09 November 2026
EMA/CHMP/235133/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda for the meeting on 09-12 November 2026
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

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

10 November 2026, 08:30 – 19:30, virtual meeting/room 2C

11 November 2026, 08:30 – 19:30, virtual meeting/room 2C

12 November 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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2026. Reproduction is authorised provided the source is acknowledged.

Table of contents

1. Introduction 8

1.1. Welcome and declarations of interest of members, alternates and experts 8

1.2. Adoption of agenda 8

1.3. Adoption of the minutes 8

2. Oral Explanations 8

2.1. Pre-authorisation procedure oral explanations 8

2.1.1. Apixaban - EMEA/H/C/006752 8

2.1.2. Pimicotinib - PRIME - Orphan - EMEA/H/C/006383 8

2.1.3. Human serum albumin - EMEA/H/D/006862 9

2.1.4. Norucholic acid - Orphan - EMEA/H/C/006515 9

2.2. Re-examination procedure oral explanations 9

2.2.1. KemSu - Sufentanil / Ketamine - PUMA - EMEA/H/C/006395 9

2.2.2. MEPLYFFA - Arimoclomol - Orphan - EMEA/H/C/006736 9

2.3. Post-authorisation procedure oral explanations 10

2.3.1. WELIREG - Belzutifan - EMA/VR/0000326853 10

2.4. Referral procedure oral explanations 10

3. Initial applications 10

3.1. Initial applications; Opinions 10

3.1.1. Aumolertinib - EMEA/H/C/007167 10

3.1.2. Baxdrostat - EMEA/H/C/006597 10

3.1.3. Fondaparinux sodium - EMEA/H/C/006824 10

3.1.4. Insulin aspart - EMEA/H/C/006677 11

3.1.5. Insulin aspart - EMEA/H/C/006864 11

3.1.6. Ruxolitinib - EMEA/H/C/006793 11

3.1.7. Sintilimab - EMEA/H/C/006743 11

3.2. Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable) 11

3.2.1. Hexaminolevulinate - EMEA/H/C/006878 11

3.2.2. Enlicitide - EMEA/H/C/006815 12

3.2.3. Enlicitide - EMEA/H/C/007131 12

3.2.4. Ianalumab - EMEA/H/C/006748 12

3.2.5. Deuruxolitinib - EMEA/H/C/006812 12

3.2.6. Veligrotug - EMEA/H/C/006813 12

3.2.7. Omalizumab - EMEA/H/C/006687 12

3.2.8. Ponatinib - EMEA/H/C/006894 13

3.2.9. Regadenoson - EMEA/H/C/006848 13

3.3. Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable) 13
3.3.1. Deucrictibant - Orphan - EMEA/H/C/006919 13
3.3.2. Vedolizumab - EMEA/H/C/006922 13
3.3.3. Denosumab - EMEA/H/C/006710 13
3.3.4. Denosumab - EMEA/H/C/006719 14
3.3.5. Bilayer engineered collagen hydrogel containing living autologous keratinocytes and fibroblasts - Orphan - ATMP - EMEA/H/C/006357 14
3.3.6. Lemborexant - EMEA/H/C/006924 14
3.3.7. Bevacizumab - EMEA/H/C/006944 14
3.3.8. Human IgG1 monoclonal antibody against insulin like growth factor-1 receptor - EMEA/H/C/006906 14
3.3.9. Atrasentan - Orphan - EMEA/H/C/006447 14
3.4. Update on on-going initial applications for Centralised procedure 15
3.5. Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004 15
3.5.1. KemSu - Sufentanil / Ketamine - PUMA - EMEA/H/C/006395 15
3.5.2. MEPLYFFA - Arimoclomol - Orphan - EMEA/H/C/006736 15
3.6. Initial applications in the decision-making phase 15
3.6.1. Lifyorli - Relacorilant - Orphan - EMEA/H/C/006731 15
3.7. Withdrawals of initial marketing authorisation application 16
3.7.1. Anselamimab - Orphan - EMEA/H/C/006422 16
3.7.2. Qezzaqar - Catequentinib - Orphan - EMEA/H/C/006317 16
4. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008 16
4.1. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion 16
4.1.1. DAPIVIRINE VAGINAL RING 25 MG - Dapivirine - EMA/X/0000314697 16
4.2. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues 16
4.2.1. DOVATO - Dolutegravir / Lamivudine - EMA/X/0000335457 16
4.2.2. TUZULBY - Methylphenidate hydrochloride - EMA/X/0000327555 17
4.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question 17
4.3.1. ALYFTREK - Deutivacaftor / Tezacaftor / Vanzacaftor - ORPHAN - EMA/X/0000358872 17
4.3.2. AUGTYRO - Repotrectinib - EMA/X/0000357212 17
4.3.3. BOPEDIAT - Furosemide - EMA/X/0000358405 18
4.3.4. EBGLYSS - Lebrikizumab - EMA/X/0000358474 18
4.3.5. Krazati - Adagrasib - EMA/X/0000358567 18
4.3.6. Prevenar 20 - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMA/X/0000358440 18

