22 June 2026
EMA/CHMP/114951/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 22-25 June 2026
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

22 June 2026, 09:00 – 19:30, virtual meeting/room 2C

23 June 2026, 08:30 – 19:30, virtual meeting/room 2C

24 June 2026, 08:30 – 19:30, virtual meeting/room 2C

25 June 2026, 08:30 – 15:00, virtual meeting/room 2C

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 22-25 June 2026. See June 2026 CHMP minutes (to be published post July 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 22-25 June 2026

1.3. Adoption of the minutes

CHMP minutes for December 2025 and February 2026.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 15 June 2026.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Catequentinib - Orphan - EMEA/H/C/006317

CATS Consultants GmbH; treatment of synovial sarcoma or leiomyosarcoma

Scope: Oral explanation

Action: Oral explanation to be held on 24 June 2026 at 14:00

List of Outstanding Issues adopted on 23.04.2026. List of Questions adopted on 13.11.2025.

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 22 June 2026 at 16:00

List of Outstanding Issues adopted on 26.03.2026. List of Questions adopted on 16.10.2025.

2.1.3. Leriglitazone - Orphan - EMEA/H/C/006693

Minoryx Therapeutics S.L.; treatment of adrenoleukodystrophy

Scope: Oral explanation

Action: Oral explanation to be held on 24 June 2026 at 09:00

List of Outstanding Issues adopted on 23.04.2026. List of Questions adopted on 13.11.2025.

2.1.4. Narsoplimab - Orphan - EMEA/H/C/005247

Omeros Ireland Limited; Treatment of patients with haemopoietic stem cell transplant-associated thrombotic microangiopathy.

Scope: Oral explanation

Action: Oral explanation to be held on 22 June 2026 at 14:00

List of Outstanding Issues adopted on 23.04.2026. List of Questions adopted on 13.11.2025.

2.2. Re-examination procedure oral explanations

2.2.1. Daybu - 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: Oral explanation

Action: Oral explanation to be held on 23 June 2026 at 16:00

Opinion adopted on 26.02.2026. List of Outstanding Issues adopted on 16.10.2025. List of Questions adopted on 22.05.2025.

See 3.5.

2.3. Post-authorisation procedure oral explanations

2.3.1. DUPIXENT - Dupilumab - EMA/VR/0000248778

Sanofi Winthrop Industrie

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

Scope: Oral explanation

Action: Oral explanation to be held on 24 June 2026 at 11:00

See 5.1.

2.3.2. IMFINZI - Durvalumab - EMA/VR/0000289524

AstraZeneca AB

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: David Olsen

Scope: Oral explanation

Action: Oral explanation to be held on 23 June 2026 at 14:00

See 5.1

2.3.3. RINVOQ – Upadacitinib - EMA/VR/0000312506

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: Oral explanation

Action: Oral explanation to be held on 23 June 2026 at 09:00

See 5.1.

2.4. Referral procedure oral explanations

2.4.1. TAVNEOS - Avacopan - EMA/REF/0000325221

Vifor Fresenius Medical Care Renal Pharma France

Rapporteur: Kristina Dunder, Co-Rapporteur: Outi Mäki-Ikola

Scope: Oral explanation

Action: Oral explanation to be held on 23 June 2026 at 11:00

See 10.1.

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated - EMEA/H/C/006692

prophylaxis of influenza

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.04.2026. List of Questions adopted on 13.11.2025.

3.1.2. Denosumab - EMEA/H/C/006626

Prevention of skeletal related events and treatment of giant cell tumour of bone

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.04.2026. List of Questions adopted on 13.11.2025.

3.1.3. Levodopa / Carbidopa - EMEA/H/C/006629

treatment of adult patients with Parkinson’s disease

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.04.2026. List of Questions adopted on 13.11.2025.

3.1.4. Pegfilgrastim - EMEA/H/C/006085

reduction of neutropoenia in adults

Scope: Opinion

Action: For adoption

List of Questions adopted on 29.01.2026.

3.1.5. Insulin efsitora alfa - EMEA/H/C/006388

treatment of type 2 diabetes mellitus

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.04.2026. List of Questions adopted on 11.12.2025.

3.1.6. Autologous melanoma-derived tumour infiltrating lymphocytes, ex vivo-expanded - ATMP - EMEA/H/C/006563

treatment of melanoma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.03.2026. List of Questions adopted on 18.07.2025.

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.03.2026. List of Questions adopted on 16.10.2025.

