08 December 2025
EMA/CHMP/347361/2025
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 08-11 December 2025
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

08 December 2025, 09:30 – 19:30, virtual meeting/room 1C

09 December 2025, 08:30 – 19:30, virtual meeting/room 1C

10 December 2025, 08:30 – 19:30, virtual meeting/room 1C

11 December 2025, 08:30 – 15:00, virtual meeting/room 1C

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 08-11 December 2025. See December 2025 CHMP minutes (to be published post January 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 08-11 December 2025

1.3. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 01 December 2025.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Tolebrutinib - EMEA/H/C/006386

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

Scope: Oral explanation

Action: Oral explanation to be held on 10 December 2025 at 11:00

List of Outstanding Issues adopted on 16.10.2025. List of Questions adopted on 19.06.2025.

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

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

Scope: Oral explanation

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

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

2.1.3. Aficamten - EMEA/H/C/006228

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

Scope: Oral explanation

Action: Oral explanation to be held on 10 December 2025 at 09:00

List of Outstanding Issues adopted on 16.10.2025. List of Questions adopted on 25.04.2025.

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. Nucala - Mepolizumab - EMA/VR/0000257645

Glaxosmithkline Trading Services Limited;

Rapporteur: Finbarr Leacy, Co-Rapporteur: Petr Vrbata, PRAC Rapporteur: Dirk Mentzer

Scope: Oral explanation

Action: Oral explanation to be held on 09 December 2025 at 16:00

See 5.1

2.3.2. Uplizna - Inebilizumab - EMA/VR/0000257358

Amgen Europe B.V.;

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

Scope: Oral explanation

Action: Oral explanation to be held on 10 December 2025 at 16:00

See 5.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

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

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

Scope: Opinion

Action: For adoption

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

3.1.2. Aumolertinib - EMEA/H/C/006069

treatment of non-small cell lung cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 14.12.2023. List of Questions adopted on 30.03.2023.

3.1.3. Blarcamesine - EMEA/H/C/006475

treatment of Alzheimer’s disease and dementia

Scope: Opinion; Third party intervention

Action: For adoption

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 25.04.2025.

3.1.4. Depemokimab - EMEA/H/C/006446

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

Scope: Opinion

Action: For adoption

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

3.1.5. Golimumab - EMEA/H/C/006621

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, ulcerative colitis, psoriatic

arthritis and ankylosing spondylitis

Scope: Opinion

Action: For adoption

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

3.1.6. COVID-19 mRNA vaccine - EMEA/H/C/006428

Active immunisation to prevent COVID 19 caused by SARS-CoV-2 in individuals 12 years of age and older.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 18.09.2025. List of Questions adopted on 25.04.2025.

3.1.7. Ranibizumab - EMEA/H/C/006502

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

Scope: Opinion

Action: For adoption

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

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

3.2.1. Nadofaragene firadenovec - ATMP - EMEA/H/C/005856

treatment of adult patients with high-grade (HG), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC).

Scope: List of outstanding issues

Action: For information

List of Questions adopted on 16.04.2025.

3.2.2. Furosemide - PUMA - EMEA/H/C/006617

treatment of all conditions requiring diuresis due to mechanical obstruction or venous insufficiency.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

3.2.3. Insulin lispro - EMEA/H/C/006158

treatment of diabetes mellitus

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

3.2.4. Influenza and COVID-19 vaccine - EMEA/H/C/006472

immunisation for the prevention of diseases associated with seasonal influenza viruses and SARS-CoV-2

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.05.2025.

3.2.5. Insulin aspart - EMEA/H/C/006187

treatment of diabetes mellitus

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.01.2024.

3.2.6. Copper (64Cu) oxodotreotide - Orphan - EMEA/H/C/006608

Cis Bio International; positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine neoplasms (NENs).

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

3.2.7. Tovorafenib - Orphan - EMEA/H/C/006140

Ipsen Pharma; treatment of paediatric low-grade glioma (LGG)

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

3.2.8. Levodopa / Carbidopa - EMEA/H/C/006429

treatment of motor fluctuations in patients with Parkinson’s disease

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 19.06.2025.

