13 October 2025
EMA/CHMP/307616/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 13-16 October 2025
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

13 October 2025, 09:00 – 19:30, virtual meeting/room 1C

14 October 2025, 08:30 – 19:30, virtual meeting/room 1C

15 October 2025, 08:30 – 19:30, virtual meeting/room 1C

16 October 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 13-16 October 2025. See October 2025 CHMP minutes (to be published post November 2025 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 13-16 October 2025

1.3. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 6 October 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 14 October 2025 at 09:00

List of Outstanding Issues adopted on 24.07.2025. List of Questions adopted on 14.11.2024.

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 14 October 2025 at 16:00

List of Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

2.2. Re-examination procedure oral explanations

2.2.1. Austedo - Deutetrabenazine - EMEA/H/C/006371

Teva GmbH; treatment of tardive dyskinesia

Scope: Oral explanation

Action: Oral explanation to be held on 15 October 2025 at 14:00

Opinion adopted on 19.06.2025. List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 25.07.2024.

2.3. Post-authorisation procedure oral explanations

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

Chiesi Farmaceutici S.p.A.,

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan

Scope: Oral explanation

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

Request for Supplementary Information adopted on 19.06.2025, 30.01.2025.

2.4. Referral procedure oral explanations

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

Pfizer Europe MA EEIG

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

Scope: Oral explanation

Action: Oral explanation to be held on 13 October 2025 at 16:00

Patient representatives

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

List of outstanding issues adopted 18.09.2025, 22.05.2025, 12.12.2024. List of questions adopted on 29.07.2024

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Brensocatib - PRIME - EMEA/H/C/005820

Accelerated assessment

treatment of non-cystic fibrosis bronchiectasis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 16.09.2025. List of Questions adopted on 22.07.2025.

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 19.06.2025. List of Questions adopted on 30.01.2025.

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

3.2.1. Nogapendekin alfa inbakicept - EMEA/H/C/006622

treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.05.2025.

3.2.2. Tolebrutinib - EMEA/H/C/006386

treatment of non-relapsing secondary progressive multiple sclerosis (nrSPMS) in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.06.2025.

3.2.3. Trofinetide - Orphan - EMEA/H/C/006482

Acadia Pharmaceuticals (Netherlands) B.V.; treatment of Rett syndrome in adults and paediatric patients 2 years of age and older

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.05.2025.

3.2.4. Depemokimab - EMEA/H/C/006446

As an add-on maintenance treatment of asthma, and as an add-on treatment of inadequately controlled Chronic rhinosinusitis with nasal polyps (CRSwNP)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.05.2025.

3.2.5. Golimumab - EMEA/H/C/006621

treatment of rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ulcerative colitis and ankylosing spondylitis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.05.2025.

3.2.6. Lutetium (177Lu) chloride - EMEA/H/C/006596

used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with Lutetium (177Lu) chloride

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.05.2025.

3.2.7. Aficamten - EMEA/H/C/006228

treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) in adult patients

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.04.2025.

3.2.8. Ranibizumab - EMEA/H/C/006502

treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment and other retinopathies

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.05.2025.

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

3.3.1. Camizestrant - EMEA/H/C/006494

treatment of adults with locally advanced or metastatic breast cancer

Scope: List of questions

Action: For adoption

3.3.2. Etanercept - EMEA/H/C/006738

Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis, paediatric plaque psoriasis

Scope: Opinion

Action: For adoption

3.3.3. Glepaglutide - EMEA/H/C/005855

treatment of adults with Short Bowel Syndrome

Scope: List of questions

Action: For adoption

3.3.4. Linerixibat - Orphan - EMEA/H/C/006241

Glaxosmithkline Trading Services Limited; treatment of cholestatic pruritus in adult patients with primary biliary cholangitis

Scope: List of questions

Action: For adoption

3.3.5. Ranibizumab - EMEA/H/C/006634

treatment of adults with neovascular (wet) age-related macular degeneration (AMD), visual impairment and other retinopathies

Scope: List of questions

Action: For adoption

3.3.6. Allogeneic faecal microbiota, pooled - Orphan - EMEA/H/C/006678

MaaT PHARMA; treatment of adult patients with acute-graft-versus-host disease (aGvHD)

Scope: List of questions

Action: For adoption

3.3.7. Lurbinectedin - Orphan - EMEA/H/C/006673

Pharma Mar S.A.; maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)

Scope: List of questions

Action: For adoption

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

No items

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

3.5.1. Austedo - Deutetrabenazine - EMEA/H/C/006371

Teva GmbH; treatment of tardive dyskinesia

Scope: Opinion

Action: For adoption

Opinion adopted on 19.06.2025. List of Outstanding Issues adopted on 27.02.2025. List of Questions adopted on 25.07.2024.