4.4. Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008 19

4.5. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008 19

5. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008 19

5.1. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information 19

5.1.1. BEXSERO - Meningococcal group b vaccine (rDNA, component, adsorbed) - EMA/VR/0000334463 19

5.1.2. COSENTYX - Secukinumab - EMA/VR/0000340032 19

5.1.3. ENFLONSIA - Clesrovimab - EMA/VR/0000358149 20

5.1.4. GAZYVARO - Obinutuzumab - EMA/VR/0000327013 20

5.1.5. GLIOLAN - 5-aminolevulinic acid, Aminolevulinic acid hydrochloride - EMA/VR/000036530221

5.1.6. ISTURISA - Osilodrostat - ORPHAN - EMA/VR/0000315678 21

5.1.7. OPDIVO, YERVOY - Nivolumab, Ipilimumab - WS - EMA/VR/0000350392 21

5.1.8. REZZAYO - Rezafungin, Rezafungin acetate - ORPHAN - EMA/VR/0000363537 22

5.1.9. STEGLATRO - Ertugliflozin - EMA/VR/0000335920 22

5.1.10. STELARA - Ustekinumab - EMA/VR/0000363450 22

5.1.11. SUNLENCA - Lenacapavir - EMA/VR/0000343413 23

5.1.12. TALZENNA - Talazoparib - EMA/VR/0000350865 23

5.1.13. TEIZEILD - Teplizumab - EMA/VR/0000363763 24

5.1.14. TIVICAY - Dolutegravir - EMA/VR/0000351003 24

5.1.15. WELIREG - Belzutifan - EMA/VR/0000326853 24

5.2. Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008 25

5.3. Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008 25

6. Medical devices 25

6.1. Ancillary medicinal substances - initial consultation 25

6.1.1. Human serum albumin - EMEA/H/D/006956 25

6.1.2. Human serum albumin - EMEA/H/D/006862 25

6.2. Ancillary medicinal substances – post-consultation update 26

6.3. Companion diagnostics - initial consultation 26

6.3.1. In vitro diagnostic medical device - EMEA/H/D/007086 26

6.3.2. In vitro diagnostic medical device - EMEA/H/D/007084 26

6.3.3. In vitro diagnostic medical device - EMEA/H/D/007090 26

6.3.4. In vitro diagnostic medical device - EMEA/H/D/007108 26

6.3.5. In vitro diagnostic medical device - EMEA/H/D/007109 26
6.4. Companion diagnostics – follow-up consultation 27
6.4.1. In vitro diagnostic medical device - EMEA/H/D/006987 27

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use) 27
7.1. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use) 27