3.2.9. Paltusotine - Orphan - EMEA/H/C/006636

Voisin Consulting Life Sciences; Maintenance treatment in adult patients with acromegaly

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

3.2.10. Pertuzumab - EMEA/H/C/006583

treatment of breast cancer

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

3.2.11. Remibrutinib - EMEA/H/C/006313

treatment of chronic spontaneous urticaria in patients with inadequate response to H1 antihistamine

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

3.2.12. Tocilizumab - EMEA/H/C/006416

treatment of rheumatoid arthritis and other immunological conditions

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 24.07.2025.

3.2.13. Mavorixafor - Orphan - EMEA/H/C/006496

X4 Pharmaceuticals (Austria) GmbH; Treatment of WHIM syndrome

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 22.05.2025.

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

3.3.1. Acoziborole - Article 58 - EMEA/H/W/006686

Accelerated assessment

Treatment of first and second-stage human African trypanosomiases (HAT) due to Trypanosoma brucei gambiense

Scope: List of questions

Action: For adoption

3.3.2. Gadoquatrane - EMEA/H/C/006443

For contrast enhancement in magnetic resonance imaging (MRI) used for adults and paediatric patients of all ages.

Scope: List of questions

Action: For adoption

3.3.3. Azacitidine - EMEA/H/C/006695

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

Scope: List of questions

Action: For adoption

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

treatment of primary hypercholesterolaemia or mixed dyslipidaemia

Scope: List of questions

Action: For adoption

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

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

Scope: List of questions

Action: For adoption

3.3.6. 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

Action: For adoption

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

treatment of type 2 diabetes mellitus

Scope: List of questions

Action: For adoption

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

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

Scope: List of questions

Action: For adoption

3.3.9. Senaparib - EMEA/H/C/006708

maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer

Scope: List of questions

Action: For adoption

3.3.10. Ranibizumab - EMEA/H/C/006527

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

Scope: List of questions

Action: For adoption

3.3.11. Tafamidis - EMEA/H/C/006711

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

Scope: List of questions

Action: For adoption

3.3.12. Obicetrapib - EMEA/H/C/006516

treatment of primary hypercholesterolaemia or mixed dyslipidaemia

Scope: List of questions

Action: For adoption

3.3.13. 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: List of questions

Action: For adoption

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

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

3.5.1. REZUROCK - Belumosudil - Orphan - EMEA/H/C/006421

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

Scope: List of Questions

Action: For adoption

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

Opinion adopted on 16.10.2025. List of Outstanding Issues adopted on 19.06.2025. List of Questions adopted on 30.01.2025.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

4.1.1. Akynzeo - Fosnetupitant / Netupitant / Palonosetron - EMA/X/0000258060

Helsinn Birex Pharmaceuticals Limited

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new pharmaceutical form (300 mg / 0.5 ml oral suspension).

Action: For adoption

4.1.2. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/X/0039

Vanda Pharmaceuticals Netherlands B.V.;

Rapporteur: Jayne Crowe, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (4 mg/ml oral solution). The new formulation is indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in paediatric patients 3 to 15 years of age. The RMP (version 5.0) is updated in accordance."

Action: For adoption

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

4.1.3. Livmarli - Maralixibat - Orphan - EMEA/H/C/005857/X/0015

Mirum Pharmaceuticals International B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Adam Przybylkowski

Scope: "Extension application to introduce a new pharmaceutical form (tablet) associated with new strengths 10 mg, 15mg, 20 mg and 30 mg.
The RMP (version 5.0) is updated in accordance."

Action: For adoption

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

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

4.2.1. Camcevi - Leuprorelin - EMA/X/0000258054

Accord Healthcare S.L.U.;

Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to add a new strength of 21 mg for Leuproelin prolonged-release suspension for injection pre-filled syringe, for subcutaneous (SC) administration.

Action: For adoption

4.2.2. Jorveza - Budesonide - EMA/X/0000257468

Dr. Falk Pharma GmbH;

Rapporteur: Janet Koenig, PRAC Rapporteur: Zane Neikena

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (0.2 mg/ml oral suspension). The new presentation is indicated for paediatric patients 2 to 17 years of age.