See 2.2

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

TETEC Tissue Engineering Technologies AG; repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV

Scope: List of questions, questions to the AHEG

Action: For adoption

Opinion adopted on 24.07.2025, 18.07.2025.

3.5.3. Nurzigma - Pridopidine - Orphan - EMEA/H/C/006261

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

Scope: List of questions to the SAG-N

Opinion adopted on 24.07.2025

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

4.1.1. 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

List of Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.03.2025.

4.1.2. Saphnelo - Anifrolumab - EMEA/H/C/004975/X/0023

AstraZeneca AB;

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new route of administration (subcutaneous use) and a new

strength (120 mg).”

Action: For adoption

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 22.05.2025.

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

4.2.1. Tremfya - Guselkumab - EMA/X/0000248626

Janssen Cilag International;

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

Scope: “Extension application to add a new strength of 45 mg (100 mg/ml) in a pre-filled syringe (glass) in pre-filled pen (VarioJect) grouped with an extension of indication (C.I.6.a) to include treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years who are candidates for systemic therapy based on results from study CNTO1959PSO3011. This is a Phase 3, Multicentre, Randomized, Placebo- and Active Comparator-Controlled Study Evaluating the Efficacy, Safety, and Pharmacokinetics of Subcutaneously Administered Guselkumab for the Treatment of Chronic Plaque Psoriasis in Paediatric Participants (≥6 To <18 Years of Age). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 10.3 of the RMP has also been submitted.”

Action: For adoption

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. Shingrix - Herpes zoster vaccine (recombinant, adjuvanted) - EMA/X/0000243671

GlaxoSmithKline Biologicals;

Rapporteur: Christophe Focke, PRAC Rapporteur: Sonja Radowan

Scope: “Extension application to introduce a new pharmaceutical form (suspension for injection in pre-filled syringe).”

Action: For adoption

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

No items

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

No items

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

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

5.1.1. Akeega - Niraparib / Abiraterone acetate - EMA/VR/0000282377

Janssen Cilag International;

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include AKEEGA with prednisone or prednisolone for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and HRR-mutations (germline and/or somatic, based on interim results from study 67652000PCR3002 (AMPLITUDE); this is a phase 3 randomized, placebo-controlled, double-blind study of niraparib in combination with abiraterone acetate and prednisone versus abiraterone acetate and prednisone for the treatment of participants with deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-sensitive Prostate cancer (mCSPC); 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 3.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. In addition, the MAH is requesting an additional year of market protection for a new indication."

Action: For adoption

5.1.2. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel – ATMP - EMA/VR/0000265024

Bristol-Myers Squibb Pharma EEIG;

CAT Rapporteur: Concetta Quintarelli, CAT Co-Rapporteur: Claire Beuneu, CHMP Coordinator: Paolo Gasparini

Scope: "A grouped application comprised of two Type II variations, as follows:

Type II (C.I.6): Extension of indication to include the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor for BREYANZI, based on results from the pivotal Study 017001 MCL Cohort (TRANSCEND-NHL-001); this is a Phase 1, Multicentre, Open-Label Study of JCAR017, CD19-targeted Chimeric Antigen Receptor (CAR)

T Cells, for Relapsed and Refractory (R/R) B-cell Non-Hodgkin Lymphoma (NHL). As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package leaflet is updated in accordance. Version 7.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.3. Cejemly - Sugemalimab - EMA/VR/0000261157

Cstone Pharmaceuticals Ireland Limited;

Rapporteur: Filip Josephson, PRAC Rapporteur: Petar Mas

Scope: "Extension of indication to include the treatment of unresectable stage III non-small-cell lung cancer (NSCLC) with no sensitising EGFR mutations, or ALK, ROS1 genomic tumour aberrations in adults whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy for CEJEMLY, based on final results from study CS1001-301; this is a Phase III, multicentre, randomised, double-blind, placebo-controlled study assessing the efficacy and safety of sugemalimab as consolidation therapy versus placebo in participants with locally advanced or unresectable stage III NSCLC who have not progressed after concurrent or sequential chemoradiotherapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted."