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

3.2.1. Omalizumab - EMEA/H/C/006756

treatment of asthma, chronic rhinosinusitis with nasal polyps (CRSwNP) and chronic spontaneous urticaria (CSU)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 29.01.2026.

3.2.2. RABIES VIRUS (INACTIVATED) STRAIN WISTAR (PM/WI 38-1503-3M) - Article 28 – OPEN - EMEA/H/C/006602

pre-exposure and post-exposure prophylaxis against rabies in all age groups

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.02.2026.

3.2.3. Glepaglutide - EMEA/H/C/005855

treatment of adults with Short Bowel Syndrome

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 16.10.2025.

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

3.3.1. Hexaminolevulinate - EMEA/H/C/006878

treatment of adult patients with histologically confirmed cervical high-grade squamous intraepithelial lesions (HSIL)

Scope: List of questions

Action: For adoption

3.3.2. Ianalumab - EMEA/H/C/006748

treatment of Sjögren's disease in adults

Scope: List of questions

Action: For adoption

3.3.3. Deuruxolitinib - EMEA/H/C/006812

treatment of severe alopecia areata in adults

Scope: List of questions

Action: For adoption

3.3.4. Veligrotug - EMEA/H/C/006813

treatment of moderate to severe thyroid eye disease in adults

Scope: List of questions

Action: For adoption

3.3.5. Omalizumab - EMEA/H/C/006687

treatment of asthma in adults and children from 6 years of age, and treatment of chronic rhinosinusitis with nasal polyps in adults

Scope: List of questions

Action: For adoption

3.3.6. Ponatinib - EMEA/H/C/006894

treatment of chronic myeloid leukaemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) in adults

Scope: List of questions

Action: For adoption

3.3.7. Regadenoson - EMEA/H/C/006848

pharmacological stress agent for myocardial perfusion imaging (MPI) and measurement of fractional flow reserve (FFR) in adults

Scope: List of questions

Action: For adoption

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

3.4.1. Sonrotoclax - EMEA/H/C/006770

treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)

Scope: Request by the applicant for an extension to the clock stop to respond to the list of questions adopted in May 2026.

Action: For information

List of Questions adopted on 21.05.2026

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

3.5.1. Daybu - 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: Opinion

Third-party interventions

Action: For adoption

Opinion adopted on 26.02.2026. List of Outstanding Issues adopted on 16.10.2025. List of Questions adopted on 22.05.2025.

See 2.2.

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. ORLADEYO - Berotralstat - EMA/X/0000268892

Biocryst Ireland Limited;

Rapporteur: Finbarr Leacy, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Julia Pallos

Scope: Extension application to introduce a new pharmaceutical form associated with new strengths (78 mg, 96 mg,108 and 132 film - coated granules). The new presentations are indicated to include treatment for paediatric patients aged 2 to less than 12 years. The extension application is grouped with a type II clinical variation (C.I.4). As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 2.1 of the RMP has also been submitted.

Action: For adoption

4.1.2. REZOLSTA - Darunavir / Cobicistat - EMA/X/0000268372

Janssen Cilag International;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (600 mg darunavir/90 mg cobicistat dispersible tablet). The new presentation is indicated to include treatment for paediatric patients aged ≥ 3 years and older weighing at least 15 kg and less than 25 kg. The extension application is grouped with a type II clinical variation (C.I.4) to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 in order to add efficacy and PK data in children based on final results from study GS-US-215-0128; this is a Phase 2/3, Multicentre, Open-label, Multicohort Study Evaluating Pharmacokinetics (PK), Safety, and Efficacy of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 Infected, Virologically Suppressed Paediatric Participants. The Package Leaflet and Labelling are updated in accordance. Version 7.2 of the RMP has also been submitted.

Action: For adoption

4.1.3. SIVEXTRO - Tedizolid phosphate - EMA/X/0000282136

Merck Sharp & Dohme B.V.;

Rapporteur: Fátima Ventura, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension application to introduce a new pharmaceutical form (powder for oral suspension, 200 mg). The RMP (version 8.1) is updated in accordance. Additionally, the marketing authorisation holder took the opportunity to align the PI with the latest QRD template.