8. Pre-submission issues 27
8.1. Pre-submission issue 27
8.1.1. Sunvozertinib - EMA/AA/0000377071 27
8.1.2. Gedatolisib - EMA/AA/0000379546 27
8.2. Priority Medicines (PRIME) 28
8.3. Eligibility 28
8.4. Rapporteurship 28

9. Post-authorisation issues 28
9.1. Post-authorisation issues 28
9.1.1. CAMZYOS – Mavacamten - EMA/VR/0000343906 28
9.1.2. Dectova – Zanamivir - EMA/S/0000339464 28
9.1.3. Dectova – Zanamivir - EMA/VR/0000341315 28
9.1.4. Skyrizi – Risankizumab - EMA/VR/0000360512 29
9.1.5. Skyrizi – Risankizumab - EMA/VR/0000370015 29
9.1.6. PEDMARQSI - Sodium thiosulfate – EMEA/H/C/005130 29

10. Referral procedures 30
10.1. Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004 30
10.2. Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004 . 30
10.3. No items Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004 30
10.4. No items Disagreement between Member States on application for medicinal product (potential serious risk to public health) –under Article 29(4) of Directive 2001/83/EC 30
10.5. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC 30
10.6. Community Interests - Referral under Article 31 of Directive 2001/83/EC 30
10.7. Re-examination Procedure under Article 32(4) of Directive 2001/83/EC 30
10.8. Procedure under Article 107(2) of Directive 2001/83/EC 30
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 30
10.10. Procedure under Article 29 of Regulation (EC) 1901/2006 31

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 31

11. Pharmacovigilance issue 31

11.1. Early Notification System 31

12. Inspections 31

12.1. GMP inspections 31

12.2. GCP inspections 31

12.3. Pharmacovigilance inspections 31

12.4. GLP inspections 31

13. Innovation Task Force 32

13.1. Minutes of Innovation Task Force 32

13.2. Innovation Task Force briefing meetings 32

13.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004 32

13.4. Nanomedicines activities 32

14. Organisational, regulatory and methodological matters 32

14.1. Mandate and organisation of the CHMP 32

14.1.1. Nominated proxy 32

14.1.2. CHMP co-opted membership 32

14.1.3. Stakeholder engagement at CHMP 32

14.2. Coordination with EMA Scientific Committees 33

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC) 33

14.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups 33

14.3.1. Scientific Advice Working Party (SAWP) 33

14.3.2. Joint 3Rs Replacement, Reduction and Refinement Working Party (3RsWP) Vice-chair election 33

14.3.3. BWP Vice-chairs election 33

14.3.4. BWP Vaccines Quality Operational Expert Group (BV-OEG) 33

14.4. Cooperation within the EU regulatory network 34

14.5. Cooperation with International Regulators 34

14.6. Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee 34

14.7. CHMP work plan 34

14.8. Planning and reporting 34

14.9. Others 34

15. Any other business 34

15.1. AOB topic 34

15.1.1. GIREX rules 34

Annex 35

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) 35

Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES 35

E.1 PMF Certification Dossiers 35

Annex F - Decision of the Granting of a Fee Reduction/Fee Waiver 35

Explanatory notes 36

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 09-12 November 2026. See November 2026 CHMP minutes (to be published post December 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 09-12 November 2026

1.3. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 03 November 2026

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. 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: Oral explanation

Action: Oral explanation to be held on 11 November 2026 at 16:00

List of Outstanding Issues adopted on 17.09.2026. List of Questions adopted on 26.03.2026.

2.1.2. 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: Oral explanation

Action: Oral explanation to be held on 10 November 2026 at 14:00

List of Outstanding Issues adopted on 17.09.2026. List of Questions adopted on 26.03.2026.

2.1.3. 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: Oral explanation

Action: Oral explanation to be held on 11 November 2026 at 14:00

List of Outstanding Issues adopted on 17.09.2026. List of Questions adopted on 26.03.2026.