Action: For adoption

5.1.4. Dupixent - Dupilumab - EMA/VR/0000282164

Sanofi Winthrop Industrie;

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Kimmo Jaakkola

Scope: "Extension of indication to include treatment of moderate to severe chronic spontaneous urticaria (CSU) in children aged 2 to 11 years whose disease is inadequately controlled by H1 antihistamines and who are naive to anti-IgE therapy for CSU for DUPIXENT, based on the results from study PKM16982; this is a multi-centre, single-arm study to investigate the pharmacokinetics and safety of dupilumab in male and female participants ≥2 years to <12 years of age with uncontrolled chronic spontaneous urticaria (CSU). Consequently, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template."

Action: For adoption

5.1.5. Eylea - Aflibercept - EMA/VR/0000264981

Bayer AG;

Rapporteur: Nicolas Beix, PRAC Rapporteur: Zoubida Amimour

Scope: "A grouped application comprised of two Type II Variations, as follows:

C.I.6: Extension of indication to include the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch, central and hemiretinal RVO) for EYLEA, based on results from study 22153 (QUASAR); this is a randomized, double-masked, active-controlled Phase 3 study of the efficacy and safety of aflibercept 8 mg in macular oedema secondary to retinal vein occlusion. 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 accordingly. The RMP version 36.1 has also been submitted.

C.I.4: Update of section 4.2 of the SmPC in order to change posology recommendations of the approved indications nAMD and DME based on the results from study 22153 (QUASAR) and post-hoc analysis of the pivotal studies 20968 (PULSAR), 21091 (PHOTON) and Phase II study 21086 (CANDELA)."

Action: For adoption

5.1.6. Gazyvaro - Obinutuzumab - EMA/VR/0000244907

Roche Registration GmbH;

Rapporteur: Boje Kvorning Pires Ehmsen, PRAC Rapporteur: Mari Thorn

Scope: "Extension of indication to include treatment of adult patients with active lupus nephritis who are receiving standard therapy for GAZYVARO, based on results from study Regency (CA41705). This is an ongoing, Phase III, randomized, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of obinutuzumab administered at standard infusion rates in patients with ISN/RPS 2003 Class III or IV lupus nephritis treated with standard-of-care therapy.

As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11 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."

Action: For adoption

5.1.7. HETRONIFLY - Serplulimab - EMA/VR/0000284402

Accord Healthcare S.L.U.;

Rapporteur: Eva Skovlund, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include, in combination with fluoropyrimidine- and platinum-based chemotherapy, the first-line treatment of adult patients with unresectable, locally advanced/recurrent or metastatic oesophageal squamous cell carcinoma whose tumours express PD-L1 with a CPS ≥ 1 for HETRONIFLY, based on results from study HLX10-007-EC301; this is a randomized, double-blind, multi-centre, phase III clinical study comparing the clinical efficacy and safety of HLX10 or placebo combined with chemotherapy in first-line treatment of locally advanced/metastatic oesophageal squamous cell carcinoma (ESCC) patients. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted."

Action: For adoption

5.1.8. HETRONIFLY - Serplulimab - EMA/VR/0000282407

Accord Healthcare S.L.U.;

Rapporteur: Eva Skovlund, PRAC Rapporteur: Jan Neuhauser

Scope: "Extension of indication to include HETRONIFLY in combination with carboplatin and pemetrexed is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung carcinoma who do not have EGFR or ALK positive mutations based on interim results from study HLX10-002-NSCLC301; this is a pivotal Phase III clinical study, patients treated with serplulimab in combination with carboplatin and pemetrexed showed statistically significant and clinically meaningful benefits in the efficacy endpoint results compared with those who received placebo with carboplatin and pemetrexed. As a consequence, sections 4.1, 4.8, 5.1, 5.2 of of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted."

