



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2026
EMA/CHMP/211366/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 12-15 October 2026

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

12 October 2026, 09:30 – 19:30, virtual meeting

13 October 2026, 09:00 – 19:30, virtual meeting

14 October 2026, 09:00 – 19:30, virtual meeting

15 October 2026, 09:00 – 15:00, virtual 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 12-15 October 2026. See October 2026 CHMP minutes (to be published post November 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 12-15 October 2026

1.3. Adoption of the minutes

CHMP minutes for 14-17 September 2026.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 05-October-2026

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Navepegritide - Orphan - EMEA/H/C/006627

Ascendis Pharma Growth Disorders A/S; treatment of achondroplasia in children

Scope: Oral explanation

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

Third-party intervention

List of Outstanding Issues adopted on 23.07.2026. List of Questions adopted on 26.02.2026.

2.2. Re-examination procedure oral explanations

2.2.1. Yartemlea - 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 14 October 2026 at 16:00

Opinion adopted on 25.06.2026.

See 3.5

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Orforglipron - EMEA/H/C/006632

treatment of obesity and type 2 diabetes mellitus in adults

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.09.2026. List of Questions adopted on 21.05.2026.

3.1.2. Ranibizumab - EMEA/H/C/006940

treatment of neovascular (wet) age-related macular degeneration (AMD), and other visual impairments in adults

Scope: Opinion

Action: For adoption

3.1.3. Filgrastim - EMEA/H/C/007009

treatment of neutropenia in adults and children

Scope: Opinion

Action: For adoption

List of Questions adopted on 17.09.2026.

3.1.4. Daraxonrasib – Orphan - EMEA/H/C/007122

Revolution Medicines Netherlands B.V.; treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy

Scope: Opinion

Action: For adoption

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

3.2.1. Emapalumab - Orphan - EMEA/H/C/006790

Swedish Orphan Biovitrum AB (publ); Treatment of acute or recurrent secondary haemophagocytic lymphohistiocytosis (sHLH) in adult and paediatric patients (6 months and older)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.05.2026.

3.2.2. Cefepime / Zidebactam - EMEA/H/C/006799

treatment of a number of infections in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.05.2026.

3.2.3. Temozolomide - Orphan - EMEA/H/C/006892

Orphelia Pharma; treatment of adults with glioblastoma multiforme and children with malignant glioma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.05.2026.

3.2.4. Influenza mRNA vaccine - EMEA/H/C/006204

immunisation for the prevention of influenza disease in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.05.2026.

3.2.5. Tanruprubarb - Orphan - EMEA/H/C/006782

Sinclair Regulatory Consulting Europe Limited; treatment of Guillain-Barré syndrome in adults and children

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.05.2026.

3.2.6. [Garetosmab - Orphan - EMEA/H/C/005750](#)

Regeneron Ireland Designated Activity Company; treatment of adult patients with fibrodysplasia ossificans progressiva (FOP)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.05.2026.

3.2.7. [Sonrotoclax - EMEA/H/C/006770](#)

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.05.2026.

3.2.8. [Etripamil - EMEA/H/C/006292](#)

indicated for the rapid conversion of paroxysmal supraventricular tachycardia (PSVT) episodes to sinus rhythm in adults.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.03.2026.

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

3.3.1. [Abatacept - EMEA/H/C/006741](#)

treatment of rheumatoid, psoriatic arthritis and polyarticular juvenile idiopathic arthritis in patients 6 years of age and older

Scope: List of questions

Action: For adoption

3.3.2. [Cemdisiran - EMEA/H/C/006877](#)

treatment of generalised myasthenia gravis in adult patients

Scope: List of questions

Action: For adoption

3.3.3. Pertuzumab - EMEA/H/C/006893

treatment of breast cancer in adults

Scope: List of questions

Action: For adoption

3.3.4. Mezigdomide - EMEA/H/C/006705

treatment of relapsed or refractory multiple myeloma in adults

Scope: List of questions

Action: For adoption

3.3.5. Rezvilutamide - EMEA/H/C/006852

treatment of high-volume metastatic hormone-sensitive prostate cancer (mHSPC) in adults