See 6.1

2.1.4. 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 11 November 2026 at 11:00

List of Outstanding Issues adopted on 17.09.2026, 23.04.2026. List of Questions adopted on 13.11.2025.

2.2. Re-examination procedure oral explanations

2.2.1. 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: Oral explanation

Action: Oral explanation to be held on 09 November 2026 at 14:00

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

See 3.5

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 10 November 2026 at 09:00

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

See 3.5

2.3. Post-authorisation procedure oral explanations

2.3.1. WELIREG - Belzutifan - EMA/VR/0000326853

Merck Sharp & Dohme B.V.;

Rapporteur: Peter Mol, PRAC Rapporteur: Dennis Lex

Scope: Oral explanation

Action: Oral explanation to be held on 10 November 2026 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. Aumolertinib - EMEA/H/C/007167

treatment of non-small cell lung cancer in adults

Scope: Opinion

Action: For adoption

3.1.2. Baxdrostat - EMEA/H/C/006597

treatment of hypertension in adults

Scope: Opinion

Action: For adoption

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

3.1.3. 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: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.09.2026. List of Questions adopted on 23.04.2026.

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

treatment of diabetes mellitus from 1 year of age

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.09.2026. List of Questions adopted on 26.03.2026.

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

treatment of diabetes mellitus from 1 year of age

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.09.2026. List of Questions adopted on 26.03.2026.

3.1.6. 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: Opinion

Action: For adoption

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

3.1.7. Sintilimab - EMEA/H/C/006743

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.09.2026. List of Questions adopted on 23.04.2026.

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

3.2.1. Hexaminolevulinate - EMEA/H/C/006878

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.06.2026.

3.2.2. Enlicitide - EMEA/H/C/006815

indicated in adults with primary hypercholesterolaemia or mixed dyslipidaemia

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 23.07.2026.

3.2.3. Enlicitide - EMEA/H/C/007131

indicated in adults with primary hypercholesterolaemia or mixed dyslipidaemia

Scope: List of outstanding issues

Action: For adoption

3.2.4. Ianalumab - EMEA/H/C/006748

treatment of Sjögren's disease in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.06.2026.

3.2.5. Deuruxolitinib - EMEA/H/C/006812

treatment of severe alopecia areata in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.06.2026.

3.2.6. Veligrotug - EMEA/H/C/006813

treatment of moderate to severe thyroid eye disease in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.06.2026.

3.2.7. Omalizumab - EMEA/H/C/006687

treatment of asthma in adults and children from 6 years of age, chronic spontaneous urticaria (CSU) in adults and adolescents from 12 years of age, and chronic rhinosinusitis with nasal polyps in adults

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.06.2026.

3.2.8. Ponatinib - EMEA/H/C/006894

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.06.2026.

3.2.9. Regadenoson - EMEA/H/C/006848

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 25.06.2026.

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

3.3.1. Deucrictibant - Orphan - EMEA/H/C/006919

Pharvaris Netherlands B.V.; treatment of acute attacks of hereditary angioedema (HAE) in adult and paediatric patients 12 years of age and older

Scope: List of questions

Action: For adoption

3.3.2. Vedolizumab - EMEA/H/C/006922

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

Scope: List of questions

Action: For adoption

3.3.3. Denosumab - EMEA/H/C/006710

treatment of adult patients with osteoporosis or bone loss

Scope: List of questions

Action: For adoption

3.3.4. Denosumab - EMEA/H/C/006719

prevention of skeletal related events in adults with advanced bone malignancies, and treatment of unresectable bone tumours in adults and adolescents

Scope: List of questions

Action: For adoption

3.3.5. Bilayer engineered collagen hydrogel containing living autologous keratinocytes and fibroblasts - Orphan - ATMP - EMEA/H/C/006357

YES Pharmaceutical Development Services GmbH; treatment of adults and children with partial deep dermal and full-thickness burns

