20 July 2026
EMA/CHMP/145907/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 20-23 July 2026
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

20 July 2026, 09:30 – 19:30, virtual meeting/room 2C

21 July 2026, 08:30 – 19:30, virtual meeting/room 2C

22 July 2026, 08:30 – 19:30, virtual meeting/room 2C

23 July 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 20-23 July 2026. See July 2026 CHMP minutes (to be published post August 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 20-23 July 2026

1.3. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 13 July 2026.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Icotrokinra hydrochloride - EMEA/H/C/006730

treatment of plaque psoriasis in adults and adolescents 12 years or older

Scope: Oral explanation

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

List of Outstanding Issues adopted on 21.05.2026. List of Questions adopted on 29.01.2026.

2.1.2. Sufentanil / Ketamine - PUMA - EMEA/H/C/006395

treatment of acute pain in children aged 1 to less than 18 years.

Scope: Oral explanation

Action: Oral explanation to be held on 22 July 2026 at 11:00

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

2.1.3. 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: Oral explanation

Action: Oral explanation to be held on 21 July 2026 at 09:00

Third-party intervention

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

2.1.4. Trilaciclib - EMEA/H/C/006709

prevention of chemotherapy-induced myelosuppression when administered prior to platinum/etoposide- or topotecan-containing regimens for extensive-stage small cell lung cancer (ES-SCLC)

Scope: Oral explanation

Action: Oral explanation to be held on 21 July 2026 at 16:00

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

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Litfulo – Ritlecitinib - EMA/PSUR/0000336091

Pfizer Europe MA EEIG

Rapporteur: Peter Mol, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Adam Przybylkowski

Scope: Oral explanation

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

See 9.1

2.3.2. RILTRAVA AEROSPHERE - Formoterol / Glycopyrronium bromide / Budesonide - EMA/X/0000287672

AstraZeneca AB

Rapporteur: Ruth Kieran, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser

Scope: Oral explanation

Action: Oral explanation to be held on 21 July 2026 at 14:00

See 4.1

2.3.3. TRIXEO AEROSPHERE - Formoterol / Glycopyrronium bromide / Budesonide - EMA/X/0000287664

AstraZeneca AB

Rapporteur: Ruth Kieran, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser

Scope: Oral explanation

Action: Oral explanation to be held on 21 July 2026 at 14:00

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Pegfilgrastim - EMEA/H/C/006937

reduction of neutropenia in adults

Scope: Opinion

Action: For adoption

3.1.2. Obicetrapib / Ezetimibe - EMEA/H/C/006517

treatment of primary hypercholesterolaemia or mixed dyslipidaemia

Scope: Opinion

Action: For adoption

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

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

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

Scope: Opinion

Action: For adoption

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

3.1.4. Lerodalcibep - EMEA/H/C/006694

is indicated in adults with primary hypercholesterolaemia (heterozygous familial (HeFH) and non-familial) or mixed dyslipidaemia as an adjunct to diet.

Scope: Opinion

Action: For adoption

A revised timetable was adopted via written procedure on 02.06.2026.

List of Outstanding Issues adopted on 23.04.2026, 26.02.2026. List of Questions adopted on 18.09.2025.

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

Minoryx Therapeutics S.L.; treatment of adrenoleukodystrophy

Scope: Opinion

Action: For adoption

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

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

CATS Consultants GmbH; treatment of synovial sarcoma or leiomyosarcoma

Scope: Opinion

Action: For adoption

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

3.1.7. Riociguat - EMEA/H/C/006838

treatment of Chronic thromboembolic pulmonary hypertension (CTEPH) in adults and treatment of Pulmonary arterial hypertension (PAH) in adults and children from 6 years of age

Scope: Opinion

Action: For adoption

List of Questions adopted on 26.02.2026.

3.1.8. Ruxolitinib hemifumarate - EMEA/H/C/006618

treatment of myelofibrosis (MF), polycythaemia vera (PV) and Graft versus host disease (GvHD)

Scope: Opinion

Action: For adoption

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

11.12.2025.