Action: For adoption

4.1.4. SYMTUZA - Darunavir / Cobicistat / Emtricitabine / Tenofovir alafenamide - EMA/X/0000248421

Janssen Cilag International;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension application to add a new strength of 675 mg/150 mg/ 20mg/ 10 mg film-coated tablets grouped with an Extension of indication (C.I.6) to include treatment of human

immunodeficiency virus type 1 (HIV 1) infection in paediatric patients (aged 6 years and older with body weight at least 25 kg) for SYMTUZA, based on the 24-week 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 Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1, 6.3, 6.4, 6.5 and 8 of the SmPC are updated. The Annex II, Labelling and Package Leaflet are updated accordingly. Version 9.1 of the RMP has also been submitted. Furthermore, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet.

Action: For adoption

4.1.5. VYNDAQEL - Tafamidis - EMA/X/0000287968

Pfizer Europe MA EEIG;

Rapporteur: Nicolas Beix, PRAC Rapporteur: Zoubida Amimour

Scope: Extension application to introduce a new pharmaceutical form (61 mg film-coated tablet). The RMP (version 10.1) is updated in accordance.

Action: For adoption

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. NEXVIADYME - Avalglucosidase alfa - EMA/X/0000258013

Sanofi B.V.;

Rapporteur: Christian Gartner

Scope: Quality variation

Action: For adoption

4.2.2. VYEPTI - Eptinezumab - EMA/X/0000296350

H. Lundbeck A/S;

Rapporteur: Jan Mueller-Berghaus

Scope: Quality variation

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. OCREVUS - Ocrelizumab - EMA/X/0000327452

Roche Registration GmbH;

Rapporteur: Thalia Marie Estrup Blicher

Scope: Quality variation

Action: For adoption

4.3.2. TUZULBY - Methylphenidate hydrochloride - EMA/X/0000327555

Neuraxpharm Pharmaceuticals S.L.;

Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Dennis Lex

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (5 mg/ml powder for prolonged-release oral suspension). 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

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. ALHEMO - Concizumab - EMA/VR/0000335954

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Extension of indication to include routine prophylaxis of bleeding in paediatric patients below 12 years of age with haemophilia A or B with or without inhibitors for ALHEMO, based on the results from the phase 3 study NN7415-4616; this is an open-label study investigating efficacy, safety and pharmacokinetics of concizumab prophylaxis in children below 12 years with haemophilia A or B with or without inhibitors. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor edits to the PI.

Action: For adoption

5.1.2. BETMIGA - Mirabegron - EMA/VR/0000327362

Astellas Pharma Europe B.V.;

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Maria del Pilar Rayon

Scope: A grouped application comprised of a Type IB and a Type II variation, as follows:

Type IB (C.7.a): To delete the Betmiga 8 mg/ml granules for prolonged-release oral suspension from the Betmiga marketing authorisation (EU/1/12/809/019, EU/1/12/809/020)

Type II (C.6.a): To modify the approved therapeutic indication for neurogenic detrusor overactivity (NDO) to patients less than 18 years of age, weighing 35 kg or more. The updated indication aligns the weight criteria for children with the remaining tablet posology. Consequently, sections 4.1, 4.2 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. The RMP version 9.3 has been submitted. In addition, the MAH took the opportunity to introduce additional changes to the PI.

Action: For adoption

5.1.3. BEXSERO - Meningococcal group b vaccine (rdna, component, adsorbed) - EMA/VR/0000334463

Glaxosmithkline Vaccines S.r.l.;

Rapporteur: Filip Josephson

Scope: Extension of indication to include active immunisation of infants from 6 weeks of age against invasive meningococcal disease caused by Neisseria meningitidis group B, based on final results from study 205239 (MENB REC 2ND GEN-023 (V72_57)); this is a phase 3b, observer-blind, randomised, placebo-controlled, multi-centre study to assess the safety and immunogenicity of Bexsero and 13-valent pneumococcal vaccine when administered concomitantly with routine vaccines to healthy infants. 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. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI.

Action: For adoption

5.1.4. DATROWAY - Datopotamab deruxtecan - EMA/VR/0000316654

Daiichi Sankyo Europe GmbH;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include, as monotherapy, the first-line treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy for DATROWAY, based on final results from study D926PC00001 (TROPION-Breast02). This is a Phase 3, randomised, open-label, 2 arm, multicentre, international study assessing the efficacy and safety of Dato-DXd compared with investigator's choice chemotherapy in participants with locally recurrent inoperable or metastatic TNBC who are not candidates for PD-1/PD-L1 inhibitor therapy. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. 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.

