14 September 2026
EMA/CHMP/168748/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 14-17 September 2026
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

14 September 2026, 09:00 – 19:30, virtual meeting/room 2C

15 September 2026, 08:30 – 19:30, virtual meeting/room 2C

16 September 2026, 08:30 – 19:30, virtual meeting/room 2C

17 September 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 14-17 September 2026. See September 2026 CHMP minutes (to be published post October 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 14-17 September 2026

1.3. Adoption of the minutes

CHMP minutes for the 26-29 January 2026, 23-26 March 2026, 20-23 July 2026 meetings and the 17-20 August 2026 written procedure.

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 07 September 2026.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Norucholic acid - ORPHAN - EMEA/H/C/006515

Dr. Falk Pharma GmbH; treatment of primary sclerosing cholangitis (PSC) in adults.

Scope: Oral explanation

Action: Oral explanation to be held on 15 September 2026 at 14:00

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

2.1.2. Navepegritide - ORPHAN - EMEA/H/C/006627

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

Scope: Oral explanation

Third party intervention

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

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

2.1.3. Glepaglutide - EMEA/H/C/005855

treatment of adults with Short Bowel Syndrome

Scope: Oral explanation

Action: Oral explanation to be held on 15 September 2026 at 16:00

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

2.2. Re-examination procedure oral explanations

2.2.1. SOGROYA - Somapacitan - ORPHAN - EMA/VR/0000264734

Novo Nordisk A/S;

Scope: Oral explanation

Action: Oral explanation to be held on 15 September 2026 at 09:00

Opinion adopted on 21.05.2026.

See 5.3

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 14 September 2026 at 16:00

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

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. IBRANCE - Palbociclib - EMA/VR/0000316536

Pfizer Europe MA EEIG;

Rapporteur: Filip Josephson

Scope: Oral explanation

Action: Oral explanation to be held on 15 September 2026 at 11:00

See 5.1

2.3.2. TRUQAP - Capivasertib - EMA/VR/0000293735

AstraZeneca AB;

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

Scope: Oral explanation

Action: Oral explanation to be held on 16 September 2026 at 09:00

See 5.1

2.3.3. WEGOVY – Semaglutide - EMA/VR/0000327359

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt

Scope: Oral explanation

Action: Oral explanation to be held on 16 September 2026 at 14:00

See 9.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Omalizumab - EMEA/H/C/006756

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.06.2026. List of Questions adopted on 29.01.2026.

3.1.2. Denecimig - EMEA/H/C/006344

prophylaxis of bleeding episodes in patients with haemophilia A

Scope: Opinion

Action: For adoption

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

26.02.2026.

3.1.3. Ensartinib - EMEA/H/C/006757

the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).

Scope: opinion

Action: For adoption

List of Questions adopted on 26.03.2026.

3.1.4. 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: Opinion

Action: For adoption

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

3.1.5. Gefurulimab - EMEA/H/C/006558

Treatment of adult patients with generalised myasthenia gravis (gMG)

Scope: Opinion

Action: For adoption

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

3.1.6. 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: Opinion

Action: For adoption

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

3.1.7. Pertuzumab - EMEA/H/C/006844

treatment of breast cancer in adults

Scope: Opinion

Action: For adoption

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

23.04.2026.

3.1.8. Povorcitinib - EMEA/H/C/006727

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

Scope: Opinion

Action: For adoption

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

3.1.9. 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: Opinion

Action: For adoption

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

3.1.10. Senaparib - EMEA/H/C/006708

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

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

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.06.2026. List of Questions adopted on 26.02.2026.

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

3.2.1. 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 outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

3.2.2. Anselamimab - ORPHAN - EMEA/H/C/006422

Alexion Europe; treatment of adult patients with kappa light chain amyloidosis

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.04.2026.

3.2.3. Baxdrostat - EMEA/H/C/006597

treatment of hypertension in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.05.2026.

3.2.4. Apixaban - EMEA/H/C/006752

prevention of venous thromboembolic events (VTE), stroke and systemic embolism; treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) in adults; treatment of VTE in children from 28 days to < 18 years of age.

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.03.2026.

3.2.5. Bevacizumab - EMEA/H/C/005995

treatment of adult patients with advanced or metastatic cancers

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.04.2026.

3.2.6. Fondaparinux sodium - EMEA/H/C/006824

prevention of venous thromboembolic events (VTE), treatment of deep vein thrombosis (DVT), treatment of pulmonary embolism, treatment of unstable angina and myocardial infarction in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.04.2026.

3.2.7. Orforglipron - EMEA/H/C/006632

treatment of obesity and type 2 diabetes mellitus in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 21.05.2026.

3.2.8. Insulin aspart - EMEA/H/C/006677

treatment of diabetes mellitus from 1 year of age

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.03.2026.

3.2.9. Insulin aspart - EMEA/H/C/006864

treatment of diabetes mellitus from 1 year of age

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.03.2026.