Scope: List of questions

Action: For adoption

3.3.6. Semaglutide - EMEA/H/C/006902

treatment of type 2 diabetes in adults

Scope: List of questions

Action: For adoption

3.3.7. Tozorakimab - EMEA/H/C/006606

treatment for chronic obstructive pulmonary disease (COPD) in adult patients

Scope: List of questions

Action: For adoption

3.3.8. Abatacept - EMA/MAA/0000371984

treatment of rheumatoid, psoriatic arthritis and polyarticular juvenile idiopathic arthritis in patients 6 years of age and older

Scope: List of questions

Action: For adoption

3.3.9. Semaglutide - EMEA/H/C/006910

weight management including weight loss and weight maintenance in adults

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. MEPLYFFA - Arimoclomol - Orphan - EMEA/H/C/006736

Zevra Denmark A/S; treatment of Niemann-Pick disease type C (NPC) in patients aged 6 months and older in combination with miglustat

Scope: List of questions to the AHEG

Action: For adoption

Opinion adopted on 23.07.2026. List of Outstanding Issues adopted on 21.05.2026. List of Questions adopted on 11.12.2025.

3.5.2. Qezzaqar - Catequentinib - Orphan - EMEA/H/C/006317

CATS Consultants GmbH; treatment of synovial sarcoma or leiomyosarcoma

Scope: List of questions to the SAG

Action: For adoption

Opinion adopted on 23.07.2026. List of Outstanding Issues adopted on 23.04.2026. List of Questions adopted on 13.11.2025.

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

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

Scope: Opinion

Action: For adoption

Opinion adopted on 25.06.2026.

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. IMRALDI - Adalimumab - EMA/X/0000321285

Samsung Bioepis NL B.V.;

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Karin Bolin

Scope: Extension application to add a new strength of 80 mg solution for injection in a single dose 0.8 ml pre-filled pen. This is a grouped line extension application including four quality variations

Version 9.0 of the RMP has also been submitted. Additionally, product information has been updated to ensure consistency with the updated terminology in the RMP and to include the polysorbate excipient statement in accordance with the Annex of the Excipients Guideline, ensuring alignment with current regulatory standards.

Action: For adoption

4.1.2. OCREVUS - Ocrelizumab - EMA/X/0000327452

Roche Registration GmbH;

Rapporteur: Thalia Marie Estrup Blicher

Scope: Extension application to replace a biological substance or product of biotechnology

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. ZERCEPAC - Trastuzumab - EMA/X/0000321364

Accord Healthcare S.L.U.;

Rapporteur: Sol Ruiz, PRAC Rapporteur: Dirk Mentzer

Scope: Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (600 mg) and a new route of administration (subcutaneous use).

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. TRIMBOW - Beclometasone / Formoterol / Glycopyrronium bromide - EMA/X/0000350398

Chiesi Farmaceutici S.p.A.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Jan Neuhauser

Scope: Extension application to change the strength of Trimbrow, pressurised inhalation, solution, from 87 µg / 5 µg / 9 µg to 85 µg / 5 µg / 9 µg In addition, a new presentation has been included (Trimbrow, pressurised inhalation, solution, 169 µg / 5 µg / 9 µg,

Action: For adoption

4.3.2. UPTRAVI - Selexipag - EMA/X/0000355108

Janssen Cilag International;

Rapporteur: Janet Koenig, PRAC Rapporteur: Zoubida Amimour

Scope: Extension application to introduce a new strength, 150 µg film-coated tablet, grouped with a type II variation (C.I.6.a) to add a new indication for selexipag (long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged 2 years to less than 18 years with WHO FC II to III). The RMP (version 12.2) 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. 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