Scope: List of questions

Action: For information

3.3.6. Lemborexant - EMEA/H/C/006924

treatment of adult patients with insomnia

Scope: List of questions

Action: For adoption

3.3.7. Bevacizumab - EMEA/H/C/006944

treatment of adult patients with advanced or metastatic cancers

Scope: List of questions

Action: For adoption

3.3.8. Human IgG1 monoclonal antibody against insulin like growth factor-1 receptor - EMEA/H/C/006906

treatment of thyroid eye disease (TED) in adults

Scope: List of questions

Action: For adoption

3.3.9. Atrasentan - Orphan - EMEA/H/C/006447

Novartis Europharm Limited; indicated for the treatment of adults with primary immunoglobulin A nephropathy

Scope: List of questions

Action: For adoption

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

None

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: Opinion

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.

See 2.2

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

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

Scope: Opinion

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.

The list of questions to the AHEG was adopted via written procedure on 20 October 2026.

See 2.2

3.6. Initial applications in the decision-making phase

3.6.1. Lifyorli - 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: Revised opinion and assessment report adopted via written procedure on 23.10.2026.

Action: For information

Opinion adopted on 17.09.2026. List of Outstanding Issues adopted on 23.07.2026. List of Questions adopted on 26.02.2026.

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Anselamimab - Orphan - EMEA/H/C/006422

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

Scope: Withdrawal of marketing authorisation application

Action: For information

List of Outstanding Issues adopted on 17.09.2026. List of Questions adopted on 23.04.2026.

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

CATS Consultants GmbH; treatment of synovial sarcoma or leiomyosarcoma

Scope: Withdrawal of re-examination of marketing authorisation application

Action: For information

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

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

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

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

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

ViiV Healthcare B.V.;

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

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

Action: For adoption

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

Neuraxpharm Pharmaceuticals S.L.;

Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Dennis Lex

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

The RMP version 1.1 is updated in accordance.

Action: For adoption

4.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question

4.3.1. ALYFTREK - Deutivacaftor / Tezacaftor / Vanzacaftor - ORPHAN - EMA/X/0000358872

Vertex Pharmaceuticals (Ireland) Limited;

Rapporteur: Peter Mol, PRAC Rapporteur: Dennis Lex

Scope: Extension Application to introduce a new pharmaceutical form (granules) in two dosage strengths (100 mg/32 mg/8 mg and 150 mg/48 mg/12 mg) for a new indication, to support inclusion of patients with Cystic Fibrosis aged 2 to less than 6 years old. The RMP version 1.1 has also been submitted.

Action: For adoption

4.3.2. AUGTYRO - Repotrectinib - EMA/X/0000357212

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Eva Skovlund, PRAC Rapporteur: Marina Lesičar

Scope: Extension application to introduce a new pharmaceutical form (oral suspension) associated with a new strength (32mg/ml), grouped with an Extension of Indication to extend existing indication to paediatric patients (age ≥1 month to <18 years) with advanced solid tumours expressing an NTRK gene fusion for AUGTYRO based on interim results from pivotal study CA1271029 (CARE). The RMP version 2.0 has also been submitted.

Action: For adoption

4.3.3. BOPEDIAT - Furosemide - EMA/X/0000358405

Proveca Pharma Limited;

Rapporteur: Jana Klimasová, PRAC Rapporteur: Carla Torre

Scope: Extension application to introduce a new strength (1 mg orodispersible tablets). The application is grouped with a quality variation. The RMP has been updated (version 1.1).

Action: For adoption

4.3.4. EBGLYSS - Lebrikizumab - EMA/X/0000358474

Almirall S.A.;

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Selma Arapovic Dzakula, PRAC Rapporteur: Liana Martirosyan

Scope: Extension application to introduce a new strength (125 mg solution for injection in pre-filled syringe) grouped with an Extension of Indication to extend existing treatment of moderate-to-severe atopic dermatitis to the paediatric patients of 6 months and older for EBGLYSS based on interim results from clinical studies J2T-MC-KGBI (ADorable-1) and J2T-MC-KGBJ (ADorable-2). As part of the application, the MAH is requesting a 1-year extension of the market protection. The RMP version 2.0 has also been submitted.

