applicant for a change to the timetable to respond to the list of questions adopted in February 2025.

Action: For information

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. Benlysta - Belimumab - EMEA/H/C/002015/II/0133

GlaxoSmithKline (Ireland) Limited;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Karin Bolin

Scope: "Extension of indication to include treatment of paediatric patients from 5 years of age with active, autoantibody-positive systemic lupus erythematosus (SLE) for BENLYSTA, based on final results from study 200908; this is a worldwide population pharmacokinetic analysis of subcutaneous administered belimumab plus standard therapy to paediatric patients aged 5-17 years with systematic lupus erythematous (SLE), which was aimed to describe the pharmacokinetic (PK) analysis of belimumab to support an appropriate weight-based dosing regimen for subcutaneous administration in paediatric patients aged 5-17 years with SLE. 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 46.0 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.

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

Ipsen Pharma;

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

Scope: "Extension of indication to include the treatment of adult patients with progressive extra-pancreatic (epNET) and pancreatic (pNET) neuroendocrine tumours after prior systemic therapy for CABOMETYX based on final results from study CABINET (A021602). This is a multicentre, two-arm, randomised, double-blind, placebo-controlled phase 3 study investigating cabozantinib versus placebo in patients with advanced Neuroendocrine Tumours (NET). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

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

AstraZeneca AB;

Rapporteur: Filip Josephson, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: "Extension of indication to include CALQUENCE in combination with bendamustine and rituximab (BR) as treatment of adult patients with previously untreated Mantle Cell Lymphoma (MCL) based on interim results from study ACE-LY-308 (ECHO, D8220C00004); this is a Phase III, Randomized, Double-blind, Placebo-controlled, Multicentre Study of Bendamustine and Rituximab (BR) Alone Versus in Combination with Acalabrutinib (ACP-196) in Subjects with Previously Untreated Mantle Cell Lymphoma. As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 6, succession 1 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. As part of the application the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

5.1.4. Flucelvax - Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) - EMEA/H/C/006532/II/0001

Seqirus Netherlands B.V.;

Rapporteur: Sol Ruiz, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication to include treatment of children from 6 months of age and older for FLUCELVAX, based on results from study V130_14. This is a Phase III, Randomized, Observer-blind, Multicentre Study to Evaluate the Efficacy, Immunogenicity

and Safety of Seqirus Cell-Based Quadrivalent Subunit Influenza Virus Vaccine (QIVc) Compared to a Non-Influenza Vaccine When Administrated in Healthy Subjects Aged 6 Months Through 47 Months. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The package leaflet is updated in accordance. Version 4.0 of the RMP is also being submitted.
In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the MAH took the opportunity to implement changes to sections 4.4 and 4.5 of the SmPC."

Action: For adoption

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

Janssen-Cilag International N.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

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

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024.

5.1.6. LUTATHERA - Lutetium (177Lu) oxodotreotide - Orphan - EMEA/H/C/004123/II/0058

Advanced Accelerator Applications;

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension of indication to include the treatment of unresectable or metastatic, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adolescents aged 12 years and older for LUTATHERA based on primary analysis results from study CAAA601A32201 (also referred to as NETTER-P) as well as results from modelling and simulation analysis of PK and dosimetry data of Lutathera in adolescents. NETTER-P study is a Phase II, multicentre open-label study which evaluated the safety and dosimetry of Lutathera in adolescent patients with somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) and pheochromocytoma and paragangliomas (PPGLs). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 11 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted."

Action: For adoption

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

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Gabriele Maurer

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

Action: For adoption

Request for Supplementary Information adopted on 25.07.2024, 25.04.2024.

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

Incyte Biosciences Distribution B.V.;

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

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

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024, 25.07.2024, 25.04.2024.

5.1.9. SARCLISA - Isatuximab - EMEA/H/C/004977/II/0035

Sanofi Winthrop Industrie;

Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau

Scope: "Extension of indication to include, in combination with bortezomib, lenalidomide and dexamethasone, the induction treatment of adult patients with newly diagnosed multiple myeloma (NDMM) who are eligible for autologous stem cell transplant (ASCT) for SARCLISA, based on the results from study IIT15403 (GMMG-HD7); this is a randomized phase III study designed to assess the efficacy and safety of Sarclisa for the induction and maintenance treatment of NDMM. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. In addition, the

MAH took the opportunity to introduce minor editorial and formatting changes to the PI."

Action: For adoption

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

Eli Lilly and Co (Ireland) Limited;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Gabriele Maurer

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

Action: For adoption

Request for Supplementary Information adopted on 14.11.2024.

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

Beigene Ireland Limited;

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

Scope: "Extension of indication to include first-line treatment of adult patients with extensive-stage Small Cell Lung Cancer (SCLC) for Tevimbra in combination with etoposide and platinum chemotherapy based on final results from study BGB-A317-312; a phase 3, randomized, double-blind, placebo-controlled study of platinum plus etoposide with or without tislelizumab in patients with untreated extensive-stage small cell lung cancer. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The MAH also took the opportunity to make editorial changes to the SmPC, Annex II and Package Leaflet.
The supportive studies BGB-A317-309 and BGB-A317-315 are provided for the purpose of updating the safety data package as well as updated data (latest CSR versions with new data cut-off) from the monotherapy pool (tislelizumab used at 200mg Q3W) consisting of the studies 001, 102, 203, 204, 208, 209, 301, 302, and 303 and from the combination with chemotherapy pool consisting of the studies 205, 206, 304, 305, 306, 307 and 312. Version 2.4 of the RMP has also been submitted."

Action: For adoption

Request for Supplementary Information adopted on 30.01.2025.

5.1.12. Tevimbra - Tislelizumab - EMEA/H/C/005919/II/0018

Beigene Ireland Limited;

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

Scope: "Extension of indication for Tevimbra in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, for the treatment of adult patients with resectable NSCLC based on interim results from study BGB-A317-315. Study BGB-A317-315 is a phase 3 randomized, placebo-controlled, double-blind study to compare the efficacy and safety of neoadjuvant treatment with tislelizumab plus platinum-based doublet chemotherapy followed by adjuvant tislelizumab versus neoadjuvant treatment with placebo plus platinum-based doublet chemotherapy followed by adjuvant placebo in patients with resectable Stage II or IIIA NSCLC. 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 2.7 of the RMP has also been submitted."

Action: For adoption

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

Janssen-Cilag International N.V.;

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

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

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024, 19.09.2024.