5.1.2. COSENTYX - Secukinumab - EMA/VR/0000340032

Novartis Europharm Limited;

Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Extension of indication to include treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents 12 years and older with an inadequate response to conventional systemic HS therapy for COSENTYX, based on modelling and extrapolation of existing data. As a consequence, sections 4.1, 4.2, 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 introduce minor editorial changes to the PI, including to the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.3. ENFLONSIA - Clesrovimab - EMA/VR/0000358149

Merck Sharp & Dohme B.V.;

Rapporteur: Daniela Philadelphia, PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season for ENFLONSIA, based on final results from study MK-1654-007; this is a Phase 3, multicentre, randomized, partially blinded, palivizumab-controlled study to evaluate the safety, efficacy, and pharmacokinetics of MK-1654 in infants and children at increased risk for severe RSV disease. As a consequence, sections 2, 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 1.1 of the RMP has also been submitted.

Action: For adoption

5.1.4. [FETCROJA - Cefiderocol - EMA/VR/0000347573](#)

Shionogi B.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include treatment of infections due to aerobic Gram-negative organisms in paediatric (birth to less than 18 years old) patients with limited treatment options, for FETCROJA, based on supportive clinical and non-clinical data. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.1.5. [GAZYVARO - Obinutuzumab - EMA/VR/0000327013](#)

Roche Registration GmbH;

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Alexandre Moreau, PRAC
Rapporteur: Jenny-Maria Jönsson

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

C.6.a: Extension of indication to include treatment of adult patients with active systemic lupus erythematosus (SLE) who are receiving standard therapy, for GAZYVARO, based on the results from study CA42750 (ALLEGORY); this is a Phase III, randomized, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of obinutuzumab in patients with SLE 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. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the SmPC with minor edits. Version 12 of the RMP has also been submitted.

C.4: Update of section 4.2 of the SmPC to introduce short duration infusion (SDI) as method of administration for SLE patients, supported by previously submitted data in patients with Follicular Lymphoma and by simulations conducted using an integrated population PK model to estimate exposures following administration as an SDI to SLE patients.

Action: For adoption

5.1.6. IMFINZI - Durvalumab - EMA/VR/0000358434

AstraZeneca AB;

Rapporteur: Mette Linnert Jensen, PRAC Rapporteur: David Olsen

Scope: Extension of the indication for IMFINZI in combination with enfortumab vedotin as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, for the treatment of adults with Muscle Invasive Bladder Cancer (MIBC) who are ineligible for or have refused cisplatin-based chemotherapy, based on the pivotal study D910PC00001 (VOLGA); this is a Phase III randomized, open-label, multicentre study to determine the efficacy and safety of durvalumab in combination with tremelimumab and enfortumab vedotin or durvalumab in combination with enfortumab vedotin for perioperative treatment in patients ineligible for cisplatin or who refuse cisplatin undergoing radical cystectomy for muscle-invasive bladder cancer. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 18 of the RMP has been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI.

Action: For adoption

5.1.7. KYINSU - Insulin icodec / Semaglutide - EMA/VR/0000322527

Novo Nordisk A/S;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise for KYINSU, based on results from the Phase 3b study NN1535-4988 (COMBINE 4); this is a 40-week study comparing the efficacy and safety of once weekly IcoSema and daily insulin glargine 100 units/mL in participants with type 2 diabetes inadequately controlled on oral anti-diabetic drugs. 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 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.1.8. MYLOTARG - Gemtuzumab ozogamicin - ORPHAN - EMA/VR/0000304835

Pfizer Europe MA EEIG;

Rapporteur: Mette Linnert Jensen, 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

5.1.9. [PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA - Pandemic influenza vaccine \(H5N1\) \(live attenuated, nasal\) - EMA/VR/0000321324](#)

AstraZeneca AB;

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Ingrid Wang, PRAC Rapporteur: Sonja Radowan