Action: For adoption

4.3.5. Krazati - Adagrasib - EMA/X/0000358567

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Mette Linnert Jensen, PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension application to add two new strengths (300 mg and 400 mg, film-coated tablets in blister). The RMP (version 3.0) is updated in accordance.

The MAH took also the opportunity to correct the product name in the PI from KRAZATI to Krazati.

Action: For adoption

4.3.6. Prevenar 20 - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMA/X/0000358440

Pfizer Europe MA EEIG;

Rapporteur: Daniela Philadelphy

Scope: addition of a new pharmaceutical form - suspension for injection in multidose container.

Action: For adoption

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

None

4.5. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

None

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. 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

5.1.2. COSENTYX - Secukinumab - EMA/VR/0000340032

Novartis Europharm Limited;

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

Scope: Extension of indication to include treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents 12 years and older with an inadequate response to conventional systemic HS therapy for COSENTYX, based on modelling and extrapolation of existing data. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 14.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI, including to the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.3. ENFLONSIA - Clesrovimab - EMA/VR/0000358149

Merck Sharp & Dohme B.V.;

Rapporteur: Daniela Philadelphy, PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season for ENFLONSIA, based on final results from study MK-1654-007; this is a Phase 3, multicentre, randomized, partially blinded, palivizumab-controlled study to evaluate the safety, efficacy, and pharmacokinetics of MK-1654 in infants and children at increased risk for severe RSV disease. As a consequence, sections 2, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.

Action: For adoption

5.1.4. 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

5.1.5. GLIOLAN - 5-aminolevulinic acid, Aminolevulinic acid hydrochloride - EMA/VR/0000365302

Photonamic GmbH & Co. KG;

Rapporteur: Paulo Paixão, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include visualisation of tumour tissue during surgery for meningioma (WHO Grade I to III) in adults for GLIOLAN, based on the results from the US/EU pivotal Phase 3 clinical study MEN 301; this is a Phase 3 multicentre study of Gleolan (aminolevulinic acid hydrochloride) to enhance visualization of tumour in patients with newly diagnosed or recurrent meningiomas. 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 10.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) brought the PI in line with the latest QRD template version 10.4 and introduced editorial and administrative changes to the PI including an update to the list of local representatives in the Package Leaflet. As part of the application, the MAH is requesting one year of additional data exclusivity.

Action: For adoption

5.1.6. ISTURISA - Osilodrostat - ORPHAN - EMA/VR/0000315678

Recordati Rare Diseases;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include the treatment of endogenous Cushing's syndrome in adolescents and children aged 6 years and older for ISTURISA, based on results from study CLCI699C2203; this is a Phase II, multicentre, open-label, non-comparative study to evaluate the pharmacokinetics, pharmacodynamics, and tolerability of osilodrostat in children and adolescent patients with Cushing's disease. 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 4.1 of the RMP has also been submitted.

Action: For adoption

5.1.7. OPDIVO, YERVOY - Nivolumab, Ipilimumab - WS - EMA/VR/0000350392

Bristol-Myers Squibb Pharma EEIG;

Rapporteur: Carolina Prieto Fernandez, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include nivolumab (OPDIVO) in combination with ipilimumab (YERVOY) for the neoadjuvant treatment of resectable stage III melanoma in adults and adolescents 12 years of age and older, based on results of the NADINA study (CA2096FR; NCT04949113): this is a multicentre, international, open-label, 2-arm, randomised, Phase 3 trial including 423 subjects with Stage III (≤ 3 resectable in-transit metastases allowed) cutaneous or unknown primary melanoma. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflets are updated in accordance. Version 54.0 of the RMP for OPDIVO and version 47.0 of the RMP for YERVOY

have also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI for OPDIVO and YERVOY.