Action: For adoption

5.1.9. Imfinzi - Durvalumab - EMA/VR/0000282058

AstraZeneca AB;

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

Scope: "Extension of indication for IMFINZI to include in combination with FLOT chemotherapy as neoadjuvant and adjuvant treatment, followed by adjuvant IMFINZI monotherapy, for the treatment of adults with resectable gastric or gastro-oesophageal junction adenocarcinoma , based on interim results from study MATTERHORN, (D910GC00001); this is a randomized, double-blind, placebo-controlled, phase 3 study of neoadjuvant-adjuvant durvalumab and FLOT chemotherapy followed by adjuvant durvalumab in patients with resectable gastric and gastroesophageal junction cancer (GC/GEJC); As a consequence, sections 4.1, 4.2, 4.5, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14.0 of the RMP has also been submitted."

Action: For adoption

5.1.10. LIBTAYO – Cemiplimab - EMA/VR/0000264999

Regeneron Ireland Designated Activity Company;

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

Scope: "Extension of indication to include treatment of adjuvant treatment of adult patients with Cutaneous Squamous Cell Carcinoma (CSCC) at high risk of recurrence after surgery and radiation for LIBTAYO, based on interim results from study R2810-ONC-1788; this is a phase 3, randomized, placebo-controlled, double-blind study of adjuvant cemiplimab versus placebo after surgery and radiation therapy in patients with high risk CSCC; As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the warnings for the excipients proline and polysorbate to reflect EU guidance (Section 4.4) and also updated Annex IID of the PI in line with the updates made to the RMP v4.2 to

consolidate the aRMMs."

Action: For adoption

5.1.11. MenQuadfi - Meningococcal Group A, C, W and Y conjugate vaccine - EMA/VR/0000281377

Sanofi Winthrop Industrie;

Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Jean-Michel Dogné

Scope: "Extension of indication for MENQUADFI to include the active immunisation of patients from 6 weeks of age based on final results from study MET58 and additional supportive clinical studies. Study MET58 is a Phase 3, immunogenicity and Safety Study of an Investigational Quadrivalent Meningococcal Conjugate Vaccine when Administered Concomitantly with Routine Paediatric Vaccines in Healthy Infants and Toddlers in Europe. As a consequence, sections 4.1, 4.2, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. An updated Risk Management Plan (RMP) version 4.0 is also included."

Action: For adoption

5.1.12. MINJUVI - Tafasitamab - EMA/VR/0000255975

Incyte Biosciences Distribution B.V.;

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

Scope: "Extension of indication to include in combination with lenalidomide and rituximab treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least one line of systemic therapy for MINJUVI, based on interim results from study INCMOR 0208-301 (inMIND); this is a phase 3, randomized, double-blind, placebo-controlled, multicentre study to evaluate the efficacy and safety of tafasitamab plus lenalidomide and rituximab vs lenalidomide and rituximab in patients with relapsed/refractory (R/R) follicular lymphoma grade 1 to 3a or R/R marginal zone lymphoma. As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection."

Action: For adoption

5.1.13. Mounjaro - Tirzepatide - EMA/VR/0000281937

Eli Lilly Nederland B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include treatment of adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise for MOUNJARO, based on final results from study I8F-MC-GPGV (SURPASS-PEDS); this is a study to evaluate efficacy, safety, and pharmacokinetics/pharmacodynamics of tirzepatide compared to placebo in paediatric and

adolescent participants with type 2 diabetes mellitus inadequately controlled with metformin, or basal insulin, or both. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has also been submitted."

Action: For adoption

5.1.14. Nucala - Mepolizumab - EMA/VR/0000257645

Glaxosmithkline Trading Services Limited;

Rapporteur: Finbarr Leacy, Co-Rapporteur: Petr Vrbata, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication for NUCALA to include treatment of Chronic Obstructive Pulmonary Disease (COPD) based on final results from study 208657 (MATINEE). This is a randomized, double-blind, parallel-group, placebo-controlled study of mepolizumab 100 mg SC as add-on treatment in participants with COPD experiencing frequent exacerbations and characterized by eosinophil levels. 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 14.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, 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

5.1.15. OPDIVO - Nivolumab - EMA/VR/0000282199

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Peter Mol, PRAC Rapporteur: Gabriele Maurer

Scope: "Extension of indication for OPDIVO to include treatment of patients paediatric and adults, with relapsed/refractory classical Hodgkin Lymphoma, based on results from study CA209744; a phase 2, open-label study of nivolumab + brentuximab vedotin for children, adolescents, and young adults with R/R CD30+ classical Hodgkin lymphoma after failure of first-line therapy, followed by brentuximab vedotin + bendamustine for participants with a suboptimal response. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 44.0 of the RMP has also been submitted"