3.2.10. Zopapogene imadenovec - ORPHAN - ATMP - EMEA/H/C/006508

FGK Representative Service GmbH; treatment of respiratory papillomatosis in adults

Scope: List of outstanding issues; Request by the applicant for an extension to the clock stop to respond to the list of outstanding issues to be adopted in September 2026.

Action: For information

List of Questions adopted on 20.03.2026.

3.2.11. Pimicotinib - PRIME - ORPHAN - EMEA/H/C/006383

Merck Europe B.V.; treatment of tenosynovial giant cell tumour in adults and adolescents from 12 years of age

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 26.03.2026.

3.2.12. Ruxolitinib - EMEA/H/C/006793

treatment of myelofibrosis (MF) and 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 21.05.2026.

3.2.13. Sintilimab - EMEA/H/C/006743

treatment of non-squamous non-small cell lung cancer in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.04.2026.

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

3.3.1. Vedolizumab - EMEA/H/C/006853

treatment of Ulcerative Colitis, Crohn’s Disease and pouchitis in adults

Scope: List of questions

Action: For adoption

3.3.2. Doravirine / Islatravir - EMEA/H/C/006642

treatment of HIV-1 infection in adults

Scope: List of questions

Action: For adoption

3.3.3. Venglustat - Orphan - EMEA/H/C/006778

Sanofi B.V.; treatment of Type 3 Gaucher disease (GD3) in adults and children

Scope: List of questions

Action: For adoption

3.3.4. JAPANESE ENCEPHALITIS VIRUS (INACTIVATED) - EMEA/H/C/006764

immunisation against Japanese encephalitis in adults, adolescents, children and infants aged 9 months and older

Scope: List of questions

Action: For adoption

3.3.5. Filgrastim - EMEA/H/C/007009

treatment of neutropenia in adults and children

Scope: List of questions

Action: For adoption

3.3.6. Lunsotogene parvec - ORPHAN - ATMP - EMEA/H/C/006802

Accelerated assessment

Regeneron Ireland Designated Activity Company; treatment of biallelic OTOF variant-associated hearing loss in adults and children

Scope: List of questions

Action: For information

3.3.7. Semaglutide - EMEA/H/C/006847

treatment of type 2 diabetes in adults

Scope: List of questions

Action: For adoption

3.3.8. Asundexian - EMEA/H/C/006640

prevention of ischaemic stroke in adults

Scope: List of questions

Action: For adoption

3.3.9. Cosibelimab - EMEA/H/C/006880

treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma

Scope: List of questions

Action: For adoption

3.3.10. Olanzapine - EMEA/H/C/006637

treatment of schizophrenia in adults

Scope: List of questions

Action: For adoption

3.3.11. Cladribine - ORPHAN - EMEA/H/C/006825

Lipomed GmbH; treatment of acute myeloid leukaemia (AML) in adults

Scope: List of questions

Action: For adoption

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

3.4.1. Aceclidine - EMEA/H/C/006857

treatment of presbyopia in adults

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

Action: For adoption

List of Questions adopted on 23.07.2026.

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

3.5.1. KemSu - Sufentanil / Ketamine - PUMA - EMEA/H/C/006395

Proveca Pharma Limited; treatment of acute pain in children aged 1 to less than 18 years.

Scope: Appointment of re-examination rapporteur; timetable

Action: For adoption

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

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

CATS Consultants GmbH; treatment of synovial sarcoma or leiomyosarcoma

Scope: Timetable

Action: For adoption

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

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

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

Scope: Opinion

Action: For adoption

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

Third party interventions

See 2.2

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

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

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

4.1.1. NEXVIADYME - Avalglucosidase alfa - EMA/X/0000258013

Sanofi B.V.;

Rapporteur: Christian Gartner

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. DAPIVIRINE VAGINAL RING 25 MG - Dapivirine - EMA/X/0000314697

International Partnership For Microbicides;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Jan Neuhauser

Scope: Extension application to add a new strength of 100 mg for dapivirine vaginal delivery system, for vaginal use grouped with a type IA variation (A.2.a) to change the (invented)

name of the medicinal product from 'Dapivirine Vaginal Ring 25 mg' to 'Dapivirine Vaginal Ring'. The RMP (version 2.1) is updated in accordance.

Action: For adoption

4.2.2. IMRALDI - Adalimumab - EMA/X/0000321285

Samsung Bioepis NL B.V.;

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

Scope: Extension application to add a new strength of 80 mg solution for injection This is a grouped line extension application including four quality variations.

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. HERZUMA - Trastuzumab - EMA/X/0000343856

Celltrion Healthcare Hungary Kft.;

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Dirk Mentzer

Scope: Extension application to introduce addition of a new pharmaceutical form, new strength and new route of admin (600 mg solution for injection, subcutaneous use). Due to the introduction of the subcutaneous formulation, the Product Information of the IV formulations (150mg + 420mg powder for concentrate for solution for infusion) were also updated in addition to editorial changes according to the last version of the QRD guidance.