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

AbbVie Deutschland GmbH & Co. KG;

Rapporteur: Filip Josephson, PRAC Rapporteur: Rugile Pilviniene

Scope: "Extension of indication to include the treatment of acute bacterial skin and skin structure infections (ABSSSI) in paediatric patients from birth, including paediatric patients aged less than 3 months with suspected or confirmed sepsis associated with skin and subcutaneous tissue infections for Xydalba, based on final results from study DUR001-306, together with data from three Phase 1 PK studies (A8841004, DUR001-106, and DUR001-107 (DAL-PK-02); DUR001-306 was a Phase 3, multicentre, open-label, randomized, comparator controlled trial evaluating the safety and efficacy of a single dose of IV dalbavancin and a 2-dose regimen of once weekly IV dalbavancin (for a total of 14 days of

coverage) for the treatment of ABSSSI known or suspected to be due to susceptible Gram-positive organisms in children. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

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

6.4. 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. Onasemnogene abeparvovec – H0006498

Treatment of spinal muscular atrophy (SMA)

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. Riarify - Beclometasone/Formoterol/Glycopyrronium bromide – EMEA/H/C/004836

Chiesi Farmaceutici S.p.A.; symptomatic treatment and reduction of exacerbations in adult patients with chronic obstructive pulmonary disease (COPD) with airflow limitation and who are at risk of exacerbations

Rapporteur: Janet Koenig, Co-Rapporteur: Finbarr Leacy

Scope: Withdrawal of marketing authorization

Action: For information

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

Bristol-Myers Squibb Pharma EEIG

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

Scope: "A grouped application consisting of:
C.I.4: Update of section 5.1 of the SmPC based on final results from study 849-012 (KRYSTAL-12) listed as a specific obligation in the Annex II. This is a Randomized Phase 3 Study of MRTX849 versus Docetaxel in Patients with Previously Treated Non-Small Cell Lung Cancer with KRAS G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex IIE of the PI.
C.I.4: Update of section 4.8 of the SmPC in order to update safety information based on an integrated analysis of data from interventional studies 849-012 (KRYSTAL-12), 849-007 (KRYSTAL-7) and 849-001 (KRYSTAL-1)."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

9.1.3. Rybelsus – Semaglutide - EMA/VR/0000244874

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt

Scope: "A grouped application consisting of:

C.I.4: Update of sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC in order to update clinical efficacy and safety information based on the final results from study EX9924-4473 (SOUL); this is a phase 3b study comparing oral semaglutide versus placebo and added to standard of care in patients with type 2 diabetes at high risk of cardiovascular events; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI.

C.I.4: Update of sections 4.2, and 5.1 of the SmPC in order to introduce chronic kidney disease outcomes based on final results from study NN9535-4321 (FLOW); this is a phase 3b study evaluating the effect of semaglutide versus placebo on the progression of renal impairment in subjects with type 2 diabetes and chronic kidney disease; the Package Leaflet is updated accordingly."

Update on the procedure

Action: For discussion

9.1.4. Mosquirix - Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0086

GlaxoSmithkline Biologicals SA

Rapporteur: Jan Mueller-Berghaus

Scope: "Update of sections 4.2, 4.5, 4.8 and 5.1 of the SmPC in order to update posology, efficacy and safety information based on final results from study MALARIA-094 and literature. This is a Phase 2b, randomized, open-label, controlled, multi-centre study of the efficacy, safety and immunogenicity of RTS,S/AS01E evaluating schedules with or without fractional doses, early dose 4 and yearly doses, in children living in sub-Saharan Africa. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the

opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI."

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

9.1.5. 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 authorisation

Action: For adoption

Request for Supplementary Information adopted on 12.12.2024.

9.1.6. Imfinzi - Durvalumab - EMEA/H/C/004771/II/0069

AstraZeneca AB;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: David Olsen

Scope: Revised opinion adopted via written procedure on 07 March 2025.

Action: For information

Opinion adopted on 30.01.2025. Request for Supplementary Information adopted on 17.10.2024.

9.1.7. Mycapssa (SRD) – Octreotide – EMEA/H/C/005826

Amryt Pharmaceuticals DAC; treatment of acromegaly

Rapporteur: Larisa Gorobets, Co-Rapporteur: Ewa Balkowiec Iskra

Scope: Withdrawal of marketing authorisation

Action: For information

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

Eli Lilly Nederland B.V.

Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber

Scope: Withdrawal of Type II extension of indication application

Action: For information

10. Referral procedures

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

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

Orexigen Therapeutics Ireland Limited

Rapporteur: Kristina Dunder, Co-Rapporteur: Daniela Philadelphy

Scope: List of Outstanding issues/opinion

Action: For adoption

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

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

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

March 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 March 2025

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at March 2025 PDCO

Action: For information

Agenda of the PDCO meeting held on 25-28 March 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. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 10-13 March 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.

14.3.3. Election of new Scientific Advice Working Party (SAWP) Vice-Chair

Election of new SAWP vice-chair. The first mandate of Scientific Advice Working Party Vice-Chair Pierre Demolis will expire on 1 May 2025.

Nomination(s) received

Action: For election

14.3.4. Election of new ONCWP Chair

Election of new ONCWP Chair. The mandate of ONCWP Chair Pierre Demolis will expire on 21 April 2025.

Nomination(s) received

Action: For election

14.3.5. MWP Chair and Vice-Chair election

Election of new Methodology Working Party (MWP) Chair and Vice-Chair. The mandate of the MWP Chair Kit Roes will expire on 21 April 2025. The mandate of the MWP Vice-Chair Kristin Karlsson will expire on 21 April 2025.

Nomination(s) received for the position of the Chair

Nomination(s) received for the position of the Vice-Chair

Action: For election

14.3.6. BWP Vaccines Quality Operational Expert Group (BV-OEG) Influenza meeting

Chair: Koen Brusselmans

Scope: EU Strain selection for the Influenza Vaccines for the Season 2025/2026: Draft Report from the BV-OEG to the BWP

Action: For adoption

Scope: Draft EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2025/2026

Action: For adoption

14.4. Cooperation within the EU regulatory network

14.4.1. Exchange of views with European Commission on Pharmaceutical Legislation Reform

Action: For discussion

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

No items

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)*

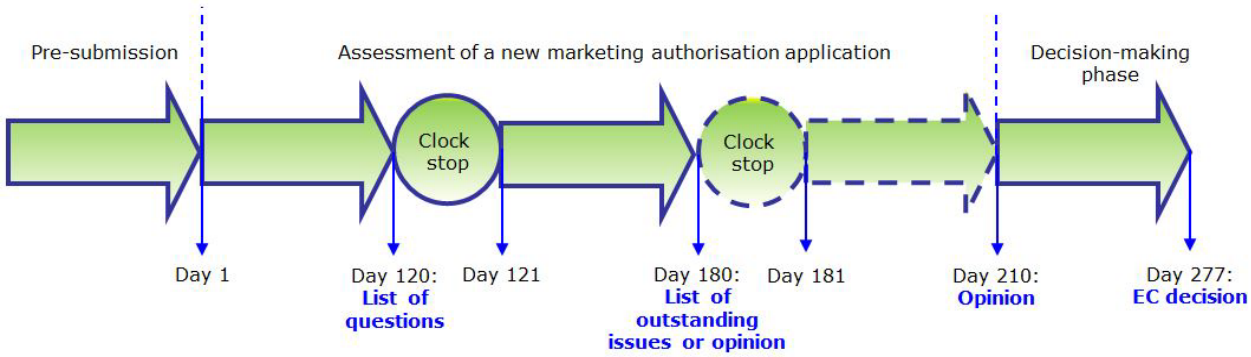
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (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 March 2025
EMA/CHMP/76605/2025

Annex to 24-27 March 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 March 2025: **For adoption**

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

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

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

Defitelio - Defibrotide - EMEA/H/C/002393/S/0069, Orphan
Gentium S.r.l., Rapporteur: Kristina Dunder, PRAC Rapporteur: Mari Thorn

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

ARIKAYCE liposomal - Amikacin - EMEA/H/C/005264/R/0014, Orphan
Insmed Netherlands B.V., Rapporteur: Jayne Crowe, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jean-Michel Dogné

Cabazitaxel Accord - Cabazitaxel - EMEA/H/C/005178/R/0012
Accord Healthcare S.L.U., Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Tiphaine Vaillant