Action: For adoption

5.1.16. Paxlovid - Nirmatrelvir / Ritonavir - EMEA/H/C/005973/II/0061/G

Pfizer Europe MA EEIG;

Rapporteur: Nicolas Beix (FR) (MNAT with DE-BfArM for Quality), Co-Rapporteur: Fátima Ventura, PRAC Rapporteur: Martin Huber

Scope: "A grouped application comprised of a Type II Variation and a Type IB Variation, as follows: Type II (C.I.6.a): Extension of indication to include treatment of coronavirus disease 2019 (COVID-19) in paediatric patients 6 years of age and older weighing at least 20 kg for PAXLOVID, based on the final analysis of Cohorts 1 and 2 from pivotal Study

C4671026; this is a Phase 2/3, Interventional Safety, Pharmacokinetics, and Efficacy, Open-Label, Multi-Centre, Single-Arm Study to Investigate Orally Administered PF 07321332 (Nirmatrelvir)/Ritonavir in Nonhospitalized Symptomatic Paediatric Participants With COVID-19 Who Are at Risk of Progression to Severe Disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Type IB (B.II.e.5.a.2): To add a new pack-size specific to paediatric patients 6 years and older weighing 20 kg to less than 40 kg and moderate renal impaired patients (EU/1/22/1625/003); the Package Leaflet and Labelling are updated accordingly."

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

Action: For adoption

Request for Supplementary Information adopted on 25.04.2025.

5.1.17. Retsevmo - Selpercatinib - EMA/VR/0000282012

Eli Lilly Nederland B.V.;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Bianca Mulder

Scope: "Extension of indication to include paediatric patients 2 years and older with: (1) Advanced RET fusion-positive thyroid cancer who are radioactive iodine-refractory, (2) Advanced RET-mutant medullary thyroid cancer, (3) Advanced RET fusion-positive solid tumours, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted, for RETSEVMO, based on final results from study J2G-OX-JZJJ (LOXO RET 18036, LIBRETTO-121); this is a multicentre, open-label Phase 1/2 study in paediatric patients with advanced solid or primary CNS tumours harbouring an activating RET alteration. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.6 of the SmPC are updated. The Package Leaflet and labelling are updated in accordance. Version 15.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the information related to Quality part of the dossier."

Action: For adoption

5.1.18. Scemblix - Asciminib - EMA/VR/0000265010

Novartis Europharm Limited;

Rapporteur: Janet Koenig, PRAC Rapporteur: Eva Jirsová

Scope: "A grouped application consisting of:

C.I.6.a: Extension of indication to include treatment of adult patients with newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in chronic phase (CP) for SCEMBLIX, based on primary and key secondary analysis results from study CABL001J12301 (ASC4FIRST, J12301); this is an ongoing Phase III, multi-centre, open-label, randomized study of oral asciminib (80 mg once daily, q.d.) versus Investigator selected tyrosine kinase inhibitor (TKI) in patients with newly diagnosed

Ph+ CML-CP, with the primary and key secondary objectives to compare the major molecular response (MMR) rates at Week 48 and Week 96, respectively. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. RMP version 4.0 has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.

C.I.4: Update of sections 4.2, 4.5, 5.1, 5.2 and 5.3 of the SmPC in order to introduction of a new posology regimen based on results from studies CABL001J12301 and CABL001A2302 (ASC4OPT, A2302). CABL001A2302 is an ongoing Phase IIIb, multi-centre, open-label, treatment optimization study of oral asciminib (80 mg daily, randomized to 40 mg b.i.d. or 80 mg q.d.) in patients with Ph+ CML-CP previously treated with two or more TKIs, with the primary objective to estimate the MMR rate at Week 48 of all the patients (40 mg b.i.d. and 80 mg q.d.) with no evidence of MMR at baseline. The Package Leaflet is updated accordingly. RMP version 4.0 has also been submitted."

Action: For adoption

5.1.19. Simponi - Golimumab - EMEA/H/C/000992/II/0121

Janssen Biologics B.V.;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Karin Bolin

Scope: "Extension of indication to include treatment of paediatric ulcerative colitis for SIMPONI, based on results from study CNTO148UCO3003; this is a Phase 3 Randomized, Open-label Study to Assess the Efficacy, Safety, and Pharmacokinetics of Golimumab Treatment, a Human anti-TNFα Monoclonal Antibody, Administered Subcutaneously in Paediatric Participants with Moderately to Severely Active Ulcerative Colitis; As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. Version 28.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is updated in accordance with the latest EMA excipients guideline and aligned with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 25.04.2025.