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. ABIRATERONE MYLAN|IBIRON - Abiraterone acetate - WS - EMA/VR/0000291298

Mylan Pharmaceuticals Limited;

Rapporteur: John Joseph Borg, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Grouped application comprising of 3 Extension of indication variations for ABIRATERONE MYLAN, as follows:

C.I.6: to update the currently approved indication for metastatic hormone sensitive prostate cancer (mHSPC) patients to also include non-high risk mHSPC

C.I.6: to include the treatment of newly diagnosed mHSPC in adult men in combination with androgen deprivation therapy (ADT) and docetaxel in patients who are fit for chemotherapy

C.I.6: to include the treatment of newly diagnosed high risk non-metastatic hormone sensitive prostate cancer (HSPC) in adult men in combination with ADT and radiotherapy

The variations are based on literature data. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.2 of the RMP has also been submitted.

Action: For adoption

5.1.2. ANZUPGO - Delgocitinib - EMA/VR/0000315280

LEO PHARMA A/S;

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Hrvoje Rimac, PRAC Rapporteur: Liana Martirosyan

Scope: Extension of indication to include treatment of adolescents 12 years and older with moderate to severe chronic hand eczema (CHE) for whom topical corticosteroids are inadequate or inappropriate for ANZUPGO, based on final results from study LP0133-1426 (DELTA TEEN); this is a phase 3 pivotal clinical trial to evaluate efficacy and safety of twice-daily applications of delgocitinib cream compared with cream vehicle for a 16-week treatment period in adolescents 12-17 years of age with moderate to severe chronic hand eczema. The trial is a randomized, double-blind, vehicle-controlled study. 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 accordingly. Version 1.1 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.

Action: For adoption

5.1.3. AQNEURSA - Levacetylleucine - ORPHAN - EMA/VR/0000354947

Intrabio Ireland Limited;

Rapporteur: Alexandre Moreau, Co-Rapporteur: Frantisek Drafi, PRAC Rapporteur: Dennis Lex

Scope:

A grouped application consisting of:

C.6: Extension of indication to include treatment of Ataxia-telangiectasia for AQNEURSA based on results from study IB1001-303. This is a Phase 3 study to investigate the effects of N-Acetyl-L-Leucine on Ataxia-Telangiectasia (A-T). 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 2.0 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

C.6: Modification of the approved indication for Niemann-Pick type C disease to include treatment of the neurological manifestations in patients aged 4 years and older and weighing at least 15 kg based on results from study IB1001-301. This is a Phase III study to assess the safety and efficacy of N-Acetyl-L-Leucine versus Placebo for the treatment of Niemann-Pick type C disease (NPC). 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.

C.4: Update of sections 4.2 and 6.6 of the SmPC in order to add the use of smaller feeding tubes for enteral administration and to add yoghurt as an alternative administration method for young children based on results from studies IB1001-201, IB1001-202, IB1001 203, and IB1001-301. The Package Leaflet is updated accordingly.

Action: For adoption

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

Glaxosmithkline Vaccines S.r.l.;

Rapporteur: Filip Josephson

Scope: Extension of indication to include active immunisation of infants from 6 weeks of age against invasive meningococcal disease caused by Neisseria meningitidis group B, based on final results from study 205239 (MENB REC 2ND GEN-023 (V72_57)); this is a phase 3b, observer-blind, randomised, placebo-controlled, multi-centre study to assess the safety and immunogenicity of Bexsero and 13-valent pneumococcal vaccine when administered concomitantly with routine vaccines to healthy infants. As a consequence, sections 4.1, 4.2, 4.5, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI.

Action: For adoption

5.1.5. COSENTYX - Secukinumab - EMA/VR/0000326984

Novartis Europharm Limited;

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

Scope: Extension of indication to include treatment of polymyalgia rheumatica in adults who have had an inadequate response to glucocorticoids or who experience a relapse during glucocorticoid taper for COSENTYX, based on the week 52 primary analysis results from study CAIN457C22301 as well as supportive safety data from the Phase 3 study CAIN457R12301 (GCAptAIN) in giant cell arteritis (GCA) patients. Study CAIN457C22301 is a randomized, parallel-group, double-blind, placebo-controlled, multicentre Phase 3 trial to evaluate efficacy and safety of secukinumab administered subcutaneously versus placebo, in combination with a glucocorticoid taper regimen, in patients with polymyalgia rheumatica (PMR). 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 13.0 of the RMP has also been submitted. In addition, the MAH is taking this opportunity to implement updates regarding polysorbate 80 in the PI following the guidance on excipients, and to introduce minor editorial changes to the PI.