Jyseleca - Filgotinib - EMEA/H/C/005113/R/0038
Alfasigma S.p.A., Rapporteur: Kristina Dunder, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Petar Mas

Lumeblue - Methylthioninium chloride - EMEA/H/C/002776/R/0007
Cosmo Technologies Limited, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari

Thorn	

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Arsenic trioxide medac - Arsenic trioxide - EMEA/H/C/005218/R/0006 medac Gesellschaft fur klinische Spezialpraparate mbH, Generic of TRISENOX, Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Tiphaine Vaillant	
Kaftrio - Ivacaftor / Tezacaftor / Elexacaftor - EMEA/H/C/005269/R/0059, Orphan Vertex Pharmaceuticals (Ireland) Limited, Rapporteur: Peter Mol, Co-Rapporteur: Finbarr Leacy, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 30.01.2025.	
PHELINUN - Melphalan - EMEA/H/C/005173/R/0005 ADIENNE S.r.l., Rapporteur: Peter Mol, PRAC Rapporteur: Mari Thorn	

B.2.3. Renewals of Conditional Marketing Authorisations

Columvi - Glofitamab - EMEA/H/C/005751/R/0012, Orphan Roche Registration GmbH, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Jana Lukacisinova	
Lytgobi - Futibatinib - EMEA/H/C/005627/R/0008 Taiho Pharma Netherlands B.V., Rapporteur: Peter Mol, PRAC Rapporteur: Mari Thorn	
Pemazyre - Pemigatinib - EMEA/H/C/005266/R/0019, Orphan Incyte Biosciences Distribution B.V., Rapporteur: Alexandre Moreau, Co-Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder Request for Supplementary Information adopted on 12.12.2024.	See 9.1
Rozlytrek - Entrectinib - EMEA/H/C/004936/R/0026 Roche Registration GmbH, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder	

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

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

Signal of hyperammonaemia

Tegafur, gimeracil, oteracil – TEYSUNO (CAP)
Rapporteur: Peter Mol, Co-Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Bianca Mulder
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 March 2025 meeting:

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda - Dengue tetravalent vaccine (live, attenuated) - EMEA/H/W/005362/PSUV/0019 (without RMP)
Takeda GmbH, PRAC Rapporteur: Liana Martirosyan, "19/02/2024 to 18/08/ 2024"

EMEA/H/C/PSUSA/00000099/202408
(talquetamab)
CAPS:
TALVEY (EMEA/H/C/005864) (Talquetamab), Janssen-Cilag International N.V., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Barbara Kovacic Bytyqi, "09/02/2024 To: 08/08/2024"

EMEA/H/C/PSUSA/00010520/202407
(saxagliptin / dapagliflozin)
CAPS:
Qtern (EMEA/H/C/004057) (Saxagliptin / Dapagliflozin), AstraZeneca AB, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli, "15/07/2021 To: 14/07/2024"

EMEA/H/C/PSUSA/00010702/202408
(tisagenlecleucel)
CAPS:
Kymriah (EMEA/H/C/004090) (Tisagenlecleucel), Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, PRAC Rapporteur: Gabriele Maurer, "13/08/2023 To: 12/08/2024"

EMEA/H/C/PSUSA/00010823/202408
(upadacitinib)

CAPS:
RINVOQ (EMEA/H/C/004760) (Upadacitinib), AbbVie Deutschland GmbH & Co. KG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas, "16/02/2024 To: 15/08/2024"

EMEA/H/C/PSUSA/00010990/202408
(lisocabtagene maraleucel / lisocabtagene maraleucel)
CAPS:
Breyanzi (EMEA/H/C/004731) (Lisocabtagene maraleucel / Lisocabtagene maraleucel), Bristol-Myers Squibb Pharma EEIG, Rapporteur: Concetta Quintarelli, CHMP Coordinator: Paolo Gasparini, PRAC Rapporteur: Gabriele Maurer, "05/02/2024 To: 04/08/2024"

EMEA/H/C/PSUSA/00011034/202408
(dengue tetravalent vaccine (live, attenuated) [Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated / Dengue virus, serotype 2, live, attenuated.])
CAPS:
Qdenga (EMEA/H/C/005155) (Dengue tetravalent vaccine (live, attenuated)), Takeda GmbH, Rapporteur: Sol Ruiz, PRAC Rapporteur: Liana Martirosyan, "18/02/2024 To: 18/08/2024"

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

AJOVY - Fremanezumab - EMEA/H/C/004833/II/0052
TEVA GmbH, Rapporteur: Jan Mueller-Berghaus
Request for Supplementary Information adopted on 19.12.2024.

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

Request for Supplementary Information adopted on 30.01.2025.	
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.	
Brukinsa - Zanubrutinib - EMEA/H/C/004978/II/0026/G BeiGene Ireland Ltd, Rapporteur: Boje Kvorning Pires Ehmsen Request for Supplementary Information adopted on 16.01.2025.	
Ceprotin - Human protein C - EMEA/H/C/000334/II/0143/G Takeda Manufacturing Austria AG, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 20.02.2025.	
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.	
Flixabi - Infliximab - EMEA/H/C/004020/II/0090/G Samsung Bioepis NL B.V., Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 16.01.2025.	
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.	
Hizentra - Human normal immunoglobulin - EMEA/H/C/002127/II/0161 CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 06.03.2025. Request for Supplementary Information adopted on 30.01.2025.	Positive Opinion adopted by consensus on 06.03.2025.
Idacio - Adalimumab -	

EMEA/H/C/004475/II/0024/G Fresenius Kabi Deutschland GmbH, Rapporteur: Peter Mol, PRAC Rapporteur: Karin Bolin	
Omlyclo - Omalizumab - EMEA/H/C/005958/II/0004/G Celltrion Healthcare Hungary Kft., Rapporteur: Finbarr Leacy, PRAC Rapporteur: Mari Thorn Request for Supplementary Information adopted on 30.01.2025.	
Ondexxya - Andexanet alfa - EMEA/H/C/004108/II/0046/G AstraZeneca AB, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 12.09.2024.	
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0060 Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race Opinion adopted on 13.03.2025.	Positive Opinion adopted by consensus on 13.03.2025.
POTELIGEO - Mogamulizumab - EMEA/H/C/004232/II/0028/G, Orphan Kyowa Kirin Holdings B.V., Rapporteur: Peter Mol	
Respreeza - Human alpha1-proteinase inhibitor - EMEA/H/C/002739/II/0078/G CSL Behring GmbH, Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 16.01.2025.	
Rybrevant - Amivantamab - EMEA/H/C/005454/II/0018/G Janssen-Cilag International N.V., Rapporteur: Filip Josephson Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 12.12.2024.	Positive Opinion adopted by consensus on 13.03.2025.
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0054/G AbbVie Deutschland GmbH & Co. KG, Rapporteur: Finbarr Leacy Request for Supplementary Information adopted on 13.03.2025.	Request for supplementary information adopted with a specific timetable.
Skyrizi - Risankizumab - EMEA/H/C/004759/II/0056/G AbbVie Deutschland GmbH & Co. KG,	

Rapporteur: Finbarr Leacy	
Sogroya - Somapacitan - EMEA/H/C/005030/II/0016, Orphan Novo Nordisk A/S, Rapporteur: Patrick Vrijlandt Opinion adopted on 20.03.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 20.03.2025.
STEQEYMA - Ustekinumab - EMEA/H/C/005918/II/0004/G Celltrion Healthcare Hungary Kft., Rapporteur: Jayne Crowe Request for Supplementary Information adopted on 16.01.2025.	
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.	
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.	