3.1.9. Ranibizumab - EMEA/H/C/006527

treatment of adults with neovascular (wet) age-related macular degeneration (AMD)

Scope: Opinion

Action: For adoption

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

3.1.10. Tafamidis - EMEA/H/C/006711

treatment of hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).

Scope: Opinion

Action: For adoption

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

3.1.11. Obicetrapib - EMEA/H/C/006516

treatment of primary hypercholesterolaemia or mixed dyslipidaemia

Scope: Opinion

Action: For adoption

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

3.1.12. Ensitrelvir - EMEA/H/C/006063

post exposure prophylaxis of COVID-19

Scope: Opinion

Action: For adoption

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

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

3.2.1. Denecimig - EMEA/H/C/006344

prophylaxis of bleeding episodes in patients with haemophilia A

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.02.2026.

3.2.2. Tofacitinib - EMEA/H/C/006698

treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis in adults, and juvenile idiopathic arthritis (JIA) in children from 2 years old

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.04.2026.

3.2.3. Gefurulimab - EMEA/H/C/006558

Treatment of adult patients with generalised myasthemia gravis (gMG)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.04.2026.

3.2.4. Relacorilant - Orphan - EMEA/H/C/006731

Corcept Therapeutics Netherlands B.V.; treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.02.2026.

3.2.5. Pertuzumab - EMEA/H/C/006844

treatment of breast cancer in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.04.2026.

3.2.6. Povorcitinib - EMEA/H/C/006727

treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.02.2026.

3.2.7. Ruxolitinib - EMEA/H/C/006791

treatment of myelofibrosis (MF) in adults, treatment of polycythaemia vera (PV) in adults and treatment of Graft versus host disease (GvHD) in adults and children

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.02.2026.

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

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

Scope: List of outstanding issues

Third party interventions

Action: For adoption

List of Questions adopted on 26.02.2026.

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

3.3.1. Aceclidine - EMEA/H/C/006857

treatment of presbyopia in adults

Scope: List of questions

Action: For adoption

3.3.2. Zamtocabtagene autoleucel - PRIME - Orphan - ATMP - OPEN - EMEA/H/C/005495

Miltenyi Biomedicine GmbH; treatment of adults with large B-cell lymphoma

Scope: List of questions

Action: For information

3.3.3. Enlicitide - EMEA/H/C/006815

indicated in adults with primary hypercholesterolaemia or mixed dyslipidaemia

Scope: List of questions

Action: For adoption

3.3.4. Bepirovirsen - EMEA/H/C/006715

treatment of chronic hepatitis B virus (HBV) infection in adults

Scope: List of questions

Action: For adoption

3.3.5. Molgramostim - Orphan - EMEA/H/C/006495

Savara ApS; treatment of pulmonary alveolar proteinosis in adults

Scope: List of questions

Action: For adoption

3.3.6. Taletrectinib - EMEA/H/C/006896

treatment of adults with ROS1 positive advanced non-small cell lung cancer

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

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

Scope: Appointment of re-examination rapporteurs and adoption of the timetable at the PROM meeting on 13 July 2026

Third-party intervention

Action: For information

Opinion adopted on 25.06.2026. List of Outstanding Issues adopted on 26.03.2026. List of Questions adopted on 16.10.2025

3.5.2. Yartemlea - Narsoplimab - Orphan - EMEA/H/C/005247

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

Scope: Re-examination request, Appointment of re-examination rapporteurs, timetable

Action: For adoption

Opinion adopted on 25.06.2026. List of Outstanding Issues adopted on 23.04.2026. List of Questions adopted on 13.11.2025.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Azacitidine - EMEA/H/C/006695

Treatment of myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) and acute myeloid leukaemia (AML)