Action: For adoption

5.1.6. ELIQUIS - Apixaban - EMA/VR/0000327005

Bristol-Myers Squibb Pfizer EEIG;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include neonates in the currently approved indication treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age for ELIQUIS, based on final results from pivotal study CV185325. This is an open-label, multi-centre, randomized, active controlled trial to provide PK data and data on anti-Xa activity to support the extrapolation of efficacy to children, to evaluate safety and efficacy of apixaban in children (full term neonates to less than 18 years of age) who require anticoagulation for venous thromboembolism, and Study 2, modelling and simulation study to derive dosing of apixaban for use in neonates for treatment of venous thromboembolism; As a consequence, section 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 24.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the Patient Card to mention Eliquis only once on the title page and refer to apixaban throughout the rest of the card.

Action: For adoption

5.1.7. ENHERTU - Trastuzumab deruxtecan - EMA/VR/0000326482

Daiichi Sankyo Europe GmbH;

Rapporteur: Mette Linnert Jensen, PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include treatment of adult patients with HER2-positive breast cancer (IHC3+ or ISH+) who have residual invasive disease after neoadjuvant HER2 targeted treatment for ENHERTU, based on interim results from study DS8201-A-U305

(DESTINY-Breast05); this is a phase 3, multicentre, randomized, open-label, active-controlled study of trastuzumab deruxtecan (T-DXd) versus trastuzumab emtansine (T-DM1) in subjects with high-risk HER2-positive primary breast cancer who have residual invasive disease in breast or axillary lymph nodes following neoadjuvant therapy. 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 10.2 of the RMP has also been submitted.

Action: For adoption

5.1.8. FINTEPLA - Fenfluramine - ORPHAN - EMA/VR/0000350494

UCB Pharma;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include treatment of seizures associated with Dravet syndrome in patients aged 1 to <2 years for FINTEPLA based on results from EP0213 study. EP0213 is an open- label, single-arm, phase 3 study to evaluate safety, tolerability, and pharmacokinetics of fenfluramine HCl (Hydrochloride) in infants 1 year to less than 2 years of age with Dravet syndrome. As 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 5.3 of the RMP has also been submitted. The PI is brought in line with the latest QRD template version 10.4. In addition, the MAH took the opportunity to implement editorial changes to the PI.

Action: For adoption

5.1.9. FINTEPLA - Fenfluramine - EMA/VR/0000350597

UCB Pharma;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include treatment of seizures associated with cyclin-dependant kinase-like 5 (CDKL5) deficiency disorder (CDD) for patients aged 1 year and older as adjunctive therapy in patients inadequately controlled with anti-seizure medicines, for FINTEPLA, based on results from study ZX008-2103 (EP0216). This is a Phase 3, randomized, double-blind, placebo-controlled, fixed-dose, multicentre study to assess the efficacy and safety of fenfluramine HCl when used as adjunctive therapy for seizures in participants with CDD. 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 5.4 of the RMP has also been submitted.

Action: For adoption

5.1.10. GAZYVARO - Obinutuzumab - EMA/VR/0000327013

Roche Registration GmbH;

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

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

C.6.a: Extension of indication to include treatment of adult patients with active systemic lupus erythematosus (SLE) who are receiving standard therapy, for GAZYVARO, based on the results from study CA42750 (ALLEGORY); this is a Phase III, randomized, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of obinutuzumab in patients with SLE treated with standard-of-care therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the SmPC with minor edits. Version 12 of the RMP has also been submitted.

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

Action: For adoption

5.1.11. GAZYVARO - Obinutuzumab - EMA/VR/0000349826

Roche Registration GmbH;

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

Scope: Extension of indication to include treatment of patients 2 years of age and older with idiopathic nephrotic syndrome (INS) for GAZYVARO, based on final results from Phase 3 INShore (WA43380) study; this is a Phase 3, international, multicentre, randomised open label study to evaluate the efficacy and safety of Gazyvaro versus mycophenolate mofetil (MMF) in patients with childhood onset idiopathic nephrotic syndrome. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13 of the RMP has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI.

Action: For adoption

5.1.12. GAZYVARO - Obinutuzumab - EMA/VR/0000350995

Roche Registration GmbH;

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

Scope: Extension of indication to include treatment of adult patients with primary membranous nephropathy (pMN) for GAZYVARO, based on the results from study WA41937 (MAJESTY); this is a Phase III, randomized, open-label active comparator-controlled multicentre study to evaluate efficacy and safety of obinutuzumab in patients with pMN. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor edits to the PI.

Action: For adoption

5.1.13. IBRANCE - Palbociclib - EMA/VR/0000316536

Pfizer Europe MA EEIG;

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

Scope: Extension of indication to include, in combination with anti-HER2 and endocrine therapies, the maintenance treatment of adult patients with HR-positive, HER2-positive locally advanced or metastatic breast cancer (MBC) following induction treatment for IBRANCE, based on the interim results from the open-label Phase 3 study PATINA (AFT-38/WI215662). This is a randomized, open-label Phase 3 study evaluating the efficacy and safety of IBRANCE (palbociclib) in combination with anti-HER2 therapy and endocrine therapy compared to anti-HER2 therapy and endocrine therapy alone as a first-line maintenance therapy (following induction chemotherapy treatment) for patients with HR positive, HER2-positive MBC. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. RMP version 1.10 has also been submitted.