Action: For adoption

4.2.3. Olumiant - Baricitinib - EMA/X/0000257923

Eli Lilly Nederland B.V.;

Rapporteur: Peter Mol, PRAC Rapporteur: Adam Przybylkowski

Scope: Extension application to introduce a new pharmaceutical form (oral suspension) associated with a new strength (2 mg/ml).

Action: For adoption

4.2.4. Rybrevant - Amivantamab - EMA/X/0000268898

Janssen Cilag International;

Rapporteur: Filip Josephson, PRAC Rapporteur: Dirk Mentzer

Scope: Extension application to add a new strength of 2400 mg and 3520 mg (solution for injection) grouped with the following variations:

C.I.4: Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 6.6 in order to include the Q3W dosing regimen based on data from relevant cohorts from the Phase 2 bridging study PALOMA-2 (NSC2002) and supported by data from the Phase 1 PALOMA study (NSC1003). The Package Leaflet and Labelling are updated accordingly. The RMP version 7.1 has also been submitted.

C.I.4: Update of sections 4.2, 4.4, 4.8, 5.1, 5.2, 6.5 and 6.6 in order to introduce a new Q4W dosing regimen based on data from the PALOMA-2 study (NSC2002) and supported by data from the Phase 1 PALOMA study (NSC1003). The Package Leaflet and Labelling are updated accordingly. The RMP version 7.1 has also been submitted.

Action: For adoption

4.2.5. Scemblix - Asciminib - EMA/X/0000256688

Novartis Europharm Limited;

Rapporteur: Martin Mengel Co-Rapporteur: Peter Mol, PRAC Rapporteur: Eva Jirsová

Scope: Extension application to introduce a new strength (100 mg film-coated tablets) grouped with a type II variation (C.I.6.a) to add a new indication (treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) harbouring the T315I mutation), based on final results from study CABL001X2101 and study CABL001A2004. Study CABL001X2101 is a Phase I, multicentre, open-label, dose escalation FIH study to define the MTD/RDEs, to characterize safety and tolerability, and to assess the PK profile and preliminary evidence of efficacy of asciminib given as single agent or in combination with either nilotinib or imatinib or dasatinib in

patients with Ph+ CML or Ph+ ALL.

Study CABL001A2004 assessed the real-world effectiveness of asciminib and treatment patterns in patients with Chronic Myeloid Leukaemia with T315I mutation. As a consequence, sections 1, 2, 3, 4, 5, 6 and 8 of the SmPC are updated. The Package Leaflet and Labelling are 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

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. Riltrava Aerosphere - Formoterol / Glycopyrronium bromide / Budesonide - EMA/X/0000287672

AstraZeneca AB;

Rapporteur: Finbarr Leacy, 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

4.3.2. 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

4.3.3. Trixeo Aerosphere - Formoterol / Glycopyrronium bromide / Budesonide - Orphan - EMA/X/0000287664

AstraZeneca AB;

Rapporteur: Finbarr Leacy, 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

4.3.4. Vyndaqel - Tafamidis - EMA/X/0000287968

Pfizer Europe MA EEIG;

Rapporteur: Nicolas Beix, PRAC Rapporteur: Zoubida Amimour

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

Action: For adoption

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

4.4.1. Symtuza – Darunavir / Cobicistat / Emtricitabine / Tenofovir alafenamide - EMA/X/0000248421

Janssen Cilag International

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

Scope: Re-adoption of List of Outstanding Issues

Extension application to add a new strength of 675 mg/150 mg/ 20mg/ 10 mg film-coated tablets grouped with an Extension of indication (C.I.6) to include treatment of human immunodeficiency virus type 1 (HIV 1) infection in paediatric patients (aged 6 years and older with body weight at least 25 kg) for SYMTUZA, based on the 24-week interim results from study GS-US-216-0128 (Cohort 2); this is a Phase II/III, multicentre, open-label, multicohort interventional study evaluating efficacy, safety, and pharmacokinetics of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 infected children. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1, 6.3, 6.4, 6.5 and 8 of the SmPC are updated. The Annex II, Labelling and Package Leaflet are updated accordingly. Version 9.1 of the RMP has also been submitted. Furthermore, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to update the list of local representatives in the Package Leaflet.