Action: For adoption

5.1.5. DUPIXENT - Dupilumab - EMA/VR/0000248778

Sanofi Winthrop Industrie;

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

Scope: Extension of indication to include treatment of adults with bullous pemphigoid (BP) for DUPIXENT, based on final results from study R668-BP-1902 (LIBERTY-BP ADEPT); this is a phase 2/3, multicentre, randomized, double blind, placebo-controlled, parallel group study to assess the efficacy and safety of dupilumab in adult patients with bullous pemphigoid; 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 12.0 of the RMP has also been submitted.

Action: For adoption

See 2.3

5.1.6. IBRANCE - Palbociclib - EMA/VR/0000316536

Pfizer Europe MA EEIG;

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

Scope: Extension of indication to include, in combination with anti-HER2 and endocrine therapies, the maintenance treatment of adult patients with HR-positive, HER2-positive locally advanced or metastatic breast cancer (MBC) following induction treatment for IBRANCE, based on the interim results from the open-label Phase 3 study PATINA (AFT-38/WI215662). This is a randomized, open-label Phase 3 study evaluating the efficacy and safety of IBRANCE (palbociclib) in combination with anti-HER2 therapy and endocrine therapy compared to anti-HER2 therapy and endocrine therapy alone as a first-line maintenance therapy (following induction chemotherapy treatment) for patients with HR positive, HER2-positive MBC. 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. RMP version 1.10 has also been submitted.

Action: For adoption

5.1.7. IMFINZI - Durvalumab - EMA/VR/0000289524

AstraZeneca AB;

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: David Olsen

Scope: Extension of indication for IMFINZI in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adults with BCG-naive, high-risk non-muscle-invasive bladder cancer (NMIBC), based on results from the POTOMAC study. POTOMAC is a phase 3, randomized multi-centre, open-label, global study to determine the efficacy and safety of durvalumab + BCG (induction + maintenance) combination therapy vs BCG (induction + maintenance) alone, and durvalumab + BCG (induction only) combination therapy vs BCG (induction + maintenance) alone for the treatment of patients with high-risk NMIBC. 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 with the SmPC. In addition, the Applicant took the opportunity to implement editorial changes to SmPC sections 4.2 and 5.1. Version 15 (Succession 1) of the RMP has also been submitted.

Action: For adoption

See 2.3

5.1.8. IMVANEX - Smallpox and monkeypox vaccine (live modified vaccinia virus Ankara) - EMA/VR/0000337204

Bavarian Nordic A/S;

Rapporteur: Jan Mueller-Berghaus

Scope: Extension of indication to include the active immunisation against smallpox, monkeypox and disease caused by vaccinia virus in individuals 2 years of age and older for IMVANEX, based on interim results from study POX-MVA-045; this is an open-label, multicentre immunogenicity and safety trial of the modified vaccinia Ankara-Bavaria Nordic (MVA-BN) vaccine in children from 2 years to less than 12 years of age compared to adults for the prevention of smallpox, mpox, and related orthopoxvirus infections. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.1.9. JAYPIRCA - Pirtobrutinib - EMA/VR/0000316267

Eli Lilly Nederland B.V.;

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

Scope: Extension of indication to include treatment of adult patients with chronic lymphocytic leukaemia (CLL) for JAYPIRCA, based on interim results from studies LOXO-BTK-20023 (BRUIN-CLL-313) and LOXO-BTK-20030 (BRUIN-CLL-314). Study 20023 is a phase 3 open-label, randomized study of pirtobrutinib (LOXO-305) versus bendamustine plus rituximab in untreated patients with CLL/SLL. Study 20030 is a phase 3 open-label, randomized study of pirtobrutinib (LOXO-305) versus ibrutinib in patients with CLL/SLL. As a consequence, sections 4.1, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted.

Action: For adoption

5.1.10. KEYTRUDA - Pembrolizumab - EMA/VR/0000336194

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include KEYTRUDA, in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment, is indicated for the treatment of adults with muscle invasive bladder cancer (MIBC) who are eligible for cisplatin containing chemotherapy, based on the results from Interim Analysis 1 of the pivotal Study KN-B15 (EV-304); this is a phase 3, randomized, open-label study to evaluate perioperative enfortumab vedotin plus pembrolizumab (MK-3475) versus neoadjuvant gemcitabine and cisplatin in cisplatin-eligible participants with Muscle-Invasive Bladder Cancer. As consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC have been updated; the Package Leaflet is updated accordingly. Version 54.1 of the RMP is submitted, to reflect the updated data.