Scope: Extension of indication to remove the upper age limit from the indication for Pandemic influenza vaccine (H5N1) (live, nasal), based on efficacy and safety data previously submitted in the Marketing Authorisation Application (MAA). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, and 5.3 of the SmPC are updated. The Annex II and the Package Leaflet are updated in accordance. Version 2.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes throughout the PI and update the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.10. [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 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, $\pm$ 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

5.1.11. [TALVEY - Talquetamab - ORPHAN - EMA/VR/0000339914](#)

Janssen Cilag International;

Rapporteur: Alexandre Moreau, PRAC Rapporteur: Barbara Kovacic Bytyqi

Scope: Extension of indication for TALVEY in combination with daratumumab and pomalidomide, or in combination with daratumumab, to include treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior therapy based on interim analysis from Phase 3 study MonumenTAL-3 (64407564MMY3002) and data

from the supportive Phase 1b study TriMM-2 (64407564MMY1002). 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 accordingly. The updated RMP version 4.1 has also been submitted. Consequently, the MAH proposes a switch from conditional marketing authorisation to full marketing authorisation. In addition, the MAH took the opportunity to update Annex II and to update the list of local representatives in the Package Leaflet. Furthermore, as part of the application the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.12. [TECENTRIQ - Atezolizumab - EMA/VR/0000358940](#)

Roche Registration GmbH;

Rapporteur: Mette Linnert Jensen, PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include (1) Tecentriq IV, in combination with oxaliplatin and fluoropyrimidine-based chemotherapy, for the adjuvant treatment of adult and paediatric patients 2 years of age and older with Stage III, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colon cancer; (2) Tecentriq SC, in combination with oxaliplatin and fluoropyrimidine-based chemotherapy, for the adjuvant treatment of adult patients with Stage III, MSI-H or dMMR colon cancer based on interim results from study ML39057 (ATOMIC); this is an interventional randomized phase III study to evaluate the efficacy and safety of atezolizumab administered in combination with mFOLFOX6 compared with mFOLFOX6 in patients with stage III colon cancer and deficient DNA mismatch repair. 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 34.0 of the RMP has also been submitted.

Action: For adoption

5.1.13. [TRYNGOLZA - Olezarsen - ORPHAN - 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

5.1.14. [TUKYSA – Tucatinib - EMA/VR/0000337235](#)

Pfizer Europe MA EEIG;

Rapporteur: Mette Linnert Jensen, 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, randomized, 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

5.1.15. ZERBAXA - Ceftolozane / Tazobactam - EMA/VR/0000320716

Merck Sharp & Dohme B.V.;

Rapporteur: Ingrid Wang, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Adam Przybylkowski

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

C.I.6: Extension of indication to include treatment of hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP), in paediatric patients from birth to less than 18 years of age for ZERBAXA, based on the final results from study MK-7625A-036. This is a Phase 1, open-label, non-comparative, multicentre clinical study to evaluate the safety, tolerability, and pharmacokinetics of ceftolozane/tazobactam in paediatric participants with nosocomial pneumonia. 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 accordingly.

C.I.4: Update of sections 4.2 and 5.2 of the SmPC in order to include dosing recommendations for paediatric patients with impaired renal function, for the indications of complicated Intra-Abdominal Infections (cIAI), Acute pyelonephritis (AP) and complicated Urinary Tract Infections (cUTI), based on an M&S analysis integrating adult and paediatric data sources as described in M&S report "Population pharmacokinetic and probability of target attainment analyses of MK-7625A (ZERBAXA) in paediatric patients in support of nosocomial pneumonia".

Version 4.1 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, section 5.1 "Susceptibility testing breakpoints" in the SmPC has been brought in line with the Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections.