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

AQUIPTA - Atogepant - EMEA/H/C/005871/II/0008 AbbVie Deutschland GmbH & Co. KG, Rapporteur: Janet Koenig, "Update of section 4.6 of the SmPC in order to amend information on pregnancy and lactation based on data from study M22-394; this is a phase 1 lactation study to evaluate the pharmacokinetics and safety of ubrogepant and atogepant in healthy adult lactating female subjects one to six months post-partum. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 13.03.2025.	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.	
EVOTAZ - Atazanavir / Cobicistat - EMEA/H/C/003904/II/0050 Bristol-Myers Squibb Pharma EEIG, Rapporteur: Carla Torre, "Update of sections 4.3 and 4.5 of the SmPC in order to add a new contraindication and to include Drug-Drug Interactions (DDIs) information for the coadministration of Atazanavir/cobicistat (ATV/COBI) with the kinase inhibitor, fostamatinib, and the gonadotropin-releasing hormone receptor antagonist, elagolix based on post-marketing safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI." Request for Supplementary Information adopted on 30.01.2025.	
Fintepla - Fenfluramine - EMEA/H/C/003933/II/0030, Orphan UCB Pharma SA, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC in order to include new efficacy data for Lennox-Gastaut syndrome (LGS) based on final results from EP0214 'ZX008-1601' study. This phase 3 Open-Label Extension (OLE) international multicentre study was conducted in two parts and two cohorts. Part 1 was a randomized, double-blind, placebo-controlled trial of two fixed doses of ZX008 (fenfluramine hydrochloride) oral solution as adjunctive therapy for seizures in children and adults with LGS. Part 2 was an open-label extension to assess the long-term safety and tolerability of ZX008 in children and adults." Opinion adopted on 13.03.2025.	Positive Opinion adopted by consensus on 13.03.2025.
Keytruda - Pembrolizumab - EMEA/H/C/003820/II/0165 Merck Sharp & Dohme B.V., Rapporteur: Paolo Gasparini, "C.I.13: Submission of the final	Positive Opinion adopted by consensus on 13.03.2025.

safety analysis report of participants with hematologic malignancies enrolled in MSD Sponsored studies who received an allogenic hematopoietic stem cell transplantation (HSCT) following therapy with pembrolizumab."
Opinion adopted on 13.03.2025.

LysaKare - L-lysine hydrochloride / L-arginine hydrochloride - EMEA/H/C/004541/II/0019
Advanced Accelerator Applications, Rapporteur: Janet Koenig, "Update of sections 4.2, 4.4 and 4.9 of the SmPC in order to align it with Lutathera SmPC based on post-marketing data and literature. In addition, the MAH took the opportunity to implement editorial changes to the PI and to update the list of local representatives in the Package Leaflet."
Request for Supplementary Information adopted on 16.01.2025.

Mayzent - Siponimod - EMEA/H/C/004712/II/0032
Novartis Europharm Limited, Rapporteur: Thalia Marie Estrup Blicher, "Update of section 5.1 of the SmPC in order to update efficacy and safety information from study CBAF312A2304 (EXPAND) listed as a category 3 study in the RMP. This is a phase III study and is comprised of two parts: a Core Part and an Extension Part. The Core Part was a multicentre, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of siponimod in SPMS patients. This was followed by an open-label Extension Part, collecting long-term efficacy and safety data on siponimod for up to 7 years. In addition, the MAH took the opportunity to add editorial changes to the PI."
Request for Supplementary Information adopted on 12.12.2024.

Mosquirix - Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0086
GlaxoSmithkline Biologicals SA, Rapporteur: Jan Mueller-Berghaus, "Update of sections 4.2, 4.5, 4.8 and 5.1 of the SmPC in order to update posology, efficacy and safety information based on final results from study MALARIA-094 and literature. This is a Phase 2b, randomized, open-label, controlled, multi-centre study of the

efficacy, safety and immunogenicity of RTS,S/AS01E evaluating schedules with or without fractional doses, early dose 4 and yearly doses, in children living in sub-Saharan Africa. The Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI."
Request for Supplementary Information adopted on 12.12.2024.

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

Novavax CZ a.s., Rapporteur: Patrick Vrijlandt, "Submission of the final report from clinical study 2019nCoV-301 (Adolescent part) listed as a category 3 study in the RMP. This is a phase 3 study of efficacy, effectiveness, safety, and immunogenicity in adolescents."
Request for Supplementary Information adopted on 16.01.2025.

Omjjara - Momelotinib - EMEA/H/C/005768/II/0004/G, Orphan

Glaxosmithkline Trading Services Limited, Rapporteur: Christophe Focke, "A grouped application comprised of one Type II, one Type IB and one Type IA Variation, as follows:

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

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

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

Characteristics (SmPC).” Request for Supplementary Information adopted on 19.12.2024.	
Skytrofa - Lonapegsomatropin - EMEA/H/C/005367/II/0036, Orphan Ascendis Pharma Endocrinology Division A/S, Rapporteur: Patrick Vrijlandt, “Update of section 5.1 of the SmPC in order to update efficacy and safety information following the request by CHMP in the outcome for procedure EMEA/H/C/005367/P46/003.1 based on final results from the paediatric study CT-301EXT (enliGHten). In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.” Request for Supplementary Information adopted on 13.03.2025.	Request for supplementary information adopted with a specific timetable.
Strensiq - Asfotase alfa - EMEA/H/C/003794/II/0070, Orphan Alexion Europe SAS, Rapporteur: Paolo Gasparini, “Update of section 5.1 of the SmPC in order to reflect data on effectiveness of asfotase alfa in treating adults with paediatric-onset with hypophosphatasia (HPP) based on real world evidence [RWE], and publications from the Global HPP Registry (ALXN-HPP-501), an observational study [EmPATHY] and UK managed access agreement study another observational prospective study. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4 and add editorial changes to the Labelling.” Request for Supplementary Information adopted on 19.12.2024.	
Tabrecta - Capmatinib - EMEA/H/C/004845/II/0016 Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes, “Update of sections 4.8 and 5.1 of the SmPC in order to update information on based on the results of the clinical study CINC280A2201 'GEOMETRY mono-1' and add 'body temperature increased' to the list of adverse drug reactions (ADRs) with frequency 'very common'. CINC280A2201 is a global, multi-cohort, non-randomized, open-label Phase II study designed to evaluate the efficacy and safety of single-agent capmatinib in	Positive Opinion adopted by consensus on 13.03.2025.