Action: For adoption

5.1.11. LEQVIO - Inclisiran - EMA/VR/0000293324

Novartis Europharm Limited;

Rapporteur: Janet Koenig, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Kimmo Jaakkola

Scope: Grouping of two Type II C.I.6 variations to support the extension of the LEQVIO indication to paediatric patients aged 12 to less than 18 years with heterozygous and homozygous familial hypercholesterolaemia, as follows:

C.I.6: Extension of indication to include the treatment of paediatric patients aged 12 to less than 18 years with heterozygous familial hypercholesterolaemia (HeFH) for LEQVIO based on the final results from study CKJX839C12301 (ORION-16). ORION-16 is two parts (double-blind inclisiran versus placebo [Year 1] followed by open-label inclisiran [Year 2]) randomized multicentre study to evaluate safety, tolerability, and efficacy of inclisiran in paediatric patients (12 to less than 18 years) with heterozygous familial hypercholesterolemia and elevated LDL-cholesterol.

C.I.6: Extension of indication to include the treatment of paediatric patients aged 12 to less than 18 years with homozygous familial hypercholesterolaemia (HoFH) for LEQVIO based on the final results from study CKJX839C12302 (ORION-13). ORION-13 is two parts (double-blind inclisiran versus placebo [Year 1] followed by open-label inclisiran [Year 2]) randomized

multicentre study to evaluate safety, tolerability, and efficacy of inclisiran in paediatric patients (12 to less than 18 years) with homozygous familial hypercholesterolemia and elevated LDL-cholesterol.

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 4.0 of the RMP has also been submitted.

Action: For adoption

5.1.12. 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

5.1.13. MOUNJARO - Tirzepatide - EMA/VR/0000310637

Eli Lilly Nederland B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, or stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease for MOUNJARO, based on final results from study I8F-MC-GPGN (SURPASS-CVOT). SURPASS-CVOT was a Phase 3, event-driven, multicentre, international, randomized, double-blind, active-comparator, parallel-group study to assess the effect of tirzepatide versus dulaglutide on major adverse cardiovascular events in participants with type 2 diabetes. 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. Version 8.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI.

Action: For adoption

5.1.14. MYLOTARG - Gemtuzumab ozogamicin - EMA/VR/0000304835

Pfizer Europe MA EEIG;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include, in combination with mitoxantrone and cytarabine (AraC), the treatment of paediatric patients aged 1 year to less than 18 years with newly diagnosed CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL) for MYLOTARG, based on results from study MyeChild 01 (WI203680). This is a Phase 3, randomised, open-label, multicentre study incorporating an embedded dose finding study in children with newly diagnosed AML/high risk MDS /isolated myeloid sarcoma (de novo or secondary). As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.3 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.

Action: For adoption

5.1.15. OCREVUS - Ocrelizumab - EMA/VR/0000309389

Roche Registration GmbH;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include treatment of paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (RRMS) for OCREVUS, based on primary analysis results from the pivotal phase III study (WN42086/Operetta 2) and primary and updated results from a supportive phase II study (WA39085/Operetta 1). Operetta 1 is an open-label, parallel-group, dose-finding Phase II study to determine the dosing regimen of ocrelizumab to be further investigated in Operetta 2, and Operetta 2 is a Phase III, randomized, double-blind, double-dummy, parallel-group, multicentre, non-inferiority study to evaluate the efficacy and safety of intravenous ocrelizumab in comparison with fingolimod. As a consequence, sections 2, 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 15.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce updates to other sections of the SmPC and PL as per previous procedures linguistic review comments (sodium, pH and osmolality), updates to comply with the Excipient Guideline (polysorbates), changes to the list of local representatives in the Package Leaflet, as well as editorial and clarification changes to the PI.

Action: For adoption

5.1.16. OPZELURA - Ruxolitinib - EMA/VR/0000313318

Incyte Biosciences Distribution B.V.;

Rapporteur: Peter Mol, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include treatment of moderate atopic dermatitis in adult patients who are inadequately controlled with, have a contraindication to, or are intolerant to topical corticosteroids and topical calcineurin inhibitors for OPZELURA, based on the results of the pivotal Phase III study INCB 18424-326 and the two supportive Phase III studies INCB 18424-303 and INCB 18424-304. INCB 18424-326 is a Phase 3b, double-blind, multicentre, randomized, vehicle-controlled, efficacy, and safety study of ruxolitinib cream in adults with moderate atopic dermatitis. 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 1.0 of the RMP has also been submitted.