5.1.20. SOTYKTU - Deucravacitinib - EMA/VR/0000282554

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Alexandre Moreau, Co-Rapporteur: Margareta Bego, PRAC Rapporteur: Liana Martirosyan

Scope: "Extension of indication to include, for SOTYKTU, alone or in combination with conventional synthetic disease modifying antirheumatic drugs (DMARDs), the treatment of active psoriatic arthritis (PsA) in adults who have had an inadequate response or who have been intolerant to a prior DMARD therapy, based on results from the following phase 3 studies: Study IM011-054 (POETYK PsA-1); this is a phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of deucravacitinib in participants with active psoriatic arthritis who are naïve to biologic disease-modifying anti-rheumatic drugs, and Study IM011-055 (POETYK PsA-2); this is a multi-centre, randomized, double-blind, placebo-controlled phase 3 study to evaluate the efficacy and safety of BMS-

986165 in participants with active psoriatic arthritis (PsA) who are naïve to biologic disease modifying anti-rheumatic drugs or had previously received TNFα inhibitor treatment. 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 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, as well as introduce administrative changes to the PI."

Action: For adoption

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

5.2.1. Uplizna - Inebilizumab - EMA/VR/0000257358

Amgen Europe B.V.;

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

Scope: Update on the procedure; "A grouped application consisting of:

C.I.6 (Extension of indication): Extension of indication to include add-on to standard therapy for the treatment of adult patients with generalised myasthenia gravis (gMG) for Uplizna, based on primary analysis results from Study MINT (VIB0551.P3.S1); this is a pivotal phase 3 multicentre, randomised, double-blind, placebo-controlled, parallel-cohort study to evaluate the efficacy and safety of inebilizumab in adults subjects with myasthenia gravis. As a consequence, sections 4.1, 4.2, 4.4 ,4.5, 4.6, 4.8, 5.1, 5.2, and 7 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

A.6: Update of the ATC code of inebilizumab to L04AG10 in line with the 2024 ATC INDEX."

Action: For adoption

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

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/006768

qualitative determination of antibodies to adeno-associated virus serotype 74 (AAVrh74) in human serum and/or plasma

Scope: Withdrawal of the consultation procedure

Action: For information

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006882

detection of single nucleotide variants (SNVs), insertions and deletions (indels) in seventy-four (74) genes, copy number amplifications (CNAs) in eighteen (18) genes, fusion in six (6) genes, and microsatellite instability (MSI)-High status

Scope: Opinion

Action: For adoption

6.3.3. In vitro diagnostic medical device - EMEA/H/D/006840

detection of a novel panel of seven (7) monomorphic biomarkers for identification of microsatellite instability (MSI) in colorectal cancer tissue

Scope: Opinion

Action: For adoption

6.3.4. In vitro diagnostic medical device - EMEA/H/D/006809

targeted next-generation sequencing to detect variants in 517 genes using nucleic acids extracted from formalin-fixed, paraffin embedded (FFPE) tumour tissue samples from cancer patients with solid malignant neoplasms.

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. Anselamimab – H0006422

treatment of adult patients with kappa light chain (AL) amyloidosis

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

Chiesi Farmaceutici S.p.A.,

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan

Scope: "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC in order to introduce an alternative posology regimen based on results from study PB-102-F50 (BRIGHT) and interim results from its extension study CLI-06657AA1-03 (formerly presented as PB-102-F51), as well as results of the observational patient reporting outcome study CLI-06657AA1-05. CLI-06657AA1-03 is an Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Pegunigalsidase Alfa (PRX-102)2 mg/kg Administered by Intravenous Infusion Every 4 Weeks in Patients with Fabry Disease. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4."

Action: For adoption

Request for Supplementary Information adopted on 19.06.2025, 30.01.2025.