Action: For adoption

4.5. 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. AGAMREE - Vamorolone - EMA/VR/0000293535

Santhera Pharmaceuticals (Deutschland) GmbH;

Rapporteur: Janet Koenig, PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of 2 to <4 year olds for AGAMREE, based on final results from study VBP15-006; this is a phase II open-label, multiple dose study to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and exploratory efficacy of vamorolone in boys ages 2 to <4 years and 7 to <18 years with Duchenne Muscular Dystrophy (DMD) and an updated paediatric extrapolation report referencing 4 to <7-year-old subjects with DMD from Study VBP15-004, compared to the 2 to <4-year-old population from Study VBP15-006. 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 2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to make some editorial corrections to SmPC.

Action: For adoption

5.1.2. AREXVY - Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E - EMA/VR/0000276225

GlaxoSmithKline Biologicals;

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 18 years of age and older for AREXVY, based on results from study 222253 (RSV OA=ADJ-025); this is a Phase 3b, open-label study to evaluate the non-inferiority of the immune response and to evaluate the safety of the RSVPreF3 OA investigational vaccine in adults 18-49 years of age at increased risk of respiratory syncytial virus disease, compared to older adults ⩾60 years of age. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.1.3. ASPAVELI - Pegcetacoplan - EMA/VR/0000248937

Swedish Orphan Biovitrum AB (publ);

Rapporteur: Alexandre Moreau, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension of indication to include treatment of adults and adolescents aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulopathy (IC-MPGN) for ASPAVELI, based on interim results from study APL2-C3G-310; this is a randomized, placebo-controlled, double-blinded, multicentre study to evaluate the safety and efficacy of twice-weekly s.c. infusions of pegcetacoplan in patients diagnosed with C3G or primary IC-MPGN and results from Phase 2 study APL2-C3G-204, an open-label, randomized, controlled study to evaluate the efficacy and safety of pegcetacoplan in posttransplant recurrence of C3G or primary IC-MPGN. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

Action: For adoption

5.1.4. CAPVAXIVE - Pneumococcal polysaccharide conjugate vaccine (21-valent) - EMA/VR/0000294070

Merck Sharp & Dohme B.V.;

Rapporteur: Kristina Dunder, Co-Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jean-Michel Dogné

Scope: Extension of indication to include treatment of children and adolescents 2 to less than 18 years of age for CAPVAXIVE, based on final results from study V116-013 (P013V116); this is a phase 3, randomized, double-blind study to evaluate the safety, tolerability, and immunogenicity of V116 in children and adolescents with increased risk of pneumococcal disease; As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, 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

5.1.5. Dovprela - Pretomanid - EMA/VR/0000258124

Mylan IRE Healthcare Limited;

Rapporteur: Filip Josephson

Scope: Extension of indication to include in combination with bedaquiline, linezolid and moxifloxacin the treatment of adults with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to rifampicin, with or without resistance to isoniazid, for DOVPRELA and to update the current regimen, based on final results of the TB-PRACTECAL study; this is a randomised, controlled, open-label, phase II-III trial to evaluate the safety and efficacy of regimens containing bedaquiline and pretomanid for the treatment of adult patients with pulmonary multidrug resistant tuberculosis. 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. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.1.6. Elucirem/Vueway - Gadopiclenol - EMA/VR/0000249008

Guerbet; Bracco Imaging S.p.A.;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber

Scope: Extension of indication to include treatment of new population (0 to 2 years of age patients) for ELUCIREM / VUEWAY, based on final results from study GDX-44-015; this is a phase ii clinical study concerning gadopiclenol pharmacokinetics, safety and efficacy in paediatric patients < 2 years of age undergoing contrast-enhanced MRI; extension of indication is also supported with the non-clinical data. 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 0.4 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to remove Annex IV from the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.7. Enhertu - Trastuzumab deruxtecan - EMA/VR/0000293327