Action: For adoption

5.1.17. PADCEV - Enfortumab vedotin - EMA/VR/0000336191

Astellas Pharma Europe B.V.;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include Padcev, in combination with pembrolizumab, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment, is indicated for the treatment of adults with muscle invasive bladder cancer (MIBC) who are eligible for cisplatin-containing chemotherapy, based on the results from Interim Analysis 1 of the pivotal Study KN-B15 (EV-304); this is a phase 3, randomized, open-label study to evaluate perioperative enfortumab vedotin plus pembrolizumab (MK-3475) versus neoadjuvant gemcitabine and cisplatin in cisplatin-eligible participants with Muscle-Invasive Bladder Cancer. As consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC have been updated; the Package Leaflet is updated accordingly. Version 6.1 of the RMP is submitted, to reflect the updated data. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.18. RINVOQ – Upadacitinib - EMA/VR/0000312506

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include the treatment of severe alopecia areata (AA) in adult and adolescents 12 years and older for RINVOQ, based on interim results from 2 pivotal, Phase 3 studies (M23-716 Study 1 and Study 2); those are randomized, double blind, placebo-controlled, multi-centre studies of Upadacitinib evaluating the efficacy and safety of Upadacitinib 15 mg QD and 30 mg QD versus placebo for the treatment of severe AA in subjects who are at least 12 years of age. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Annex II are updated in accordance. Version 18.0 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

PRAC advice to CHMP

Action: For adoption

See 2.3.

5.1.19. RINVOQ - Upadacitinib - EMA/VR/0000325958

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include the treatment of non-segmental vitiligo in adults and adolescents 12 years and older who are candidates for systemic therapy, for RINVOQ, based on results from the two replicate Phase 3 studies M19-044: study 1 (R&D/25/1342) and study 2 (R&D/25/1343), as well as from integrated long-term safety data. Study 1 and study 2 are Phase 3, global, randomized, double-blind, placebo-controlled multi-centre studies that evaluate the safety and efficacy of upadacitinib in adult and adolescent patients with non-segmental vitiligo. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet has been updated in accordance. Version 19.0 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. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.20. STEGLATRO - Ertugliflozin - EMA/VR/0000335920

Merck Sharp & Dohme B.V.;

Rapporteur: Kristina Dunder, Co-Rapporteur: Beata Maria Jakline Ullrich, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of new paediatric population aged 10 years and older for STEGLATRO, based on final results from paediatric study MK-8835-P059/B1521066 (P059). This is a randomised, double-blind, placebo-controlled trial to evaluate the safety and efficacy of two doses of ertugliflozin in paediatric patients from 10 years to less than 18 years of age with type 2 diabetes mellitus and inadequate glycaemic control on metformin therapy, ± insulin. 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 2.5 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to implement minor editorial/formatting corrections.

Action: For adoption

5.1.21. STELARA - Ustekinumab - EMA/VR/0000316205

Janssen Cilag International;

Rapporteur: Ruth Kieran, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of ulcerative colitis in paediatric patients from the age of 2 years and older for STELARA, based on results from study CNTO1275PUC3001; this is a Phase 3 Study of the Efficacy, Safety and Pharmacokinetics of Ustekinumab as Open-label Intravenous Induction Treatment Followed by Randomized Double-blind Subcutaneous Ustekinumab Maintenance in Paediatric Participants (2 to <18 Years of Age) with Moderately to Severely Active Ulcerative Colitis. 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 32.2 of the RMP has also been submitted.

Action: For adoption

5.1.22. TECVAYLI - Teclistamab - EMA/VR/0000322279

Janssen Cilag International;

Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Veronika Macurova

Scope: Extension of indication to include in combination with daratumumab treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy for TECVAYLI, based on interim analysis data from the pivotal study MajesTEC-3 (64007957MMY3001). This is an on-going multicentre, randomised, open-label, Phase 3 study to determine whether adding teclistamab to daratumumab (Tec-Dara) is more efficacious than adding pomalidomide/dexamethasone (DPd) or bortezomib/dexamethasone (DVd) to daratumumab in participants with multiple myeloma who previously received 1 to 3 prior line(s) of therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.7, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated accordingly. References to the conditional MA have been removed throughout the document. Additionally, the MAH took the opportunity to update the latest renewal date in section 9 of the SmPC, the list of local representatives in the Package Leaflet and made editorial changes throughout. And updated RMP version 6.1 has been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.23. TECVAYLI - Teclistamab - EMA/VR/0000336274

Janssen Cilag International;

Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Veronika Macurova

Scope: Extension of indication to include treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy, for TECVAYLI as monotherapy, based on interim analysis data from the pivotal study 64007957MMY3006 (MajesTEC-9). This is a Phase 3 randomized study comparing teclistamab monotherapy versus pomalidomide, bortezomib, dexamethasone (PVd) or carfilzomib, dexamethasone (Kd) in participants with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy, including an anti-CD38 monoclonal antibody and lenalidomide. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Labelling and Package Leaflet are updated accordingly. The RMP version 6.2 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.24. TRYNGOLZA - Olezarsen - EMA/VR/0000336189

Swedish Orphan Biovitrum AB (publ);

Rapporteur: Larisa Gorobets, PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of adult patients with severe hypertriglyceridemia for Tryngolza, based on final results from phase 3 studies ISIS 678354-CS5 (CORE), ISIS 678354-CS6 (CORE2) and ISIS 678354-CS9; and open-label extension study ISIS 678354-CS15. 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 1.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.25. TUKYSA – Tucatinib - EMA/VR/0000337235

Pfizer Europe MA EEIG;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Jean-Michel Dogné

Scope: Extension of indication to include in combination with trastuzumab and pertuzumab for the maintenance treatment of adult patients with unresectable locally advanced or metastatic HER2-positive breast cancer based on final results from Study H2C05. This is a Phase 3, global, randomised, double-blind, placebo-controlled study of tucatinib vs placebo in combination with trastuzumab and pertuzumab as maintenance therapy in participants with advanced HER2+ breast cancer who had last received trastuzumab, pertuzumab, and a taxane with no evidence of progression. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

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

No items

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

5.3.1. SOGROYA - Somapacitan - EMA/VR/0000264734

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Dennis Lex

Scope: Appointment of re-examination rapporteur, adoption of timetable

Action: For adoption

Opinion adopted on 21.05.2026.

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/007011

qualitative detection and classification of single nucleotide variants (SNVs), insertions and deletions (InDels), and homozygous deletions (HDs) in protein coding regions and intron/exon boundaries of 20 homologous recombination repair (HRR) genes from formalin-fixed paraffin embedded (FFPE) tumour tissue specimens in prostate cancer patients.

Scope: Opinion

Action: For adoption

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006885

detection of single nucleotides variants (SNVs), insertion and deletions (indels) in seventy-four (74) genes, copy number amplifications (CNAs) in eighteen (18) genes, fusions 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/006987

assessment of phosphatase and tensin homolog (PTEN) protein in formalin-fixed paraffin-embedded (FFPE) prostatic adenocarcinoma tissue specimens by light microscopy

Scope: Opinion

Action: For adoption

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.2. Priority Medicines (PRIME)

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. BIMERVAX - COVID-19 vaccine (recombinant, adjuvanted) - EMA/VR/0000316063

Hipra Human Health S.L.

Rapporteur: Beata Maria Jakline Ullrich

Scope: Update of section 4.5 of the SmPC in order to add coadministration information with seasonal influenza vaccines based on final results from study HIPRA-HH-11. HIPRA-HH-11 was a Phase II randomized, double-blind, multi-centre trial to evaluate the safety and immunogenicity of BIMERVAX when coadministered with seasonal surface antigen, inactivated adjuvanted influenza vaccine (SIIV) in adults older than 65 years of age fully vaccinated against COVID-19. The Package Leaflet is updated accordingly. The RMP version 3.0 is also submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI.

Action: For adoption

9.1.2. DECTOVA - Zanamivir - EMA/VR/0000341315

Glaxosmithkline Trading Services Limited

Rapporteur: Ingrid Wang

Scope: Submission of the final study report for the post-authorisation efficacy study (PAES) 208165, listed as a specific obligation in the Annex II. This is a retrospective observational chart review study to evaluate the clinical effectiveness of treatment with zanamivir 10 mg/ml solution for infusion in a cohort of intensive care unit treated (ICU) patients with complicated influenza infection.

Action: For adoption

9.1.3. FLUENZ - Influenza vaccine (live, nasal) - EMA/VR/0000302352

AstraZeneca AB

Rapporteur: Christophe Focke, PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.2 and 4.4 of the SmPC in order to introduce self-administration instructions based on postmarketing data and literature. The Package Leaflet and Labelling updated accordingly. The RMP version 13.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

9.1.4. IXCHIQ - Chikungunya vaccine (live) - EMA/PSUR/0000327923

Valneva Austria GmbH

Rapporteur: Christophe Focke, PRAC Rapporteur: Dirk Mentzer

Scope: PSUSA recommendation

Action: For adoption

9.1.5. OCREVUS - Ocrelizumab - EMA/VR/0000313041

Roche Registration GmbH

Rapporteur: Thalia Marie Estrup Blicher

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning on 'Liver Injury' and to add it to the list of adverse drug reactions (ADRs) with frequency 'rare', based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to submit a DHPC Letter and to introduce minor changes to the PI, including the Labelling section.