adult patients with epidermal growth factor receptor (EGFR) wild type (wt), advanced non-small cell lung cancer (NSCLC). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI." Opinion adopted on 13.03.2025.	
Taltz - Ixekizumab - EMEA/H/C/003943/II/0054 Eli Lilly and Co (Ireland) Limited, Rapporteur: Kristina Dunder, "Update section 4.8 of the SmPC to add eczematous eruptions (dyshidrotic eczema and exfoliative dermatitis) to the list of adverse drug reactions (ADRs) with frequency uncommon and rare, respectively, following a review of all associated data. The package leaflet is updated in accordance." Request for Supplementary Information adopted on 13.03.2025.	Request for supplementary information adopted with a specific timetable.
Vectibix - Panitumumab - EMEA/H/C/000741/II/0105 Amgen Europe B.V., Rapporteur: Eva Skovlund, "Update of section 4.8 of the SmPC in order to update the information regarding the incidence of infusion-related reactions to reflect the total number of subjects. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial and administrative changes to the PI and to bring it in line with the latest QRD template version 10.4, and to update the list of local representatives in the Package Leaflet." Opinion adopted on 13.03.2025.	Positive Opinion adopted by consensus on 13.03.2025.
Zykadia - Ceritinib - EMEA/H/C/003819/II/0057 Novartis Europharm Limited, Rapporteur: Antonio Gomez-Outes, "Submission of the final report from study CLDK378A2301; a phase III multicentre, randomized study evaluating oral LDK378 against standard chemotherapy in previously untreated adults with ALK rearranged (ALK-positive), stage IIIB or IV, non- squamous non-small cell lung cancer." Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 28.11.2024.	Positive Opinion adopted by consensus on 13.03.2025.
WS2754 **Iscover-** **EMEA/H/C/000175/WS2754/0156**	

Plavix-EMEA/H/C/000174/WS2754/0157 Sanofi Winthrop Industrie, Lead Rapporteur: Fátima Ventura, "Update of sections 4.2 and 5.1 of the SmPC in order to include information on posology enhancement and to update pharmacodynamic information based on post marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to implement editorial changes to the SmPC. " Request for Supplementary Information adopted on 14.11.2024.	
WS2762 **Finlee-EMEA/H/C/005885/WS2762/0010** **Spexotras-EMEA/H/C/005886/WS2762/0009** Novartis Europharm Limited, Lead Rapporteur: Filip Josephson, "Update of sections 4.2 and 5.2 of the SmPC in order to modify administration instructions and pharmacokinetic properties on food effect based on final results from study CDRB436G2102. This is a randomized, open-label, two independent part, 2 x 2 cross-over study to investigate the relative bioavailability of trametinib and dabrafenib liquid formulations under fasted vs. low-fat low-calorie meal conditions in adult healthy participants. In addition, the MAH took the opportunity to implement editorial changes to the PI." Request for Supplementary Information adopted on 12.12.2024.	
WS2793 **Braftovi-EMEA/H/C/004580/WS2793/0042** **Mektovi-EMEA/H/C/004579/WS2793/0036** Pierre Fabre Medicament, Lead Rapporteur: Janet Koenig, "Submission of the final report from study C4221004, aiming at investigating the potential associations between baseline tumour biomarkers and treatment outcome in the 2-part Phase III Randomized, Open Label, Multicentre Study of LGX818 Plus MEK162 Versus Vemurafenib and LGX818 Monotherapy in Patients with Unresectable or Metastatic BRAF V600 Mutant Melanoma (COLUMBUS study)." Request for Supplementary Information adopted on 13.03.2025.	Request for supplementary information adopted with a specific timetable.

WS2818 **PecFent-** **EMEA/H/C/001164/WS2818/0062** Gruenenthal GmbH, Lead Rapporteur: Janet Koenig, "Update of section 4.5 of the SmPC in order to add drug-drug interaction information between opioids and anticholinergics; the Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 13.03.2025.	Request for supplementary information adopted with a specific timetable.
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda- **EMEA/H/W/005362/WS2809/0021** **Qdenga-** **EMEA/H/C/005155/WS2809/0022** Takeda GmbH, Lead Rapporteur: Sol Ruiz, "Update of section 4.8 of the SmPC in order to add eye pain to the list of adverse drug reactions (ADRs) with frequency uncommon based on post-marketing data; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI."	

B.5.3. CHMP-PRAC assessed procedures

Bavencio - Avelumab - **EMEA/H/C/004338/II/0051** Merck Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Karin Erneholm, "Update of section 4.8 of the SmPC in order to add "neutropenia" to the list of adverse drug reactions (ADRs) with frequency "not known" based on post marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the PI in accordance with the latest EMA excipients guideline." Opinion adopted on 13.03.2025.	Positive Opinion adopted by consensus on 13.03.2025.
BIMERVAX - Covid-19 Vaccine (recombinant, adjuvanted) - **EMEA/H/C/006058/II/0017** Hipra Human Health S.L., Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Zane Neikena, "Update of sections 4.2, 4.4, and 5.1 of the SmPC in order to update information for immunocompromised individuals, based on final results from study HIPRA-HH-4 listed as a	Positive Opinion adopted by consensus on 13.03.2025.

category 3 study in the RMP; this is a Phase IIb/III, open label, single arm, multi-centre trial to assess the immunogenicity and safety of an additional dose vaccination with a recombinant protein RBD fusion heterodimer candidate (PHH-1V) against SARS-CoV-2, in adults with pre-existing immunosuppressive conditions vaccinated against COVID-19. The Package Leaflet is updated accordingly. The RMP is also updated to version 1.5. In addition, the MAH took the opportunity to include editorial changes in the PI." Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 28.11.2024.	
Bylvay - Odevixibat - EMEA/H/C/004691/II/0022/G, Orphan Ipsen Pharma, Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Adam Przybylkowski, "A grouped application including two type II variations: - Update of sections 4.2, 4.4, 4.8, and 5.1 of the SmPC based on the clinical study report for the completed 72 weeks of Study A4250-008; an open-label, phase III study to evaluate the long-term efficacy and safety of odevixibat in children with PFIC (category 3 study in the RMP; MEA 002). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and the Package Leaflet. An updated RMP version 6.3 was included in this submission. - Submission of the clinical study report for Study A4250-J001; a Phase I PK study in healthy Japanese adult male patients." Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 13.03.2025.
ELREXFIO - Elranatamab - EMEA/H/C/005908/II/0005 Pfizer Europe Ma EEIG, Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Barbara Kovacic Bytyqi, "Update of section 4.2 of the SmPC to add every four-week dosing schedule after at least 24 weeks of every two-week dosing and to update the recommendations for restarting therapy following dose delay, and update of	

sections 4.8, 5.1 and 5.2 of the SmPC with long-term efficacy, safety, and clinical pharmacology results (≥2 years of follow-up after the last participant initial dose), based on the final study report of Study C1071003; a Phase 2, open-label, multicentre, non-randomised study of elranatamab monotherapy in participants with MM who are refractory to at least one PI, one IMiD, and one anti-CD38 Ab. The Package Leaflet has been updated in accordance. In addition, the MAH took the opportunity to implement editorial changes in the SmPC and to update the list of local representatives in the Package Leaflet. Further, the provision of the final study report addresses SOB 001, and Annex II has been updated accordingly. A revised RMP version 1.2 was provided as part of the application." Request for Supplementary Information adopted on 12.12.2024.	
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 Intrahepatic Cholestasis Types 1 and 2 (PEDFIC 2)." Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 13.02.2025.	Positive Opinion adopted by consensus on 13.03.2025.
Kisplyx - Lenvatinib - EMEA/H/C/004224/II/0061 Eisai GmbH, Rapporteur: Karin Janssen van Doorn, PRAC Rapporteur: David Olsen,	Positive Opinion adopted by consensus on 13.03.2025.