Scope: Withdrawal of marketing authorisation application

Action: For information

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

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

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

4.1.1. RILTRAVA AEROSPHERE - Formoterol / Glycopyrronium bromide / Budesonide - EMA/X/0000287672

AstraZeneca AB;

Rapporteur: Ruth Kieran, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser

Scope: Extension application to introduce a new strength (5 µg / 14.4 µg / 160 µg Pressurised inhalation, suspension) associated with a new indication for the "maintenance treatment of asthma in patients 12 years of age and older who are not adequately controlled by a combination of a medium or high dose inhaled corticosteroid and a long-acting beta2-agonist". The RMP (version 3.1) is updated in accordance.

Action: For adoption

See 2.3.

4.1.2. SIALANAR - Glycopyrronium - EMA/X/0000287532

Proveca Pharma Limited;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Zane Neikena

Scope: Extension application to introduce a new pharmaceutical form associated with two new strengths (0.68 mg and 1.36 mg orodispersible tablets).

Action: For adoption

4.1.3. TRIXEO AEROSPHERE - Formoterol / Glycopyrronium bromide / Budesonide - EMA/X/0000287664

AstraZeneca AB;

Rapporteur: Ruth Kieran, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Jan Neuhauser

Scope: Extension application to introduce a new strength (5 µg / 14.4 µg / 160 µg Pressurised inhalation, suspension) associated with a new indication for the "maintenance treatment of asthma in patients 12 years of age and older who are not adequately controlled by a combination of a medium or high dose inhaled corticosteroid and a long-acting beta2-agonist". The RMP (version 3.1) is updated in accordance.

Action: For adoption

See 2.3.

4.1.4. VYEPTI - Eptinezumab - EMA/X/0000296350

H. Lundbeck A/S;

Rapporteur: Jan Mueller-Berghaus

Scope: Quality variation

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. RINVOQ - Upadacitinib - EMA/X/0000304823

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength and change of pharmacokinetics (1 mg/ml oral solution) grouped with an extension of indication (C.I.6.a) to include the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older based on clinical data and results from clinical phase 1 study (study M15-340). As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 5.3 of the SmPC have been updated. The Package Leaflet has been updated accordingly. Version 17 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II.

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. DOVATO - Dolutegravir / Lamivudine - EMA/X/0000335457

ViiV Healthcare B.V.;

Rapporteur: Filip Josephson, Co-Rapporteur: Carla Torre, PRAC Rapporteur: David Olsen

Scope: Extension application to introduce a new pharmaceutical form (dispersible tablet) associated with a new strength (5 mg/30 mg) grouped with an extension of indication type II variation (C.6.a) to include treatment of children weighing at least 20 kg for Dovato based on results from Study 207742 and Study 205861. Study 207742 is a randomised non-inferiority trial with nested PK to assess DTG/3TC fixed dose formulations for the maintenance of virological suppression in children with HIV infection aged 2 to <15 years old: Intensive PK Substudy; and study 205861 is a Phase 3b, open label, single arm study in Antiretroviral Therapy (ART)-naïve adolescents. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to update the PI in accordance with the latest EMA excipients guideline.

Action: For adoption

4.3.2. VENCLYXTO - Venetoclax - EMA/X/0000335555

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Filip Josephson

Scope: Extension application to add a new strength of 200 mg film-coated tablet grouped with a grouping of Type II, IB and IA quality variations

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. 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

5.1.2. ENHERTU - Trastuzumab deruxtecan - EMA/VR/0000322236

Daiichi Sankyo Europe GmbH;

Rapporteur: Mette Linnert Jensen, PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include the indication first-line treatment of adult patients with unresectable or metastatic HER2-positive breast cancer for Enhertu (trastuzumab deruxtecan) in combination with pertuzumab is based on results from the phase 3 DESTINY-Breast09 study. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 of SmPC are updated and the Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted.