Action: For adoption

5.1.8. REZZAYO - Rezafungin, Rezafungin acetate - ORPHAN - EMA/VR/0000363537

Mundipharma GmbH;

Rapporteur: Fátima Ventura, PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include prophylaxis of invasive fungal disease in adults undergoing allogeneic haematopoietic stem cell transplantation or with haematological malignancies who are expected to have severe neutropenia for ≥10 days for REZZAYO, based on new clinical study results including from the pivotal ReSPECT Phase 3 study (CD101.IV.3.08); this is a Phase 3, multicentre, randomised, double-blind study of the efficacy and safety of rezafungin for injection versus the standard antimicrobial regimen to prevent invasive fungal diseases in adults undergoing allogeneic blood and marrow transplantation. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.9. STEGLATRO - Ertugliflozin - EMA/VR/0000335920

Merck Sharp & Dohme B.V.;

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

Scope: Extension of indication to include treatment of new paediatric population aged 10 years and older for STEGLATRO, based on final results from paediatric study MK-8835-P059/B1521066 (P059). This is a randomised, double-blind, placebo-controlled trial to evaluate the safety and efficacy of two doses of ertugliflozin in paediatric patients from 10 years to less than 18 years of age with type 2 diabetes mellitus and inadequate glycaemic control on metformin therapy, ± insulin. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.5 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to implement minor editorial/formatting corrections.

Action: For adoption

5.1.10. STELARA - Ustekinumab - EMA/VR/0000363450

Janssen Cilag International;

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

Scope: Extension of indication to include treatment of active juvenile psoriatic arthritis in patients 5 years and older for STELARA, based on results from study CNTO1275JPA3001. This is a Phase 3 Multicentre, Open-label Study to Evaluate the Efficacy, Pharmacokinetics,

Safety, and Immunogenicity of Subcutaneously Administered Ustekinumab or Guselkumab in Paediatric Participants With Active Juvenile Psoriatic Arthritis (PSUMMIT-Jr). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet has been updated in accordance. Version 34.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to align the PI with the latest QRD template version 10.4.

Action: For adoption

5.1.11. SUNLENCA - Lenacapavir - EMA/VR/0000343413

Gilead Sciences Ireland Unlimited Company;

Rapporteur: Filip Josephson, Co-Rapporteur: Patrick Vrijlandt

Scope: A grouped application consisting of:

-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. Maximum daily dose and impurity toxicological qualification limits have also been updated. 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 updates 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

5.1.12. 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 + enzalutamide versus placebo + 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

5.1.13. TEIZEILD - Teplizumab - EMA/VR/0000363763

Sanofi Winthrop Industrie;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Terhi Lehtinen

Scope: Extension of indication to include paediatric patients 1 to <8 years of age to the approved indication to delay the onset of Stage 3 type 1 diabetes (T1D) in adult and paediatric patients 8 years of age and older with Stage 2 T1D for TEIZEILD, based on interim results from study PRV-031-005; PRV-031-005 (PETITE-T1D) is a Phase 4, Single arm, open-label study to assess the safety and pharmacokinetics of a 14-day regimen of teplizumab in paediatric Stage 2 Type 1 Diabetes (participants <8 years of age with at least two autoantibodies and dysglycemia). 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. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.14. 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

5.1.15. 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

See 2.3

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

None

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

None

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

6.1.1. Human serum albumin - EMEA/H/D/006956

binding of endogenous growth factors generated by embryos themselves and the chelation of heavy metals that may be present as contaminants in media components, and surfactant to facilitate embryo and gamete manipulation by preventing them from adhering to glass or tissue culture equipment

Scope: List of questions

Action: For adoption

6.1.2. 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 Outstanding Issues adopted on 17.09.2026. List of Questions adopted on 26.03.2026.