"Submission of the final report from study E7080-G000-307 listed as a category 3 study in the RMP. This is a multicentre, open-label, randomized, phase 3 trial to compare the efficacy and safety of lenvatinib in combination with everolimus or pembrolizumab versus sunitinib alone in first-line treatment of subjects with advanced renal cell carcinoma. The RMP version 18.0 has also been submitted." Opinion adopted on 13.03.2025.	
Krazati - Adagrasib - EMEA/H/C/006013/II/0010/G Bristol-Myers Squibb Pharma EEIG, Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Kimmo Jaakkola, "A grouped application consisting of: C.I.4: Update of section 5.1 of the SmPC based on final results from study 849-012 (KRYSTAL-12) listed as a specific obligation in the Annex II. This is a Randomized Phase 3 Study of MRTX849 versus Docetaxel in Patients with Previously Treated Non-Small Cell Lung Cancer with KRAS G12C Mutation. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to update Annex IIE of the PI. C.I.4: Update of section 4.8 of the SmPC in order to update safety information based on an integrated analysis of data from interventional studies 849-012 (KRYSTAL-12), 849-007 (KRYSTAL-7) and 849-001 (KRYSTAL-1)." Request for Supplementary Information adopted on 12.12.2024.	See 9.1
LysaKare - L-lysine hydrochloride / L-arginine hydrochloride - EMEA/H/C/004541/II/0018 Advanced Accelerator Applications, Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski, "Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the warning on 'Hyperkalaemia' as well as on 'Metabolic acidosis' and to update safety information based on final results from study CAAA001A12401 listed as a category 3 study in the RMP. This is a multicentre, open-label post authorization safety study to evaluate the effect of LysaKare infusion on serum potassium levels in GEP-NET patients eligible for Lutathera	Positive Opinion adopted by consensus on 13.03.2025.

treatment. The RMP version 3.0 has also been submitted." Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 28.11.2024.	
Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0057/G Pfizer Europe MA EEIG, Rapporteur: Jean-Michel Race, PRAC Rapporteur: Martin Huber, "Grouped application consisting of: C.I.4: Update of sections 4.2, 4.4, 4.8 and 5.2 of the SmPC in order to provide a new dosing recommendation in patients with severe renal impairment based on final results from study C4671028; this is a Phase 1, Open-Label, Non-Randomized Study to Investigate the Safety and PK Following Multiple Oral Doses of PF-07321332 (Nirmatrelvir)/Ritonavir in Adult Participants With COVID-19 and Severe Renal Impairment Either on Hemodialysis or Not on Hemodialysis. The Package Leaflet and Labelling are updated accordingly. The updated RMP version 3.1 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. B.II.e.5.a.2: To introduce a new pack size ." Request for Supplementary Information adopted on 12.12.2024, 25.07.2024.	
PONVORY - Ponesimod - EMEA/H/C/005163/II/0018/G Laboratoires Juvise Pharmaceuticals, Rapporteur: Peter Mol, PRAC Rapporteur: Karin Erneholm, "Grouped application comprised of two Type II Variations, as follows: C.I.13: Submission of the final report from study AC-058B202; this is a Multicentre, Randomized, Double-blind, Parallel-group Extension to Study AC-058B201 to Investigate the Long-term Safety, Tolerability, and Efficacy of 10, 20, and 40 mg/day Ponesimod, an Oral S1P1 Receptor Agonist, in Patients with Relapsing-remitting Multiple Sclerosis. C.I.13: Submission of the final report from study AC-058B303 (OPTIMUM-LT); this is a Multicentre, Non-Comparative Extension to Study AC-058B301, to Investigate the Long-Term Safety, Tolerability, and Control of Disease of Ponesimod 20 mg in Subjects with Relapsing	Request for supplementary information adopted with a specific timetable.

Multiple Sclerosis. The RMP version 4.1 has also been submitted." Request for Supplementary Information adopted on 13.03.2025.	
Rozlytrek - Entrectinib - EMEA/H/C/004936/II/0025 Roche Registration GmbH, Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder, "Submission of the final integrated analysis report for bone biomarkers based on GO40782 [STARTRK-2], CO40778 [STARTRK-NG], and BO41932 [TAPISTRY] studies (PAESs). The RMP version 6 has also been submitted." Request for Supplementary Information adopted on 13.03.2025.	Request for supplementary information adopted with a specific timetable.
Scemblix - Asciminib - EMEA/H/C/005605/II/0017, Orphan Novartis Europharm Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová, "Submission of a comprehensive final analysis of the data from study CABL001X2101, listed as a category 3 study in the RMP. This is a phase I, multicentre, open-label study of oral asciminib in patients with chronic myelogenous leukaemia or Philadelphia Chromosome-positive acute lymphoblastic leukaemia. The RMP version 2.1 has also been submitted." Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 28.11.2024.	Positive Opinion adopted by consensus on 13.03.2025.
SCENESSE - Afamelanotide - EMEA/H/C/002548/II/0053 Clinuvel Europe Limited, Rapporteur: Janet Koenig, PRAC Rapporteur: Martin Huber, "Submission of an updated RMP version 9.12 to include changes made to the pharmacokinetic study CUV052 including the inclusion of adolescent patients in the protocol. CUV052 is an interventional study to evaluate the pharmacokinetics of afamelanotide in patients with Erythropoietic Protoporphyria (EPP)." Request for Supplementary Information adopted on 31.10.2024.	
Shingrix - Herpes zoster vaccine (recombinant, adjuvanted) - EMEA/H/C/004336/II/0076 GlaxoSmithkline Biologicals SA, Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja	Positive Opinion adopted by consensus on 13.03.2025.

Hrabcik, "Update of sections 4.8 and 5.1 of the SmPC to include the final results of study ZOSTER-049, listed as a category 3 study in the RMP. This is a Phase 3b, open label, multi-country, long-term follow-up study that assessed the prophylactic efficacy, safety, and immunogenicity persistence of Shingrix in adults ≥50 years of age at the time of primary vaccination in studies ZOSTER 006 and ZOSTER-022. The study also assessed 1 or 2 additional doses of Shingrix on a 0 or 0, 2-month schedule in two subgroups of older adults. The updated RMP version 8.2 has been approved. In addition, the MAH took the opportunity to implement editorial changes to the SmPC, Labelling and Package Leaflet; and to bring the PI in line with the latest QRD template version 10.4. Based on this, sections 2, 4.4 and 6.6 of the SmPC have been updated." Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 16.01.2025, 05.09.2024.	
Sunlenca - Lenacapavir - EMEA/H/C/005638/II/0022/G Gilead Sciences Ireland Unlimited Company, Rapporteur: Filip Josephson, PRAC Rapporteur: Ana Sofia Diniz Martins, "Grouping of two type II variations: - Update of section 5.1 of the SmPC to include efficacy and resistance data based on week 156 interim data from Study GS-US-200-4625; a phase 2/3 study to evaluate the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with an optimized background regimen in heavily treatment experienced people living with HIV-1 infection with multidrug resistance (category 3 study in the RMP). Additionally, upon request by the CHMP following the assessment of II/0013, the MAH proposes to update section 4.8 of the SmPC to include information related to injection site nodules and induration that were non-resolved at the end of follow-up. - Provision of the final study report of Study GS-US-200-4334: a phase 2 randomized, open label, active controlled study evaluating the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with other antiretroviral agents in people living with HIV (category 3 study in the RMP).	Request for supplementary information adopted with a specific timetable.