See 2.3

9.1.2. Kinzalkomb – Telmisartan/Hydrochlorothiazide – EMEA/H/C/000415

Bayer AG; treatment of essential hypertension

Rapporteur: Paolo Gasaprini, Co-Rapporteur: Janet Koenig

Scope: Withdrawal of marketing authorization

Action: For information

9.1.3. PritorPlus – Telmisartan/Hydrochlorothiazide – EMEA/H/C/000414

Bayer AG; treatment of essential hypertension

Rapporteur: Paolo Gasaprini, Co-Rapporteur: Janet Koenig

Scope: Withdrawal of marketing authorization

Action: For information

9.1.4. Ronapreve – casirivimab/imdevimab– EMEA/H/C/005814

Roche Registration GmbH; prevention and treatment of COVID-19

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Jayne Crowe

Scope: Withdrawal of marketing authorization

Action: For information

9.1.5. Xofluza - Baloxavir marboxil - EMA/VR/0000246160

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher

Scope: Update of sections 4.8, and 5.1 of the SmPC in order to update clinical efficacy and safety information based on final results from study MV40618 (Centerstone); this is a phase 3b, multicentre, randomized, double-blind, placebo-controlled, clinical efficacy study of baloxavir marboxil for the reduction of direct transmission of influenza from otherwise healthy patients to household contacts. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and introduce editorial changes in the PI.

Action: For adoption

10. Referral procedures

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

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

Pfizer Europe MA EEIG

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

Scope: List of outstanding issues/ opinion

Action: For adoption

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

List of outstanding issues adopted 18.09.2025, 22.05.2025, 12.12.2024. List of questions adopted on 29.07.2024

See 2.4

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

10.4.1. Melatomed - melatonin - EMA/REF/0000303296

Fairmed Healthcare GmbH

Referral Rapporteur: To be appointed, Referral Co-Rapporteur: To be appointed

Scope: Appointment of Rapporteurs, List of Questions, Timetable

Action: For adoption

Decentralised Procedure number: DE/H/8092/001/DC, notification sent by the Agency of Germany notifying of the start of a referral under Article 29(4) of Directive 2001/83/EC

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

No items

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

10.6.1. Sodium oxybate syrup and oral solution for alcohol dependence - EMA/REF/0000278933

Various

Referral Rapporteur: John Joseph Borg, Referral Co- Rapporteur: Nicolas Beix

Scope: List of outstanding issues/ opinion

Action: For adoption

Procedure triggered by France (ANSM) requesting CHMP to issue an opinion on the benefit-risk balance of sodium oxybate-containing syrup and oral solution for the treatment of alcohol dependence in authorised products and pending marketing authorisation application (s) due to concerns about efficacy and the risks of abuse and misuse.

10.6.2. Ipidacrine-containing medicinal products – various - EMA/REF/0000271842

AS Grindeks, MD-Pharm S.R.O., Olpha AS

Referral Rapporteur: Jayne Crowe, Referral Co- Rapporteur: Elita Poplavska

Scope: List of outstanding issues/ opinion

Action: For adoption

Procedure triggered by Ireland requesting CHMP a review of ipidacrine-containing medicinal products. This was prompted by concerns regarding the efficacy data supporting the authorized indications of ipidacrine-containing medicinal products, as well as potential issues related with the effects of ipidacrine on hepatic safety.

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

October 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 October 2025

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at October 2025 PDCO

Action: For information

Agenda of the PDCO meeting held on 14-17 October 2025

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Action: For adoption

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 23-24 September 2025.

Action: For adoption

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi

Report from the SAWP meeting held on 29 September - 09 October 2025. Table of conclusions

Action: For information

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

14.3.4. Election of Vaccines Working Party (VWP) Vice-Chair

Following the call for nominations the CHMP will elect the Vice-Chair from the candidate (s) who submitted nominations.

Action: For election

Nomination(s) received

14.3.5. Election of Central Nervous System Working Party (CNSWP) Vice-Chair

Following the call for nominations the CHMP will elect the Vice-Chair from the candidate(s) who submitted nominations.

Action: For election

Nomination(s) received

14.3.6. Nitrosamines Multidisciplinary Expert Group (NMEG)

Feedback and Minutes of the NMEG meeting held on 26 September 2025.