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**

No items

6. **Medical devices**

6.1. **Ancillary medicinal substances - initial consultation**

No items

6.2. **Ancillary medicinal substances – post-consultation update**

No items

6.3. **Companion diagnostics - initial consultation**

6.3.1. **In vitro diagnostic medical device - EMEA/H/D/007054**

qualitative next generation sequencing (NGS)-based in vitro diagnostic (IVD) test that uses semi-automated targeted high throughput hybridization-based capture technology to detect genomic alterations including short variants, rearrangements, and copy number alterations in 324 genes across 16 cellular pathways and genomic signatures associated with cancer.

Scope: Opinion

Action: For adoption

6.3.2. **In vitro diagnostic medical device - EMEA/H/D/007086**

An in vitro diagnostic immunohistochemical assay intended for the semi-quantitative determination of HER2 protein overexpression in formalin-fixed, paraffin-embedded tissue specimens from patients with breast cancer and adenocarcinoma of the stomach, including gastroesophageal junction.

Scope: Opinion

Action: For adoption

6.3.3. **In vitro diagnostic medical device - EMEA/H/D/007084**

An in vitro diagnostic next-generation sequencing (NGS) test to detect somatic alterations in human DNA and RNA isolated from tumour specimens in formalin-fixed, paraffin paraffin-embedded (FFPE) tissue samples, and from cell-free total nucleic acid (cfTNA) in plasma samples.

Scope: Opinion

Action: For adoption

6.3.4. In vitro diagnostic medical device - EMEA/H/D/007085

to detect and identify activating FGFR alterations in RNA extracted from FFPE samples derived from patients with urothelial cancer (UC)

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

No items

8.2. Priority Medicines (PRIME)

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

8.3. Eligibility

Report on Eligibility to Centralised Procedure for October 2026

Action: For adoption

8.4. Rapporteurship

Final Outcome of Rapporteurship allocation for October 2026

Action: For adoption

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Comtess – Entacapone – EMEA/H/C/000170

Orion Corporation; Treatment of Parkinson's disease and end-of-dose motor fluctuations

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Martine Trauffler

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.2. Entacapone Orion – Entacapone – EMEA/H/C/002440

Orion Corporation; Treatment of adult patients with Parkinson's disease and end-of-dose motor fluctuations

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Martine Trauffler

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.3. Giapreza - Angiotensin II - EMA/VR/0000343583

Paion Pharma GmbH;

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

Scope: Submission of the study protocol (CRH06) in order to modify the completion date of the Post-Authorization Efficacy Study (CRH06 / ARTISTRY) listed as an obligation in the Annex II. This is a Phase 4, randomized, double-blind, placebo-controlled, parallel group, multi-centre post-authorization efficacy clinical trial of angiotensin II in adult patients with refractory vasodilatory shock and severe acute kidney injury. The Annex II and RMP version 2.1 are updated accordingly.

Action: For adoption

9.1.4. Klisyri – Tirbanibulin - EMA/VR/0000335382

Almirall S.A.

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Jana Pecherova

Scope: A grouped application consisting of quality variations and:

C.4 (Type II): Update of sections 2, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.5 and 8 of the SmPC to expand treatment field up to 100 cm² based on results from clinical study M 14867-33 (TirbAKare) and PK study M-14867-01. Study M 14867-33 is a phase 3, multicentre, randomised, double-blind, vehicle controlled, parallel-group study to evaluate the efficacy

and safety of tirbanibulin 10 mg/g ointment applied to a treatment field larger than 25 cm² and up to 100 cm² in adult participants with actinic keratosis. Study M-14867-01 is a phase 1, open-label, non-randomized, uncontrolled, maximal usage trial (must) to evaluate the systemic exposure and safety of one treatment cycle of tirbanibulin ointment 1% when applied to 100 cm² of the face or balding scalp in patients with actinic keratosis lesions. The Package Leaflet is updated accordingly.