Action: For adoption

See 2.3

5.1.14. JYSELECA - Filgotinib - EMA/VR/0000325892

Alfasigma S.p.A.;

Rapporteur: Kristina Dunder, Co-Rapporteur: Nicolas Beix, PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include treatment of axial spondyloarthritis in adult patients with active radiographic axial spondyloarthritis (r-axSpA) and with active non-radiographic axial spondyloarthritis (nr-axSpA) for JYSELECA, based on interim results from study LPG0634-CL-336 (OLINGUITO); this is a Phase 3 randomized, placebo-controlled, double-blind, parallel-group program to evaluate efficacy and safety of filgotinib in adult subjects with active axial spondyloarthritis. 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 7.1 of the RMP has also been submitted.

Action: For adoption

5.1.15. KEYTRUDA - Pembrolizumab - EMA/VR/0000336194

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

5.1.16. KEYTRUDA/WELIREG - Pembrolizumab, Belzutifan – WS - EMA/VR/0000313634

Merck Sharp & Dohme B.V.;

Rapporteur: Peter Mol, PRAC Rapporteur: Dennis Lex

Scope: Worksharing variation to extend the indication for KEYTRUDA, in combination with belzutifan, and for WELIREG, in combination with pembrolizumab, for the adjuvant treatment of adult patients with clear cell renal cell carcinoma at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions, based on results from study MK-6482-022 (LITESPARK-022). This is a multicentre, double-blind, randomized phase 3 study to compare the efficacy and safety of belzutifan plus pembrolizumab versus placebo plus pembrolizumab, in the adjuvant treatment of clear cell renal cell carcinoma (ccRCC) post nephrectomy. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC for KEYTRUDA and sections 4.1, 4.2, 4.8 and 5.1 of the SmPC for WELIREG are updated. The Package Leaflet for WELIREG is updated in accordance. The RMP version 53.1 for KEYTRUDA and version 2.1 for WELIREG have also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI for KEYTRUDA and WELIREG.

Action: For adoption

5.1.17. OCREVUS - Ocrelizumab - EMA/VR/0000309389

Roche Registration GmbH;

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

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

Action: For adoption

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

Astellas Pharma Europe B.V.;

Rapporteur: Mette Linnert Jensen, PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include Padcev, in combination with pembrolizumab, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment, is

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

Action: For adoption

5.1.19. PEPAXTI - Melphalan flufenamide - EMA/VR/0000350278

Oncopeptides AB;

Rapporteur: Peter Mol, PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include, in combination with dexamethasone, the treatment of adult patients with multiple myeloma who have received at least two prior lines of therapies, whose disease is refractory to lenalidomide and the last line of therapy, for PEPAXTI, based on final results from study OP-103 (OCEAN); this is a randomized, open-label phase 3 study in patients with relapsed or refractory multiple myeloma following 2 to 4 lines of prior therapies and who were refractory to lenalidomide and the last line of therapy. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.4 of the RMP has also been submitted.

Action: For adoption

5.1.20. SOGROYA - Somapacitan- ORPHAN - EMA/VR/0000350795

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Dennis Lex

Scope: Extension of indication for SOGROYA to include treatment of growth failure in children and adolescents with Turner Syndrome (TS) based on final results from three clinical studies, two phase 3 studies (4467 and 4469) and a phase 2 study (4245). 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 5.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the QRD template version 10.4.

Action: For adoption

5.1.21. SUNLENCA – Lenacapavir – EMA/VR/0000343413

Gilead Sciences Ireland Unlimited Company

Rapporteur: Filip Josephson, Co-Rapporteur: Patrick Vrijlandt

Scope: A grouped application consisting of 5 quality variations and:

-Type II variation C.6.a: Modification of indication to include oral bridging in case delay in receiving the scheduled 6-month subcutaneous injection by more than 2 weeks for SUNLENCA, based on final efficacy and safety results from phase 2/3 study GS-US-200-4625 (HTE PWH) and phase 2 study GS-US-200-4334 (TN PWH), supportive data from phase 3 study PURPOSE-1/2, and PopPK simulations. As a consequence, sections 4.1 (for film-coated tablets only) 4.2 and 5.1 of the SmPC have been updated accordingly. The Package Leaflet is updated in accordance.

-Type II variation C.4: Update of sections 4.2 and 5.2 of the SmPC in order to replace the currently approved Phase 2/3 initiation regimen (5-count) with simplified regimen (4-count) for initiation subcutaneous (SC) lenacapavir (LEN) 927 mg on Day 1 along with oral doses of LEN 600 mg administered on Day 1 and Day 2, followed by SC LEN injection 927 mg every 6 months [26 weeks] thereafter based on safety and efficacy data from ongoing Phase 3 studies PURPOSE-1 (GS-US-412-5624) and PURPOSE-2 (GS-US-528-9023), PK comparability data from Phase 1 study GS-US-200-5709, PopPK analyses, and supportive post-marketing utilization data. The Package Leaflet is updated accordingly.