Action: For adoption

5.1.3. ENTYVIO - Vedolizumab - EMA/VR/0000340504

Takeda Pharma A/S;

Rapporteur: Paolo Gasparini, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Adam Przybylkowski

Scope: A grouped application consisting of quality variations and:

Two Type II - C.6.a: Extension of indication to include treatment of ulcerative colitis (UC) and of Crohn's disease (CD) in the paediatric population from 2 to less than 18 years for Entyvio 300 mg powder for concentrate for solution for infusion (intravenous, IV), based on final

results from studies MLN0002-2005, vedolizumab-2005 and MLN002-3024 and interim results from studies MLN0002-3025 and MLN0002-3029. These are phase 2 and phase 3 interventional studies to assess the pharmacokinetics, efficacy and safety of vedolizumab intravenous in paediatric UC and CD. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.3 and 6.6 of the IV SmPC and Sections 4.2 and 5.1 of the subcutaneous (SC) product SmPC are updated. The IV Package Leaflet (PL) is updated in accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the PI, and to update the list of local representatives in the PL. Version 10.0 of the RMP has also been submitted

Action: For adoption

5.1.4. JIVI - Damoctocog alfa pegol - EMA/VR/0000326847

Bayer AG;

Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Bianca Mulder

Scope: Grouped application comprised of two Type II variations, as follows:

C.6.a: Extension of indication to include treatment and prophylaxis of bleeding in previously untreated patients ≥7 years of age with haemophilia A for JIVI, following the guideline for clinical investigation of recombinant and human plasma-derived factor VIII products (EMA/CHMP/BPWP/144552/2009 rev 2). As a consequence, sections 4.1, 4.2, 4.4 and 4.8 of the SmPC are updated. The Package Leaflet is updated accordingly.

C.4: Update of section 4.2 of the SmPC in order to update posology recommendations for patients 7 to <12 years of age, based on integrated analysis results from Part B of the Alfa-PROTECT study (21824) and PROTECT Kids extension study (15912). Alfa-PROTECT is a Phase 3, single-group treatment, open-label study to evaluate the safety of BAY 94-9027 infusions for prophylaxis and treatment of bleeding in previously treated children aged 7 to <12 years with severe haemophilia A. The PROTECT Kids study was a Phase 3, open-label, uncontrolled, multicentre study in previously treated children <12 years of age with severe haemophilia A (>50 prior EDs).

Version 4.1 of the RMP has also been submitted.

Action: For adoption

5.1.5. KEYTRUDA - Pembrolizumab - EMA/VR/0000340550

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include, in combination with chemotherapy with or without radiation, the adjuvant treatment of mismatch repair deficient (dMMR) endometrial cancer in adults who are at high risk of recurrence, for KEYTRUDA, based on results from the study KEYNOTE-B21; this is a phase 3, randomized, double-blind study of pembrolizumab versus placebo in combination with adjuvant chemotherapy with or without radiotherapy for the treatment of newly diagnosed high risk endometrial cancer after surgery with curative intent (KEYNOTE-B21 / ENGOT-en11 / GOG 3053). As a consequence, sections 4.1, 4.2 and 5.1 of

the SmPC are updated. The Package Leaflet is updated in accordance. Version 55.1 of the RMP has also been submitted.

Action: For adoption

5.1.6. 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

5.1.7. MINJUVI - Tafasitamab - EMA/VR/0000339938

Incyte Biosciences Distribution B.V.;

Rapporteur: Mette Linnert Jensen, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication for MINJUVI, in combination with lenalidomide and rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) to include treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL), or high-grade B-cell lymphoma (HGBL) who have high-intermediate or high-risk disease (International Prognostic Index score of 3 or greater), based on results from phase 3 study MOR208C310 (frontMIND) and results from phase 1b study MOR208C107. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is also updated in accordance. A revised RMP version 4.1 is also being submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

Action: For adoption

5.1.8. 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

5.1.9. PIQRAY - Alpelisib - EMA/VR/0000317159

Novartis Europharm Limited;

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication for PIQRAY in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following an endocrine-based regimen; based on the primary analysis (DCO 15-Oct-2024) from the Phase III Study CBYL719C2303 (C2303, EPIK-B5). This is a Phase III, randomized, double-blind, placebo-controlled study of alpelisib (BYL719) in combination with fulvestrant for men and postmenopausal women with HR-positive, HER2-negative advanced breast cancer with PIK3CA mutation, who progressed on or after aromatase inhibitor and a CDK4/6 inhibitor. As a consequence, sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.0 of the RMP has also been submitted.