Action: For adoption

9.1.5. Loargys – Pegzilarginase - EMA/VR/0000319620

Immedica Pharma AB

Rapporteur: Peter Mol

Scope: Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update information regarding children below 2 years of age based on final results from study CAEB1102-301A listed as Study 6 in the Loargys PIP (EMA-001925-PIP02-19-M0). Study 301A is a phase 3 open-label study of safety, pharmacokinetics, and activity of weekly subcutaneous pegzilarginase in subjects <24 months old with arginase 1 deficiency. In addition, the MAH took the opportunity to introduce editorial changes to the PI.

Action: For adoption

9.1.6. Mounjaro – Tirzepatide - EMA/VR/0000340438

Eli Lilly Nederland B.V.

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: C.3.c. Update of sections 4.5, and 4.6 of the SmPC pertaining to the interaction of obesity and overweight and of the gastric emptying delay due to tirzepatide on oral contraceptive exposure following PRAC request in PSUSA/00011019/202505; the Package Leaflet is updated accordingly.

CHMP Request for PRAC advice agreed via written procedure on 22.09.2026

Action: For adoption

9.1.7. Trizivir – Lamivudine/Abacavir/Zidovudine – EMEA/H/C/000338

ViiV Healthcare B.V.; treatment of HIV

Rapporteur: Alexandre Moreau, Co-Rapporteur: Christophe Focke

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.8. Xyrem - Sodium oxybate – EMEA/H/C/000593

UCB Pharma S.A.; treatment of narcolepsy with cataplexy

Rapporteur: Paulo Paixão, Co-Rapporteur: Thalia Marie Estrup Blicher

Scope: Withdrawal of marketing authorisation

Action: For information

10. Referral procedures

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

No items

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

No items

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

No items

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

No items

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

No items

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

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

Various MAHs

Referral Rapporteur: Tomas Radimersky; Referral Co-Rapporteur: Maria Grazia Evandri

Scope: List of Outstanding Issues/Opinion

Action: For adoption

The Dutch national competent authority has triggered a referral procedure under Article 31 of Directive 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

October 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. Nominated proxy

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 2026

Action: For adoption

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 28 September – 01 October 2026

Signal of neutropenia, febrile neutropenia

MEKTOVI, BRAFTOVI (CAP) - Binimetinib, Encorafenib

Rapporteur: Martin Mengel, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Carla Torre, Rugile Pilviniene

PRAC recommendation on a variation

Action: For adoption

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 22-23 September 2026.

Action: For adoption

14.3.3. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi, Vice-Chairs: Pierre Demolis and Ewa Balkowiec Iskra

Report from the SAWP meeting held on 28 September – 01 October 2026. Table of conclusions

Action: For information

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

14.3.4. Non-Clinical Working Party (NcWP) Chair election

Following the call for nominations launched in July 2026, CHMP to elect the chair from the candidate(s) who submitted nominations.

Nomination(s) received

Action: For election

14.3.5. Biologics Working Party (BWP) Chair election

Following the call for nominations launched in June 2026, CHMP to elect the chair from the candidate(s) who submitted nominations.

Nomination(s) received

Action: For election

14.3.6. Mandate, objectives and rules of procedure for Scientific Advisory Groups (SAGs) and Ad-Hoc Expert Groups (AHEGs)

Revision of the mandate, objectives and rules of procedure for SAGs/AHEGs

Action: For adoption

14.3.7. QWP response to CMDh questions

QWP response letter to CMDh questions

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

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

15.1.2. Real-world evidence (including DARWIN EU) for regulatory decision making

Regular touchpoint to explore emerging research questions at the time of pre-submission meetings and provide updates on the development of DARWIN EU, upcoming trainings and workshops and report on study requests received as well as planned/completed RWD studies. CHMP members will have an opportunity to raise RWD study proposals.

Action: For discussion

Annex

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)

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

Annex F - Decision of the Granting of a Fee Reduction/Fee Waiver

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 *(section 5.3)*

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 Pharmacovigilance Risk Assessment Committee (PRAC).

Invented name issues (section 14.3)

This section lists 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/