-Type II variation C.4: Update of sections 4.2, 4.5, 4.6, 5.1 and 5.2 in order to update information on pregnancy and lactation, and to include a new alternative subcutaneous injection site thigh, based on PK, efficacy and safety data from ongoing phase 3 study PURPOSE-1 pregnancy dataset, final PK results from Phase 1 study GS-US-200-4540 (alternative injection sites), and PopPK analyses. The Package Leaflet is updated accordingly.

Action: For adoption

5.1.22. TALZENNA - Talazoparib - EMA/VR/0000350865

Pfizer Europe MA EEIG;

Rapporteur: Filip Josephson, Co-Rapporteur: Hrefna Gudmundsdottir, PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include TALZENNA in combination with enzalutamide for the treatment of homologous recombination repair (HRR) gene-mutated metastatic hormone-sensitive prostate cancer (mHSPC), based on interim results from study C3441052 (TALAPRO-3); this is a pivotal multinational, randomised, double-blind Phase 3 study of talazoparib and enzalutamide versus placebo and enzalutamide in men with HRRm mHSPC. 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 3.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4.

Action: For adoption

5.1.23. TECVAYLI - Teclistamab - EMA/VR/0000336274

Janssen Cilag International;

Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Veronika Macurova

Scope: Extension of indication to include treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy, for TECVAYLI as monotherapy, based on interim analysis data from the pivotal study 64007957MMY3006 (MajesTEC-9). This is a Phase 3 randomized study comparing teclistamab monotherapy

versus pomalidomide, bortezomib, dexamethasone (PVd) or carfilzomib, dexamethasone (Kd) in participants with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy, including an anti-CD38 monoclonal antibody and lenalidomide. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Labelling and Package Leaflet are updated accordingly. The RMP version 6.2 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.24. TIVICAY - Dolutegravir - EMA/VR/0000351003

ViiV Healthcare B.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include, in combination with other anti-retroviral medicinal products, the treatment of Human Immunodeficiency Virus (HIV) infected neonates from birth to less than 4 weeks and weighing at least 2 kg for TIVICAY, based on safety, tolerability, and PK data from the study 212161 (IMPAACT 2023) conducted in term (gestational age >=37 weeks) neonates exposed to HIV-1 weighing at least 2 kg and enrolled within 5 days of birth who received dolutegravir (DTG) in addition to standard of care prophylaxis. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 23.0 of the RMP has also been submitted. In addition, the MAH is taking the opportunity to introduce minor amendments to the PI.

Action: For adoption

5.1.25. TUKYSA – Tucatinib - EMA/VR/0000337235

Pfizer Europe MA EEIG;

Rapporteur: Mette Linnert Jensen, PRAC Rapporteur: Jean-Michel Dogné

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

Action: For adoption

5.1.26. 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 and abiraterone versus placebo and 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

See 2.3

5.1.27. WELIREG - Belzutifan - EMA/VR/0000326853

Merck Sharp & Dohme B.V.;

Rapporteur: Peter Mol, PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include in combination with lenvatinib, treatment of adult patients with advanced clear cell renal cell carcinoma that progressed following a PD-1 or PD-L1 inhibitor for WELIREG, based on interim results from study P011V01MK6482 (LITESPARK-011); this is an open-label, randomized, Phase 3 study of belzutifan in combination with lenvatinib vs cabozantinib for treatment in participants with advanced renal cell carcinoma (RCC) who have progressed after prior anti-PD-1/L1 Therapy. 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 1.1 of the RMP has also been submitted.

Action: For adoption

5.1.28. XOFIGO - Radium-223 - EMA/VR/0000351078

Bayer AG;

Rapporteur: Janet Koenig, PRAC Rapporteur: Rugile Pilviniene

Scope: Extension of indication to include the combination treatment with enzalutamide for mCRPC with bone metastases for XOFIGO and modifications of existing indication, based on final results from study PEACE-3; this is a randomized multicentre phase III trial comparing enzalutamide vs. a combination of Ra223 and enzalutamide in asymptomatic or mildly symptomatic castration resistant prostate cancer patients metastatic to bone; 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 8.2 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

5.2.1. Klisyri – Tirbanibulin - EMA/VR/0000335382

Almirall S.A.

Rapporteur: Finbarr Leacy

Scope: CHMP request for PRAC advice;

A grouped application consisting of:

C.4 (Type II): Update of sections 2, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3, 6.5 and 8 of the SmPC to expand treatment field up to 100 cm2 based on results from clinical study M 14867-33 (TirbAKare) and PK study M-14867-01. Study M 14867-33 is a phase 3, multicentre, randomised, double-blind, vehicle controlled, parallel-group study to evaluate the efficacy and safety of tirbanibulin 10 mg/g ointment applied to a treatment field larger than 25 cm2 and up to 100 cm2 in adult participants with actinic keratosis. Study M-14867-01 is a phase 1, open-label, non-randomized, uncontrolled, maximal usage trial (must) to evaluate the systemic exposure and safety of one treatment cycle of tirbanibulin ointment 1% when applied to 100 cm2 of the face or balding scalp in patients with actinic keratosis lesions. The Package Leaflet is updated accordingly.