Daiichi Sankyo Europe GmbH;

Rapporteur: Boje Kvorning Pires Ehmsen, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumours who have received prior treatment and who have no satisfactory alternative treatment options for Enhertu, based on pooled pop-PK analysis and interim results from study D967VC00001 (DESTINY-PanTumor02); this is a Phase II, Multicentre, Open-label Study to Evaluate the Efficacy and Safety of Trastuzumab Deruxtecan (T-DXd, DS-8201a) for the Treatment of Selected HER2-expressing Tumours; 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 9.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI.

Action: For adoption

5.1.8. Eylea - Aflibercept - EMA/VR/0000264981

Bayer AG;

Rapporteur: Nicolas Beix, PRAC Rapporteur: Zoubida Amimour

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

C.I.6: Extension of indication to include the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch, central and hemiretinal RVO) for EYLEA, based on results from study 22153 (QUASAR); this is a randomized, double-

masked, active-controlled Phase 3 study of the efficacy and safety of aflibercept 8 mg in macular oedema secondary to retinal vein occlusion. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordingly. The RMP version 36.1 has also been submitted.

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

Action: For adoption

5.1.9. Keytruda - Pembrolizumab - EMA/VR/0000293815

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include in combination with paclitaxel, with or without bevacizumab, the treatment of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma in adults whose tumours express PD-L1 with a CPS $\geqslant$ 1 and who have received one or two prior systemic treatment regimens for KEYTRUDA, based on interim results from study PB96V01MK3475 (KEYNOTE-B96); this is a Phase 3, randomized, double-blind study of pembrolizumab in combination with paclitaxel with or without bevacizumab for the treatment of platinum-resistant recurrent ovarian cancer. As a consequence, sections 4.1 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 50.1 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

5.1.10. Leqvio - Inclisiran - EMA/VR/0000293324

Novartis Europharm Limited;

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

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

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

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

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

As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted.

Action: For adoption

5.1.11. Mekinist/ Tafinlar – Trametinib/ Dabrafenib – WS – EMA/VR/0000271728

Novartis Europharm Limited;

Rapporteur: Filip Josephson, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include treatment of unresectable or metastatic melanoma with a BRAF V600 mutation and adjuvant treatment of Stage III melanoma with a BRAF V600 mutation for adolescents aged 12 years and older for TAFINLAR and MEKINIST, based on an extrapolation report using a modelling and simulation approach to demonstrate PK, PD and efficacy of dabrafenib and trametinib in adolescent patients. 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. RMP versions 13.0 and 21.0 for Tafinlar and Mekinist, respectively, have also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI and to update list of local representatives in the Package Leaflet.

Action: For adoption

5.1.12. Mekinist/ Tafinlar – Trametinib/ Dabrafenib – WS – EMA/VR/0000278305

Novartis Europharm Limited;

Rapporteur: Peter Mol, PRAC Rapporteur: David Olsen

Scope: Extension of indication to include treatment of differentiated thyroid cancer (DTC) for TAFINLAR and MEKINIST based on primary analysis from pivotal study CDRB436J12301. This is a randomized, double-blind, placebo-controlled Phase 3 study to evaluate the efficacy and safety of dabrafenib plus trametinib in previously treated patients with locally advanced or metastatic, radio-active iodine refractory BRAF V600E mutation-positive differentiated thyroid cancer. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14.0 and Version 22.0 of the RMPs for Tafinlar and Mekinist, respectively, have also been submitted.

Action: For adoption

5.1.13. Mounjaro - Tirzepatide - EMA/VR/0000281937

Eli Lilly Nederland B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include treatment of adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise for MOUNJARO, based on final results from study I8F-MC-GPGV (SURPASS-

PEDS); this is a study to evaluate efficacy, safety, and pharmacokinetics/ pharmacodynamics of tirzepatide compared to placebo in paediatric and adolescent participants with type 2 diabetes mellitus inadequately controlled with metformin, or basal insulin, or both. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has also been submitted.