NMEG Chair: Priscilla Schoondermark

Action: For information

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

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)*

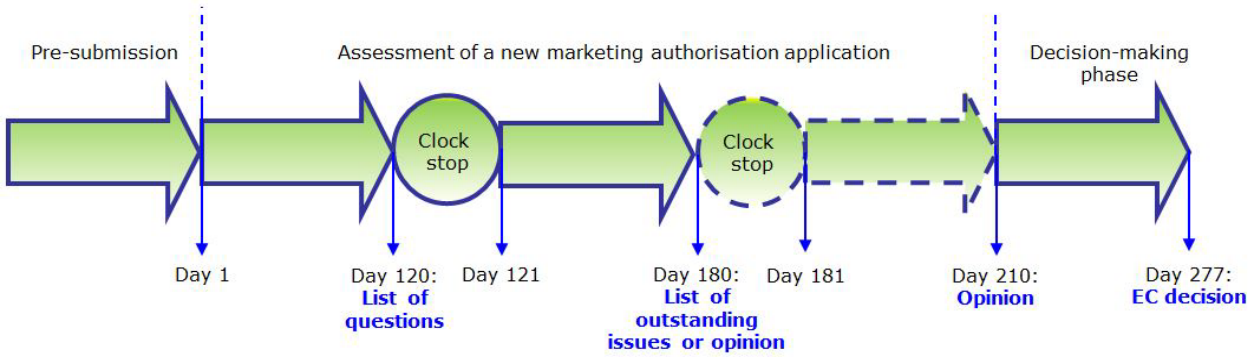
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

13 October 2025
EMA/CHMP/309201/2025

Annex to 13-16 October 2025 CHMP Agenda

Pre-submission and post-authorisations issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for October 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

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

B.2.3. Renewals of Conditional Marketing Authorisations

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 29 September – 02 October 2025 PRAC:

PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its October 2025 meeting:

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

Recarbrio - Imipenem / Cilastatin / Relebactam - EMEA/H/C/004808/II/0034 Merck Sharp & Dohme B.V., Rapporteur: Filip Josephson Opinion adopted on 25.09.2025. Request for Supplementary Information adopted on 22.05.2025, 23.01.2025, 19.09.2024.	Positive Opinion adopted by consensus on 25.09.2025.
WS2748 **Silodosin Recordati-EMEA/H/C/004964/WS2748/0015** **Silodyx-EMEA/H/C/001209/WS2748/0056** **Urorec-EMEA/H/C/001092/WS2748/0059** Recordati Ireland Ltd, Lead Rapporteur: Margareta Bego Request for Supplementary Information adopted on 19.12.2024, 14.11.2024.	

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

Cerezyme - Imiglucerase - EMEA/H/C/000157/II/0136 Sanofi B.V., Rapporteur: Patrick Vrijlandt, "Update of sections 4.4 and 4.8 of the SmPC in order to add 'Transient hypertension' to the list of adverse drug reactions (ADRs) with frequency not known as well as to reflect the warning on Infusion-associated reactions (IARs), based on a safety review. The Package Leaflet is updated accordingly." Request for Supplementary Information adopted on 19.06.2025, 13.02.2025.	
OZAWADE - Pitolisant - EMEA/H/C/005117/II/0012 Bioprojet Pharma, Rapporteur: Peter Mol, "Submission of the study note PH24048. This is an update of the final PopPK model (PH20043) submitted at initial Marketing Authorization	

Approval integrating the results of study 15-03 (HAROSA III). In addition, the results of re-estimated model parameters and covariates are provided." Request for Supplementary Information adopted on 05.06.2025, 13.02.2025.	

B.5.3. CHMP-PRAC assessed procedures

Elfabrio - Pegunigalsidase alfa - EMEA/H/C/005618/II/0007 Chiesi Farmaceutici S.p.A., Rapporteur: Alexandre Moreau, PRAC Rapporteur: Liana Martirosyan, "Update of sections 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC in order to introduce an alternative posology regimen based on results from study PB-102-F50 (BRIGHT) and interim results from its extension study CLI-06657AA1-03 (formerly presented as PB-102-F51), as well as results of the observational patient reporting outcome study CLI-06657AA1-05. CLI-06657AA1-03 is an Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Pegunigalsidase Alfa (PRX-102)2 mg/kg Administered by Intravenous Infusion Every 4 Weeks in Patients with Fabry Disease. The Package Leaflet is updated accordingly. The RMP version 1.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4." Request for Supplementary Information adopted on 19.06.2025, 30.01.2025.	See 9.1

B.5.4. PRAC assessed procedures

B.5.5. CHMP-CAT assessed procedures

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

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

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

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

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.