Action: For adoption

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 - ORPHAN - EMA/VR/0000264734

Novo Nordisk A/S;

Scope: Opinion

"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

Opinion adopted on 21.05.2026.

See 2.2

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

6.1.1. Human serum albumin - EMEA/H/D/006862

application to visible air leaks on the visceral pleura after standard visceral pleural closure techniques during resection of lung parenchyma

Scope: Opinion

Action: For adoption

List of Questions adopted on 26.03.2026.

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

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

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

Scope: Opinion

Action: For adoption

6.3.2. In vitro diagnostic medical device - EMEA/H/D/007016

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

Scope: Opinion

Action: For adoption

6.3.3. 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

6.3.4. In vitro diagnostic medical device - EMEA/H/D/006987

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

Scope: Opinion

Action: For adoption

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. Imsidolimab – H0007036

Treatment of generalized pustular psoriasis (GPP) in adults

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

Action: For adoption

8.1.2. Zoliflodacin – H0007098

Treatment of uncomplicated urogenital gonorrhoea due to *Neisseria gonorrhoeae* in adults and paediatric patients 12 years of age and older, weighing at least 35 kg

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

8.3. Eligibility requests

Report on Eligibility to Centralised Procedure for September 2026

Action: For adoption

8.4. Rapporteurship

Final Outcome of Rapporteurship allocation for September 2026

Action: For adoption

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. KAFTRIO - Ivacaftor / Tezacaftor / Elexacaftor - ORPHAN - EMA/X/0000343848

Vertex Pharmaceuticals (Ireland) Limited;

Rapporteur: Peter Mol, PRAC Rapporteur: Dennis Lex

Scope: Withdrawal of extension of marketing authorisation application

'Extension application to add a new strength, 45 mg/30 mg/60 mg granules, grouped with a type II variation (C.6.a) to extend the existing indication of cystic fibrosis (CF) to paediatric patients aged 1 to less than 6 years who have at least one non-Class I mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, for the granules strengths (60mg/40mg/80mg and 75mg/50mg/100mg). The RMP (version 10.4) is updated in accordance.'

Action: For information

9.1.2. KALYDECO - Ivacaftor - EMA/VR/0000343903

Vertex Pharmaceuticals (Ireland) Limited;

Rapporteur: Antonio Gomez-Outes, PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Withdrawal of variation application

'A grouped application consisting of a quality variation and a Type II variation (C.6.a) Extension of indication in combination with ivacaftor/tezacaftor/elexacaftor for existing treatment of cystic fibrosis (CF) to paediatric patients aged 1 to less than 6 years who have at least one non Class I mutation in the CFTR gene, for KALYDECO granules, based on interim results from study VX22-445-122; this is a phase 3, open-label study evaluating the pharmacokinetics, safety, and tolerability of elexacaftor/tezacaftor/ivacaftor in cystic fibrosis subjects 12 to less than 24 months of age; As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 16.1 of the RMP has also been submitted.

Action: For information

9.1.3. Oslif Breezhaler – Indacaterol – EMEA/H/C/001210

Novartis Europharm Limited; treatment of chronic obstructive pulmonary disease (COPD)

Rapporteur: Thalia Marie Estrup Blicher

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.4. Hirobriz Breezhaler – Indacaterol – EMEA/H/C/001211

Novartis Europharm Limited; treatment of chronic obstructive pulmonary disease (COPD)

Rapporteur: Thalia Marie Estrup Blicher

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.5. Riluzole Zentiva – Riluzole – EMEA/H/C/002622

Zentiva, k.s.; treatment of amyotrophic lateral sclerosis (ALS)

Rapporteur: Thalia Marie Estrup Blicher

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.6. Tepkinly – Epcoritamab - EMA/VR/0000358245

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Peter Mol, PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Update of sections 4.8, 5.1, and 5.2 of the SmPC in order to update the efficacy and safety information based on results from study GCT3013-05 listed as a specific obligation (category 2) in the Annex II; this is a randomized, open-label, phase 3 trial of epcoritamab vs investigator's choice chemotherapy in relapsed/refractory diffuse large B-cell lymphoma.

The Package Leaflet and Annex II are updated accordingly. The RMP version 4.1.0 has also been submitted.