Action: For adoption

5.1.14. Nucala - Mepolizumab - EMA/VR/0000257645

Glaxosmithkline Trading Services Limited;

Rapporteur: Finbarr Leacy, Co-Rapporteur: Petr Vrbata, PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication for NUCALA to include treatment of Chronic Obstructive Pulmonary Disease (COPD) based on final results from study 208657 (MATINEE). This is a randomized, double-blind, parallel-group, placebo-controlled study of mepolizumab 100 mg SC as add-on treatment in participants with COPD experiencing frequent exacerbations and characterized by eosinophil levels. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI.

Action: For adoption

See 2.3

5.1.15. Recarbrio - Imipenem / Cilastatin / Relebactam - EMA/VR/0000265089

Merck Sharp & Dohme B.V.;

Rapporteur: Filip Josephson, Co-Rapporteur: Alar Irs, PRAC Rapporteur:

Scope: Extension of indication to extend the approved adult indications for RECARBRIO to include treatment of paediatric population from birth to <18 years of age, based on final results from two paediatric studies (MK-7655A-021 and MK-7655A-020); phase 2/3 study MK-7655A-021 addressed safety, tolerability, efficacy and PK, and phase 1b study MK-7655A-020 addressed PK, safety, and tolerability of MK-7655A in paediatric subjects from birth to less than 18 years of age with confirmed or suspected gram-negative infections. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 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 and implement minor editorial corrections.

Action: For adoption

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

Janssen Cilag International;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Karin Bolin

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

Action: For adoption

Request for Supplementary Information adopted on 16.10.2025, 25.04.2025.

5.1.17. Sogroya - Somapacitan - EMA/VR/0000264734

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Martin Huber

Scope: Grouped extension of indication application to include treatment of children born small for gestational age (SGA), Noonan syndrome (NS) and idiopathic short stature (ISS) for SOGROYA, based on interim results from the pivotal, confirmatory phase 3 study NN8640-4467 supported by the phase 3 study NN8640-4469 and the phase 2 study NN8640-4245. Study 4467 is a study comparing the effect and safety of once weekly dosing of somapacitan with daily Norditropin as well as evaluating long-term safety of somapacitan in a basket study design in children with short stature either born small for gestational age or with Turner syndrome, Noonan syndrome, or idiopathic short stature. Study 4469 is a study evaluating the safety and efficacy of once-weekly dosing of somapacitan in a basket study design in paediatric participants with short stature either born small for gestational age or with turner syndrome, Noonan syndrome or idiopathic short stature. Study 4245 is a dose-finding trial evaluating the effect and safety of once-weekly treatment of somapacitan compared to daily Norditropin in children with short stature born small for gestational age with no catch-up growth by 2 years of age or older. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. Furthermore, the PI is brought 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

5.1.18. Truqap - Capivasertib - EMA/VR/0000293735

AstraZeneca AB;

Rapporteur: Martin Mengel, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Sonja Radowan

Scope: Extension of indication to include Truqap in combination with abiraterone for the treatment of metastatic castration-sensitive prostate cancer characterized by PTEN deficient tumours based on non-clinical and clinical dataset, including interim results from the pivotal

study D361BC00001 (CAPItello-281); this is a Phase III double-blind, randomised, placebo-controlled study assessing the efficacy and safety of capivasertib + abiraterone versus placebo + abiraterone as treatment for patients with de novo metastatic hormone-sensitive prostate cancer (mHSPC) characterised by PTEN deficiency; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 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

5.1.19. Uplizna - Inebilizumab - EMA/VR/0000257358

Amgen Europe B.V.;

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

Scope: A grouped application consisting of:

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

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

Action: For adoption

See 2.3

5.1.20. Winrevair - Sotatercept - EMA/VR/0000278021

Merck Sharp & Dohme B.V.;