An updated RMP version 2.1 was included as part of the application." Request for Supplementary Information adopted on 13.03.2025, 16.01.2025.	
Tibsovo - Ivosidenib - EMEA/H/C/005936/II/0012, Orphan Les Laboratoires Servier, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Marie Louise Schougaard Christiansen, "Submission of an updated RMP version 3.0 for TIBSOVO and a replacement study protocol for study S095031-218. This is a phase 1, multicentre, open-label, safety and pharmacokinetic study of orally administered ivosidenib in participants with IDH1-mutated malignancies and hepatic or renal impairment. Study milestones in RMP were updated accordingly." Opinion adopted on 13.03.2025.	Positive Opinion adopted by consensus on 13.03.2025.
Tysabri - Natalizumab - EMEA/H/C/000603/II/0150 Biogen Netherlands B.V., Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Gabriele Maurer, "Update of sections 4.2 and 4.4 of the SmPC in order to modify administration instructions to add the option for self-administration or administration by a caregiver and to update educational guidance, based on supportive data including final results from study 101MS330; this is a Single-Arm, Open-Label, Phase 3 Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Multiple Doses of Natalizumab Administered to Japanese Participants With Relapsing-Remitting Multiple Sclerosis via a Subcutaneous Route of Administration. The Annex II, Labelling and Package Leaflet are updated accordingly. The RMP version 32.1 has also been submitted."	
Zejula - Niraparib - EMEA/H/C/004249/II/0056, Orphan GlaxoSmithKline (Ireland) Limited, Rapporteur: Ingrid Wang, PRAC Rapporteur: Jan Neuhauser, "Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from PRIMA study (PR-30-5017-C) listed as a PAES in the Annex II; this is a Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicentre Study of Niraparib Maintenance Treatment in Patients with	

Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy. The RMP version 9.0 has also been submitted. In addition, the MAH took the opportunity to update section D of Annex II, and to implement editorial changes to the PI." Request for Supplementary Information adopted on 28.11.2024.	
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0004/G, Orphan Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "A grouped application comprised of 8 Type II variations as follows: 1 Type II (C.I.4): Update of section 5.2 of the SmPC in order to update ganaxolone metabolite pattern at steady state based on re-analysis of 1042-TQT-1001 listed as a category 3 study in the RMP to evaluate the ganaxolone steady-state metabolite. 7 Type II (C.I.13): Submission of the final non-clinical study reports for the in vitro DDI potential and in vivo PK of the metabolite M17 listed as category 3 studies in the RMP. The RMP version 1.2 has also been submitted. In addition, the MAH took the opportunity to introduce updates to the PI that reflect clarifications and typographical corrections, including to sections 4.2 and 4.4 of the SmPC." Request for Supplementary Information adopted on 25.07.2024, 11.04.2024.	
ZTALMY - Ganaxolone - EMEA/H/C/005825/II/0015/G, Orphan Marinus Pharmaceuticals Emerald Limited, Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski, "A grouped application consisting of five Type II variations, as follows: C.I.13: Submission of the final report from non-clinical study 1022-9241 listed as a category 3 study in the RMP. This is a 26-Week Toxicity Study of Ganaxolone Metabolite, M2, by Oral Gavage in the Sprague-Dawley rat with a 2-Week Recovery Period. The RMP version 3 has also been submitted. C.I.13: Submission of the final report from non-	Request for supplementary information adopted with a specific timetable.

clinical study 20447815 listed as a category 3 study in the RMP. This is a An Oral (Gavage) Study of the Effects of M2 (Ganaxolone Metabolite) Administration on Embryo/Fetal Development in CD (Sprague Dawley) IGS Rat. The RMP version 3 has also been submitted. C.I.13: Submission of the final report from Weight of Evidence (WoE) assessment to evaluate the need for a 2-year carcinogenicity study in rats with GNX, listed as a category 3 study in the RMP. C.I.13: Submission of the final report from WoE assessment to evaluate the need for a 2-year carcinogenicity study in rats with M2, listed as a category 3 study in the RMP. C.I.13: Submission of the final report from WoE assessment to evaluate the need for a juvenile toxicity study with M2, listed as a category 3 study in the RMP. ” Request for Supplementary Information adopted on 13.03.2025.	

B.5.4. PRAC assessed procedures

PRAC Led **Alunbrig - Brigatinib / Brigatinib - EMEA/H/C/004248/II/0056** Takeda Pharma A/S, PRAC Rapporteur: Carla Torre, PRAC-CHMP liaison: Paulo Paixão, “Submission of the final report from Brigatinib-5007 study listed as a category 3 study in the RMP. This is a non-interventional cohort study to provide real-world evidence of the occurrence of early-onset pulmonary events in patients with anaplastic lymphoma kinase-positive advanced non-small cell lung cancer treated with brigatinib: a post-authorisation safety study. The RMP version 7 has also been submitted. The MAH proposes the removal of the additional risk minimization measure, the Alunbrig Patient Alert Card (PAC), for the risk of early-onset pulmonary events (EOPEs). In addition, the MAH took the opportunity to introduce editorial changes to the PI.” Opinion adopted on 13.03.2025.	Positive Opinion adopted by consensus on 13.03.2025.
PRAC Led **BLINCYTO - Blinatumomab -**	Positive Opinion adopted by consensus on

EMEA/H/C/003731/II/0054, Orphan Amgen Europe B.V., PRAC Rapporteur: Jana Lukacisinova, PRAC-CHMP liaison: Petr Vrbata, "To update sections 4.2, 4.4, 4.8 of the SmPC to include Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS); and to update section D of Annex II to remove educational materials for physicians, pharmacists, and to include ICANS within neurologic events in educational material for nurses and patient/caregivers and patient alert card following the outcome of PSUR procedure EMEA/H/C/PSUSA/00010460/202212. The Package Leaflet is updated accordingly. The RMP version 17.2 has also been submitted." Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 28.11.2024, 11.07.2024, 08.02.2024.	13.03.2025.
PRAC Led **Imbruvica - Ibrutinib - EMEA/H/C/003791/II/0093** Janssen-Cilag International N.V., PRAC Rapporteur: Barbara Kovacic Bytyqi, PRAC-CHMP liaison: Selma Arapovic Dzakula, "Submission of the study report for additional pharmacovigilance analysis to further evaluate the risk of haemorrhage in participants receiving ibrutinib and concomitant vitamin K antagonists with or without antiplatelet drugs, listed as a category 3 study in the RMP." Opinion adopted on 13.03.2025.	Positive Opinion adopted by consensus on 13.03.2025.
PRAC Led **Lonsurf - Trifluridine / Tipiracil - EMEA/H/C/003897/II/0031** Les Laboratoires Servier, PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study DIM-95005-001 (PROMETCO), listed as a category 3 PASS in the RMP. This is a non-interventional, observational, real world evidence prospective cohort study in the management of metastatic colorectal cancer. The RMP version 11.1 has also been submitted as the missing information "Use in patients in worse condition than ECOG 0-1" has been removed based on the results from PROMETCO. The PART II - section SVII 1 & SVII 2 has been updated to comply with GVP module V revision 2." Opinion adopted on 13.03.2025.	Positive Opinion adopted by consensus on 13.03.2025.