Action: For adoption

5.1.10. REPATHA - Evolocumab - EMA/VR/0000322435

Amgen Europe B.V.;

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alar Irs, PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to extend the indication for REPATHA to include adults at high risk for a first cardiovascular event, based on the final results from study 20170625 (VESALIUS); this is a Phase 3, double-blind, randomized, placebo-controlled, multicentre study to evaluate the impact of evolocumab on major cardiovascular events in patients at high cardiovascular risk without prior myocardial infarction or stroke. 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 9.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, some typographical errors were corrected, and the PI is brought in line with the latest QRD template version.

Action: For adoption

5.1.11. TALVEY - Talquetamab - 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. TRODELVY - Sacituzumab govitecan - EMA/VR/0000320818

Gilead Sciences Ireland Unlimited Company;

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

Scope: Extension of indication to include Trodelvy, in combination with pembrolizumab, for the treatment of adult patients with unresectable locally advanced or metastatic TNBC who have not received prior systemic therapy for metastatic disease and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10, based on results from study GS-US-592-6173 (ASCENT-04), which is a phase 3 study of sacituzumab govitecan (IMMU-132) and Pembrolizumab versus treatment of physician's choice and Pembrolizumab in patients with previously untreated, locally advanced inoperable or metastatic triple-negative breast cancer, whose tumours express PD-L1. 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 4.2 of the RMP has also been submitted.

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;

Scope: Appointment of re-examination rapporteur and adoption of the timetable at the PROM meeting on 13 July 2026

Action: For information

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/007016

aid in the assessment of breast cancer patients for whom Herceptin (trastuzumab) treatment is being considered

Scope: Opinion

Action: For adoption

6.3.4. In vitro diagnostic medical device - EMEA/H/D/007014

detection of single nucleotide variants (SNVs), insertions and deletions in 22 genes using DNA isolated from formalin-fixed paraffin-embedded (FFPE) tumour tissue specimens and using the Illumina MiSeqDx.

Scope: Opinion

Action: For adoption

6.3.5. In vitro diagnostic medical device - EMEA/H/D/007015

urothelial carcinoma, esophageal cancer, triple-negative breast cancer (TNBC), cervical cancer, and gastric or gastroesophageal junction (GEJ) adenocarcinoma tissues

Scope: Opinion

Action: For adoption

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. Acetylcysteine amide – H0006983

Treatment of hereditary cerebral amyloid angiopathy (CAA)

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

Action: For adoption

8.1.2. Volixibat – H0006947

Treatment of pruritus in adults and adolescents aged 12 years and older with Primary Sclerosing Cholangitis

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

Action: For adoption

8.1.3. Vamikibart – H0006780

Treatment of Uveitic Macular Oedema

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

Action: For adoption

8.2. Priority Medicines (PRIME)

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Bimervax - COVID-19 vaccine (recombinant, adjuvanted) - EMA/VR/0000356318

Hipra Human Health S.L.