Rapporteur: Patrick Vrijlandt

Scope: Extension of indication to include in combination with other pulmonary arterial hypertension (PAH) therapies treatment of adult patients with PAH World Health Organisation Functional Class IV for WINREVAIR, based on interim results from study ZENITH (also referred as MK-7962-006 and A011-14); this is a phase 3, randomized, double-blind, placebo-controlled study to evaluate sotatercept when added to maximum tolerated background therapy in participants with pulmonary arterial hypertension (PAH) World Health Organization (WHO) Functional Class (FC) III or FC IV at high risk of mortality; 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. In addition, the MAH removed the first PSUR commitment following 6 months post authorisation as it has already been fulfilled. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

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

5.2.1. Pluvicto - Lutetium (177Lu) vipivotide tetraxetan - EMA/VR/0000288073

Novartis Europharm Limited;

Rapporteur: Janet Koenig, Co-Rapporteur: Peter Mol, PRAC Rapporteur: John Joseph Borg

Scope: Request by the applicant for an extension to the clock stop to respond to the request for supplementary information adopted in November 2025.

Extension of indication to include treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after having progressed on androgen receptor pathway inhibitor (ARPI) and for whom chemotherapy is not yet clinically indicated for PLUVICTO, based on interim results from study CAAA617B12302 (PSMAfore); this is a phase III, open-label, multi-centre, randomized study comparing 177Lu-PSMA-617 vs. a change of androgen receptor-directed therapy in the treatment of taxane naïve men with progressive metastatic castrate resistant prostate cancer; As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted to include clinical data from the PSMAfore study to support the addition of the new therapeutic indication.

Action: For adoption

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

5.3.1. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/II/0040

Vanda Pharmaceuticals Netherlands B.V.;

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

Action: For adoption

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/006840

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

Scope: Opinion

Action: For adoption

6.3.2. In vitro diagnostic medical device - EMEA/H/D/006887

assay for the detection of single nucleotide variants coding five IDH1 mutations (R132C, R132H, R132G, R132S, and R132L) in DNA

Scope: Opinion

Action: For adoption

6.3.3. In vitro diagnostic medical device - EMEA/H/D/006863

in vitro diagnostic test that uses high throughput parallel sequencing technology to detect sequence variations (SNVs, deletions, insertions, and fusions) in 46 cancer related genes

Scope: Opinion

Action: For adoption

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

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

Scope: Opinion

Action: For adoption

6.3.5. In vitro diagnostic medical device - EMEA/H/D/006859

laboratory use in the qualitative immunohistochemical detection of MSH6 protein in formalin-fixed, paraffin-embedded (FFPE) tissue specimens by light microscopy

Scope: Opinion

Action: For adoption

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. Zidebactam/Cefepime – H0006799

is indicated for the treatment of the following infections in adult patients:

- Complicated intra-abdominal infections (cIAI) in combination with metronidazole,

- Complicated urinary tract infections (cUTI), including pyelonephritis.

- Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP).

- Treatment of patients with bacteraemia that occurs in association with or is suspected to be associated with any of the indications listed above (concurrent bacteraemia).

- The product is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adult patients with limited treatment options.

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

Action: For adoption

8.1.2. Garetosmab – H0005750

treatment of adults with fibrodysplasia ossificans progressiva (FOP)

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. Deltyba – Delamanid – EMA/R/0000293774

Otsuka Novel Products GmbH

Rapporteur: Christophe Focke

Scope: Switch to full MA

Action: For adoption

9.1.2. Lyxumia – Lixisenatide – EMEA/H/C/002445

Sanofi Winthrop Industrie; treatment of type 2 diabetes mellitus

Rapporteur: Kristina Dunder, Co-Rapporteur: Karin Janssen van Doorn

Scope: Withdrawal of marketing authorization

Action: For information

9.1.3. Ozempic/Rybelsus – Semaglutide - EMA/VR/0000295392

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt

Scope: Update of section 4.4 of the SmPC in order to remove of Type 1 diabetes mellitus restriction from warnings and precautions based on a post-marketing safety assessment of off-label/T1D use for Ozempic and Rybelsus; the Package Leaflet is updated accordingly.