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. TAVNEOS - Avacopan - EMA/REF/0000325221

Vifor Fresenius Medical Care Renal Pharma France

Rapporteur: Kristina Dunder, Co-Rapporteur: Outi Mäki-Ikola

Scope: List of outstanding issues / Opinion

Third-party interventions

Action: For adoption

Article 20 procedure triggered by the European Commission asking for a review of Tavneos. This follows emerging information that raises concerns regarding the data integrity of the ADVOCATE study, the pivotal trial supporting the marketing authorisation of Tavneos

10.2. See 2.4.Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004

No items

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

No items

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

No items

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

No items

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

10.6.1. 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.

List of outstanding issues adopted on 26.02.2026, 16.10.2026

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

AS Grindeks, Olpha AS

Referral Rapporteur: Ruth Kieran, 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.

List of outstanding issues adopted on 26.03.2026, 16.10.2026

10.6.3. Rifadin oral suspension and syrup and associated names – Rifampicin - EMA/REF/0000355053

Various

Scope: Appointment of rapporteurs, list of questions and timetable

Action: For adoption

The Dutch national competent authority has triggered a referral procedure under Article 31 of Direction 2001/83/EC for Rifadin oral suspension and syrup and associated names. In the interest of the Union, the matter is referred to CHMP to assess the impact of the possibly carcinogenic risk posed by the excipient diethanolamine (DEA) on the benefit-risk balance of Rifadin oral suspension and syrup on its authorised indications and all possible options to replace DEA.

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

June 2026 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 June 2026

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at June 2026 PDCO

Action: For information

Agenda of the PDCO meeting held on 23-26 June 2026

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 16-17 June 2026.

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

14.8.1. Update of the Business Pipeline report for the human scientific committees

Q2-2026 Update of the Business Pipeline report for the human scientific committees

Action: For information

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)*

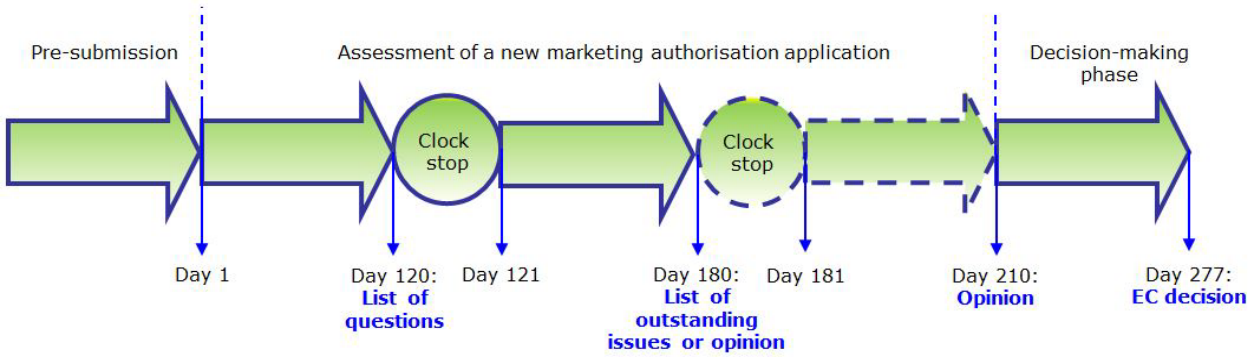
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

22 June 2026
EMA/CHMP/120621/2026

Annex to 22-25 June 2026 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 June 2026: **For adoption**

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

Final Outcome of Rapporteurship allocation for June 2026: **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 08-11 June 2026

Signal of angioedema

NUBEQA (CAP) – Darolutamide

Rapporteur: Alexandre Moreau, Co-Rapporteur: Carolina Prieto Fernandez, PRAC
Rapporteur: Jan Neuhauser
PRAC recommendation on a variation
Action: For adoption

Signal of protein-losing gastroenteropathy

VYLOY (CAP) – Zolbetuximab

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Carolina Prieto Fernandez, PRAC
Rapporteur: Bianca Mulder
PRAC recommendation on a variation
Action: For adoption

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

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

B.5.3. CHMP-PRAC assessed procedures

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

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. Timetables – 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.