Rapporteur: Beata Maria Jakline Ullrich

Scope: Quality variations

Action: For adoption

9.1.2. Comirnaty - COVID-19 mRNA vaccine - EMA/VR/0000355113

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson

Scope: Quality variation

Action: For adoption

9.1.3. Dectova – Zanamivir - EMA/S/0000339464

GlaxoSmithKline Trading Services Limited

Rapporteur: Ingrid Wang, PRAC Rapporteur: Karin Bolin

Scope: Annual reassessment for products authorised under exceptional circumstances

Action: For adoption

9.1.4. DECTOVA - Zanamivir - EMA/VR/0000341315

Glaxosmithkline Trading Services Limited

Rapporteur: Ingrid Wang

Scope: Update of timetable

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

9.1.5. GIAPREZA - Angiotensin II - EMA/VR/0000343583

Paion Deutschland GmbH

Rapporteur: Antonio Gomez-Outes

Scope: Submission of the study protocol (CRH06) in order to modify the completion date of the Post-Authorisation 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-authorisation 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

9.1.6. Kisqali – Ribociclib - EMA/VR/0000325484

Novartis Europharm Limited

Rapporteur: Filip Josephson

Scope: Update of sections 4.4 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from Study CLEE011A3201C (RIGHT Choice). This is a randomized, open-label, Phase II prospective study investigating ribociclib + ET vs. physician choice combination chemotherapy in pre/perimenopausal patients with HR+, HER2− aBC, including investigator-assessed visceral crisis, for whom combination chemotherapy was indicated.

Action: For adoption

9.1.7. LEQEMBI – Lecanemab - EMA/VR/0000321440

Eisai GmbH

Rapporteur: Alexandre Moreau

Scope: Update of sections 4.2 and 5.1 of the SmPC in order to introduce a new posology regimen based on model-based simulations derived from all observed data from intravenous lecanemab studies and long-term safety data. The Package Leaflet has been updated accordingly.

Action: For adoption

9.1.8. Leqvio – Inclisiran - EMA/VR/0000347381

Novartis Europharm Limited

Rapporteur: Janet Koenig

Scope: Update of sections 4.2 and 4.4 of the SmPC in order to update the method of administration and related information. The Package Leaflet is updated in accordance.

Action: For adoption

9.1.9. Litfulo – Ritlecitinib - EMA/PSUR/0000336091

Pfizer Europe MA EEIG

CHMP Rapporteur: Peter Mol, CHMP Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Adam Przybylkowski

Scope: PSUSA recommendation

Action: For adoption

See 2.3

9.1.10. mCOMBRIAX - Influenza and COVID 19, mRNA vaccine - EMA/VR/0000347770

Moderna Biotech Spain S.L.

Rapporteur: Daniela Philadelphy

Scope: Quality variations

Action: For adoption

9.1.11. mNEXSPIKE - COVID-19 mRNA vaccine - EMA/VR/0000333455

Moderna Biotech Spain S.L.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality variations

Action: For adoption

9.1.12. mRESVIA - Respiratory syncytial virus mRNA vaccine (nucleoside modified) - EMA/VR/0000332405

Moderna Biotech Spain S.L.

Rapporteur: Jan Mueller-Berghaus

Scope: Update of sections 4.2, 4.3 and 4.8 of the SmPC in order to add a new contraindication in children younger than 8 months of age because of an increased risk of

RSV enhanced respiratory disease (ERD), following re-evaluation of the signal of RSV-ERD in children immunized between 5 months to <8 months of age; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update section 6.6 of the SmPC.

Action: For adoption

9.1.13. Nuvaxovid - COVID-19 vaccine (recombinant, adjuvanted) - EMA/VR/0000356615

Sanofi Winthrop Industrie

Rapporteur: Patrick Vrijlandt

Scope: Quality variation

Action: For adoption

9.1.14. Spikevax - COVID-19 mRNA vaccine - EMA/VR/0000356879

Moderna Biotech Spain S.L.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality variation

Action: For adoption

9.1.15. Repaglinide Accord – Repaglinide - EMEA/H/C/002318

Accord Healthcare S.L.U.; treatment of type 2 diabetes mellitus

Rapporteur: Robert Porszasz

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

10.2.1. Colistimethate sodium (CMS) – EMEA/H/A-5(3)/1524

Various MAHs

Referral Rapporteur: Martin Mengel, Referral Co-Rapporteur: Ewa Balkowiec Iskra

Scope: List of outstanding issues

Action: For adoption

Review of the ratio of polymyxins E1 and E2 in colistin starting material and of the (sulfomethylation) composition profile of CMS finished product.