PRAC Led **Mimpara - Cinacalcet - EMEA/H/C/000570/II/0076** Amgen Europe B.V., PRAC Rapporteur: Mari Thorn, PRAC-CHMP liaison: Kristina Dunder, "Submission of the final report from study 20180204 listed as a category 3 study in the RMP. This is a non-interventional observational registry study to evaluate the use and safety of cinacalcet among paediatric patients with secondary hyperparathyroidism (HPT)." Request for Supplementary Information adopted on 13.03.2025.	Request for supplementary information adopted with a specific timetable.
PRAC Led **Mosquirix - Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted) - EMEA/H/W/002300/II/0085/G** GlaxoSmithkline Biologicals SA, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Karin Janssen van Doorn, "A grouped application comprised of two type II variations, as follows: C.I.4: Update of sections 4.4 and 5.1 of the SmPC in order to remove meningitis from the list of important potential risks and add effectiveness data based on EPI-MAL-003 study listed as a category 3 study in the RMP. This is a prospective study to evaluate the safety, effectiveness and impact of the RTS,S/AS01E vaccine in young children in sub-Saharan Africa countries. The Package Leaflet is updated accordingly. The RMP version 6.0 has also been submitted. C.I.13: Submission of the final report from study MVPE (Malaria Vaccine Pilot Evaluation) listed as a category 3 study in the RMP. This is a observational study in the context of a cluster-randomized pilot implementation in order to assess the feasibility of delivery, safety, and impact on mortality of the RTS,S/AS01E malaria vaccine delivered through the routine immunization services in Kenya, Malawi, and Ghana over 4 years." Request for Supplementary Information adopted on 13.03.2025, 28.11.2024.	Request for supplementary information adopted with a specific timetable.
PRAC Led **OPDIVO - Nivolumab -**	Positive Opinion adopted by consensus on

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 42.1 has also been submitted." Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 13.02.2025.	13.03.2025.
PRAC Led **Spravato - Esketamine - EMEA/H/C/004535/II/0026** Janssen-Cilag International N.V., PRAC Rapporteur: Terhi Lehtinen, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of the final study report for the non-interventional study PCSNSP002812 listed as a category 3 study in the RMP. This is a survey to assess the effectiveness of SPRAVATO educational materials in the European Union. The RMP version 8.1 was also submitted. The requested variation proposed amendments to the Risk Management Plan (RMP)." Opinion adopted on 13.03.2025.	Positive Opinion adopted by consensus on 13.03.2025.
PRAC Led **Zejula - Niraparib - EMEA/H/C/004249/II/0058, Orphan** GlaxoSmithKline (Ireland) Limited, PRAC Rapporteur: Jan Neuhauser, PRAC-CHMP liaison: Christian Gartner, "Submission of the final report from study 3000-04-001/ GSK213705 listed as a category 3 study in the RMP, in order to fulfil MEA 002.6; this is a non-interventional PASS to evaluate the risks of myelodysplastic syndrome/acute myeloid leukaemia and second primary malignancies in adult patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer receiving maintenance treatment with Zejula. The RMP version 10.0 has also been submitted."	Positive Opinion adopted by consensus on 13.03.2025.

Opinion adopted on 13.03.2025.	
PRAC Led **WS2794** **Segluromet-** **EMEA/H/C/004314/WS2794/0026** **Steglatro-** **EMEA/H/C/004315/WS2794/0025** **Steglujan-** **EMEA/H/C/004313/WS2794/0029** Merck Sharp & Dohme B.V., Lead PRAC Rapporteur: Bianca Mulder, PRAC-CHMP liaison: Patrick Vrijlandt, "Submission of the final report from study 8835-062 listed as a category 3 study in the RMP for Steglatro, Steglujan and Segluromet. This is a non-interventional post-authorization safety study (PASS) to assess the risk of diabetic ketoacidosis (DKA) among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents. The RMP version 2.3 have also been submitted." Opinion adopted on 13.03.2025. Request for Supplementary Information adopted on 16.01.2025.	Positive Opinion adopted by consensus on 13.03.2025.
PRAC Led **WS2808** **Iscover-** **EMEA/H/C/000175/WS2808/0158** **Plavix-EMEA/H/C/000174/WS2808/0160** Sanofi Winthrop Industrie, Lead PRAC Rapporteur: Carla Torre, PRAC-CHMP liaison: Fátima Ventura, "C.I.11.z (IB) - To provide a new RMP version to update the FUQ in Annex 4. Furthermore, the Marketing Authorisation Holder has taken the opportunity to update Part I Table 5 Product overview following approval of EMEA/H/C/WS/2150."	
PRAC Led **WS2815** **Anoro Ellipta-** **EMEA/H/C/002751/WS2815/0049** **Laventair Ellipta-** **EMEA/H/C/003754/WS2815/0052** GlaxoSmithKline (Ireland) Limited, Lead PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, "Submission of an updated RMP version 10.0 for Anoro Ellipta and Laventair Ellipta Inhalation powder, pre-dispensed [55µg/	Positive Opinion adopted by consensus on 13.03.2025.

22µg] following completion of Category 1 PASS 201038 in order to remove the safety concerns accordingly." Opinion adopted on 13.03.2025.	
PRAC Led **WS2816** **Incruse Ellipta-** **EMEA/H/C/002809/WS2816/0043** **Rolufta Ellipta-** **EMEA/H/C/004654/WS2816/0027** GlaxoSmithKline (Ireland) Limited, Lead PRAC Rapporteur: Amelia Cupelli, PRAC-CHMP liaison: Paolo Gasparini, "Submission of an updated RMP version 8.0 for Incruse Ellipta and Rolufta Ellipta in order to reflect the completion of the category 1 PASS study 201038 and remove the safety concerns accordingly." Opinion adopted on 13.03.2025.	Positive Opinion adopted by consensus on 13.03.2025.

B.5.5. 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 Request for Supplementary Information adopted on 21.02.2025.	
Luxturna - Voretigene neparvovec - **EMEA/H/C/004451/II/0054/G, Orphan, ATMP** Novartis Europharm Limited, Rapporteur: Sol Ruiz, CHMP Coordinator: Antonio Gomez-Outes	
WS2821/G **Tecartus-** **EMEA/H/C/005102/WS2821/0056/G** **Yescarta-** **EMEA/H/C/004480/WS2821/0087/G** Kite Pharma EU B.V., Lead Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus	

B.5.6. 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." Request for Supplementary Information adopted on 21.02.2025.	
Kymriah - Tisagenlecleucel - EMEA/H/C/004090/II/0092, Orphan, ATMP Novartis Europharm Limited, Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang, PRAC Rapporteur: Gabriele Maurer, "Update of section 4.2 of the SmPC in order to update the 'monitoring after infusion' recommendations, based on existing clinical trial data as well as literature references reporting real word experience. The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to introduce a minor change to the HCP educational programme in the Annex II in order to enhance readability." Request for Supplementary Information adopted on 24.01.2025.	

B.5.7. PRAC assessed ATMP procedures

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

WS2791/G **Aflunov-** **EMEA/H/C/002094/WS2791/0091/G** **Foclivia-** **EMEA/H/C/001208/WS2791/0095/G** **Zoonotic Influenza Vaccine Seqirus-**	Positive Opinion adopted by consensus on 13.03.2025.

EMEA/H/C/006375/WS2791/0009/G
Seqirus S.r.l, Lead Rapporteur: Maria Grazia Evandri
Opinion adopted on 13.03.2025.
Request for Supplementary Information adopted on 06.02.2025, 19.12.2024.

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

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

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

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

G. ANNEX G

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

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

G.2 PRIME

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