Action: For adoption

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

10.4.1. Melatomed - melatonin - EMA/REF/0000303296

Fairmed Healthcare GmbH

Referral Rapporteur: Janet Koenig, Referral Co-Rapporteur: Kristina Dunder

Scope: LoOI/ Opinion

Action: For adoption

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

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

No items

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

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

December 2025 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

Information related to GMP inspections will not be published as it undermines the purpose of such inspections

12.2. GCP inspections

Information related to GCP inspections will not be published as it undermines the purpose of such inspections

12.3. Pharmacovigilance inspections

Information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections

12.4. GLP inspections

Information related to GLP inspections will not be published as it undermines the purpose of such inspections

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

Information related to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to contain commercially confidential information

No items

13.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by Proxy

No items

14.1.2. CHMP membership

No items

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for December 2025

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at December 2025 PDCO

Action: For information

Agenda of the PDCO meeting held on 09-12 December 2025

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Action: For adoption

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 18-19 November 2025.

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 27 – 30 October 2025.

Action: For information

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

14.3.4. QWP response to CMDh question

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

Draft CHMP work plan 2026

Action: For information

14.8. Planning and reporting

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

Q4-2025 forecast report, covering initial marketing authorisation application submissions via the central procedure.

Action: For information

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

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

Action: For discussion

Explanatory notes

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

Oral explanations *(section 2)*

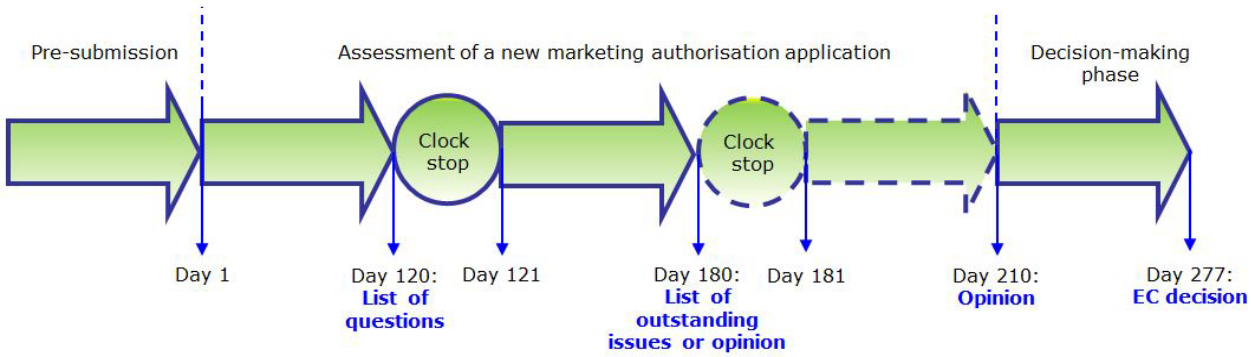
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 December 2025
EMA/CHMP/363086/2025

Annex to 08-11 December 2025 CHMP Agenda

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

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

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

B.2.3. Renewals of Conditional Marketing Authorisations

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 24-27 November 2025 PRAC

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

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

Scopes related to Chemistry, Manufacturing, and Controls cannot be released at the present time as these contain commercially confidential information.

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

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

B.5.3. CHMP-PRAC assessed procedures

Byooviz - Ranibizumab - EMEA/H/C/005545/II/0016/G Samsung Bioepis NL B.V., Rapporteur: Christian Gartner, PRAC Rapporteur: Karin Bolin Opinion adopted on 27.11.2025. Request for Supplementary Information adopted on 03.10.2024, 13.06.2024.	Positive Opinion adopted by consensus on 27.11.2025.

B.5.4. PRAC assessed procedures

B.5.5. CHMP-CAT assessed procedures

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

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

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

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

D. Annex D - Post-Authorisation Measures (PAMs), (Details on PAMs including description and conclusion, for adoption by CHMP in that given month, or finalised ones with PRAC recommendation and no adoption by CHMP needed)

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

Information related to plasma master files cannot be released at the present time as these contain commercially confidential information.

E.1. PMF Certification Dossiers

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

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

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

G. ANNEX G

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

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

G.2. PRIME

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