List of outstanding issues adopted on 21.03.2024, 22.02.2024, 22.05.2025. List of questions adopted on 22.06.2023.

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

July 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

14.1.3. Strategic Review and Learning Meeting (SRLM) under Irish EU presidency

Update on the upcoming SRLM.

CHMP: Finbarr Leacy

Action: For information

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 July 2026

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at July 2026 PDCO

Action: For information

Agenda of the PDCO meeting held on 21-24 July 2026

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Vice-Chair: Andreea Barbu

Action: For adoption

14.3.2. Scientific Advice Working Party (SAWP)

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

Report from the SAWP meeting held on 06-09 July 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.

14.3.3. Guideline on the clinical requirements for medicines intended for the treatment of thalassaemia

Adoption of the guideline following agreement by HAEMWP and consultation of MWP, PRAC, CAT, PDCO, COMP and GCG for a 4-month public consultation.

CHMP: Johanna Lähteenvuo

Presenter: Viktoriia Starokozhko, Expert: Karri Penttila

Action: For adoption

14.3.4. Guideline on the clinical requirements for medicines intended for the treatment of sickle cell disease

Adoption of the guideline following agreement by HAEMWP and consultation of MWP, PRAC, CAT, PDCO, COMP and GCG for a 4-month public consultation.

CHMP: Johanna Lähteenvuo

Expert: Viktoriia Starokozhko

Action: For adoption

14.3.5. Election of Chair - Biosimilar Medicinal Product Working Party (BMWP)

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

Nomination(s) received

Action: For election

14.3.6. Election of Chair - Quality Working Party (QWP)

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

Nomination(s) received

Action: For election

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

Analysis of requests for clock-stop extensions and feedback from GIREX.

Action: For discussion

Explanatory notes

The notes below give a brief explanation of the main sections and headings in the CHMP agenda and should be read in conjunction with the agenda or the minutes.

Oral explanations *(section 2)*

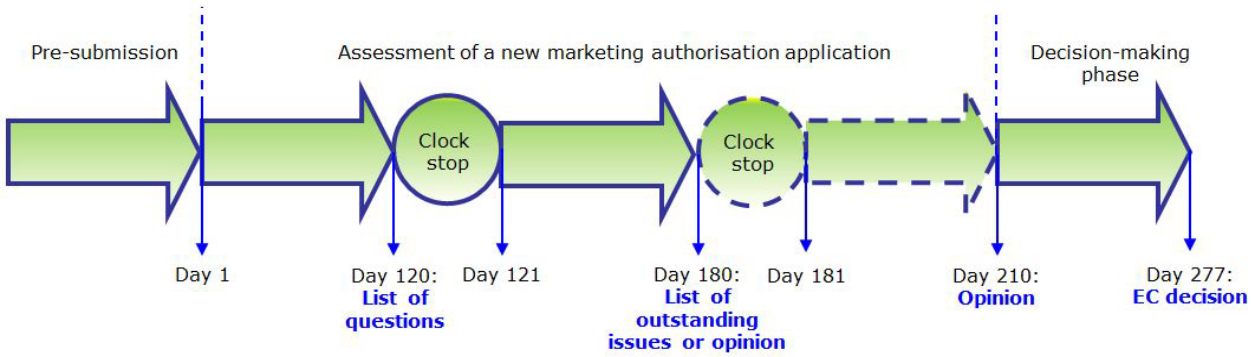
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (section 10) but can relate to any other issue for which the CHMP would like to discuss with company representatives in person.

Initial applications *(section 3)*

This section lists applications for marketing authorisations of new medicines that are to be discussed by the Committee.