Action: For adoption

9.1.7. WEGOVY – Semaglutide - EMA/VR/0000327359

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Karin Bolin

Scope: Update of sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to reflect clinical results related to adults with overweight/obesity and metabolic dysfunction-associated steatohepatitis (MASH) based on interim results from phase 3a clinical study NN9931-4553 (ESSENCE) as well as three additional clinical trials NN9931-4381, NN9931-4296 and NN9931-4492 in adults with metabolic dysfunction-associated steatotic liver disease and/or MASH; supportive non-clinical results have also been submitted. The Package Leaflet is updated accordingly. The RMP version 10.2 has also been submitted.

Action: For adoption

See 2.3

9.1.8. Ibandronic Acid Teva – Ibandronic Acid – EMEA/H/C/001195

Teva B.V; prevention of skeletal events in patients with breast cancer and bone metastases and treatment of osteoporosis

Rapporteur: Hrefna Gudmundsdottir

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.9. Ocrevus – Ocrelizumab - EMA/VR/0000357152

Roche Registration GmbH

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

Scope: Update of sections 4.4 and 4.6 of the SmPC in order to update information on the use of ocrelizumab therapy pre-conception and up to the first trimester of pregnancy, and on infants potentially exposed to ocrelizumab during pregnancy or via breastfeeding, based on the final analyses of 2 clinical studies - MN42988 (MINORE) and MN42989 (SOPRANINO) and other supportive data (the final CSR from an observational pregnancy registry (WA40063) and a cumulative review of pregnancy, lactation and infant data from women with multiple sclerosis (MS) treated with ocrelizumab from the Company Global Safety Database). The Package Leaflet is updated accordingly. The RMP version 17.0 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial updates and clarifications to the PI.

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

No items

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

No items

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

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

AS Grindeks, Olpha AS

Referral Rapporteur: Ruth Kieran, Referral Co- Rapporteur: Elita Poplavska

Scope: List of outstanding issues / Opinion

Action: For adoption

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

List of outstanding issues adopted on 25.06.2026, 26.03.2026, 16.10.2025

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

Various MAHs

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

Scope: List of outstanding issues/ Opinion

Action: For adoption

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

List of outstanding issues adopted on 25.06.2026, 26.02.2026, 16.10.2025

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

September 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

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Nominated proxy

No items

14.1.2. CHMP membership

No items

14.1.3. CHMP co-opted membership

The 3-year co-opted member mandate for Jan Mueller-Berghaus comes to an end on 13.11.2026. His area of expertise is Quality, safety and efficacy of biological medicinal products, including advanced therapies, and with specific emphasis on vaccines.

The nomination procedure foresees that the CHMP should decide on their areas of expertise in order to proceed with the nominations.

The election is anticipated at the November 2026 plenary meeting.

Action: For endorsement

14.1.4. 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 September 2026

Action: For adoption

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

14.3.1. Biologics Working Party (BWP)

Chair: vacant, Vice-Chair: Andreea Barbu

Action: For adoption

14.3.2. Election of Biosimilar Medicinal Product Working Party (BMWP) vice-chairperson

Following the call for nominations launched in July, CHMP to elect the vice-chair from the candidates who submitted nominations.

Nomination(s) received

Action: For election

14.3.3. Election of Quality Working Party (QWP) vice-chairperson

Following the call for nominations launched in July, CHMP to elect the vice-chair from the candidates who submitted nominations.

Nomination(s) received

Action: For election

14.3.4. QWP and NcWP response to CMDh questions

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

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

Q3-2026 Update of the Business Pipeline report for the human scientific committees

Action: For information

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

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

Action: For discussion

Annex

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

Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1 PMF Certification Dossiers

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

Explanatory notes

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

Oral explanations *(section 2)*

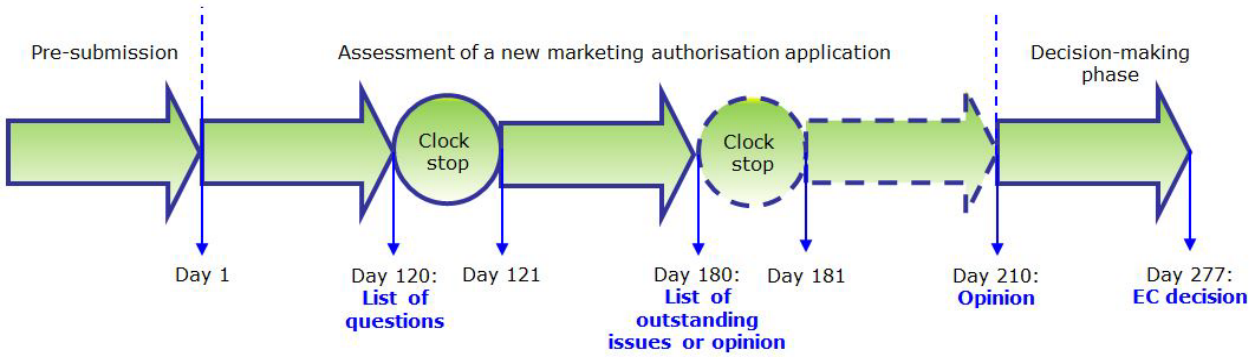
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(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/