Section 3.1 is for medicinal products nearing the end of the evaluation and for which the CHMP is expected to adopt an **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CHMP. The clock stop happens after day 120 and may also happen after day 180, when the CHMP has adopted a list of questions or outstanding issues to be addressed by the company. Related discussions are listed in the agenda under sections 3.2 (**Day 180 List of outstanding issues**) and 3.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 3.4, **update on ongoing new applications for centralised procedures**.

The assessment leads to an opinion from the CHMP by day 210. Following a CHMP opinion the European Commission takes usually 67 days to issue a legally binding decision (i.e. by day 277 of the procedure). CHMP discussions on products that have received a CHMP opinion and are awaiting a decision are listed under section 3.6, **products in the decision making phase**.

Extension of marketing authorisations according to Annex I of Reg. 1234/2008 *(section 4)*

Extensions of marketing authorisations are applications for the change or addition of new strengths, formulations or routes of administration to existing marketing authorisations. Extension applications follow a 210-day evaluation process, similarly to applications for new medicines (see figure above).

Type II variations - Extension of indication procedures *(section 5)*

Type II variations are applications for a change to the marketing authorisation which requires an update of the product information and which is not covered in section 4. Type II variations include applications for a new use of the medicine (extension of indication), for which the assessment takes up to 90 days. For the applications listed in this section, the CHMP may adopt an opinion or request supplementary information from the applicant.

Ancillary medicinal substances in medical devices *(section 6)*

Although the EMA does not regulate medical devices it can be asked by the relevant authorities (the so-called Notified Bodies) that are responsible for regulating these devices to give a scientific opinion on a medicinal substance contained in a medical device.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 *(section 3.5)*

This section lists applications for new marketing authorisation for which the applicant has requested a re-examination of the opinion previously issued by the CHMP.

Re-examination procedures *(section5.3)*

This section lists applications for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP.

Withdrawal of application *(section 3.7)*

Applicants may decide to withdraw applications at any stage during the assessment and a CHMP opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Procedure under article 83(1) of regulation (EC) 726/2004 (compassionate use) *(section 7)*

Compassionate use is a way of making available to patients with an unmet medical need a promising medicine which has not yet been authorised (licensed) for their condition. Upon request, the CHMP provides recommendations to all EU Member States on how to administer, distribute and use certain medicines for compassionate use.

Pre-submission issues *(section 8)*

In some cases the CHMP may discuss a medicine before a formal application for marketing authorisation is submitted. These cases generally refer to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation. In case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

Post-authorisation issues *(section 9)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 10)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

This section lists issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines. Feedback is provided by the PRAC. This section also refers to the early notification system, a system used to notify the European regulatory network on proposed EMA communication on safety of medicines.

Inspections Issues *(section 12)*

This section lists inspections that are undertaken for some medicinal products. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Innovation task force *(section 13)*

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes from the last ITF meeting as well as any related issue that requires discussion with the CHMP are listed in this section of the agenda. Further information on the ITF can be found here.

Scientific advice working party (SAWP) *(section 14.3.1)*

This section refers to the monthly report from the CHMP's Scientific Advice Working Party (SAWP) on scientific advice given to companies during the development of medicines. Further general information on SAWP can be found here.

Satellite groups / other committees *(section 14.2)*

This section refers to the reports from groups and committees making decisions relating to human medicines: the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), the Committee for Orphan Medicinal Products (COMP), the Committee for Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmamacovigilance Risk Assessment Committee (PRAC).

Invented name issues *(section 14.3)*

This section list issues related to invented names proposed by applicants for new medicines. The CHMP has established the Name Review Group (NRG) to perform reviews of the invented names. The group's main role is to consider whether the proposed names could create a public-health concern or potential safety risk. Further information can be found here.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 July 2026
EMA/CHMP/147540/2026

Annex to 20-23 July 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 July 2026: **For adoption**

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

Final Outcome of Rapporteurship allocation for July 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

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.