See 2.1

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/007086

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

Scope: Opinion

Action: For adoption

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

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

Scope: Opinion

Action: For adoption

6.3.3. In vitro diagnostic medical device - EMEA/H/D/007090

in vitro diagnostic test that uses 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

6.3.4. In vitro diagnostic medical device - EMEA/H/D/007108

detection of HER2 antigen by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin embedded breast carcinoma, gastric carcinoma, and biliary tract cancer (BTC, i.e. gallbladder adenocarcinoma, intrahepatic cholangiocarcinoma, and extrahepatic cholangiocarcinoma) tissue stained on a BenchMark IHC/ISH instrument.

Scope: Opinion

Action: For adoption

6.3.5. In vitro diagnostic medical device - EMEA/H/D/007109

to determine HER2 gene status by enumeration of the ratio of the HER2 gene to

Chromosome 17 by light microscopy

Scope: Opinion

Action: For adoption

6.4. Companion diagnostics – follow-up consultation

6.4.1. 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: Withdrawal of the application for the companion diagnostic consultation procedure

Action: For information

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. Sunvozertinib - EMA/AA/0000377071

as monotherapy is indicated for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR Exon 20 insertion mutations.

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

Action: For adoption

8.1.2. Gedatolisib - EMA/AA/0000379546

is indicated in combination with fulvestrant and palbociclib for the treatment of patients with hormone receptor-positive (HR+) human epidermal growth factor receptor 2-negative (HER2-) locally advanced or metastatic breast cancer following progression on or after at least one line of endocrine therapy

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

Report on Eligibility to Centralised Procedure for November 2026

Action: For adoption

8.4. Rapporteurship

Final Outcome of Rapporteurship allocation for November 2026

Action: For adoption

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. CAMZYOS – Mavacamten - EMA/VR/0000343906

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Kimmo Jaakkola

Scope: Submission of the final report from study CV0271148, listed as a category 3 study in the RMP. This is a meta-analysis to assess cardiovascular safety of mavacamten. RMP version 8.0 has also been submitted.

Action: For adoption

9.1.2. Dectova – Zanamivir - EMA/S/0000339464

Glaxosmithkline Trading Services Limited

Rapporteur: Ingrid Wang, PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Annual reassessment; interim results

Action: For adoption

9.1.3. Dectova – Zanamivir - EMA/VR/0000341315

Glaxosmithkline Trading Services Limited

Rapporteur: Ingrid Wang

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

Action: For adoption

9.1.4. Skyrizi – Risankizumab - EMA/VR/0000360512

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan

Scope: Update of section 4.4 of the SmPC in order to amend an existing warning on infections and tuberculosis, based on clinical trial, postmarketing, and real-world evidence, together with mechanistic insights regarding selective IL-23 inhibition; the Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted.

Action: For adoption

9.1.5. Skyrizi – Risankizumab - EMA/VR/0000370015

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Finbarr Leacy, PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to introduce a new posology regimen of an alternative sub-cutaneous induction dosing scheme for Crohn’s Disease using 360 mg solution for injection in cartridge based on interim results from Phase 3 study M23-784 and final results from Phase 1 studies M24-460 and M25-814. Study M23-784 is a randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of risankizumab subcutaneous induction treatment in subjects with moderately to severely active Crohn's Disease; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted.

Action: For adoption

9.1.6. PEDMARQSI - Sodium thiosulfate – EMEA/H/C/005130

Norgine B.V.

Rapporteur: Elita Poplavska, Co-Rapporteur: Alexandre Moreau

Scope: DHPC and communication plan adopted via written procedure on 24.10.2026

Action: For information

10. Referral procedures

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

No items

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

No items

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

No items

10.4. No items Disagreement between Member States on application for medicinal product (potential serious risk to public health) –under Article 29(4) of Directive 2001/83/EC

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

11. Pharmacovigilance issue

11.1. Early Notification System

November 2026 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

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

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Nominated proxy

No items

14.1.2. CHMP co-opted membership

The 3-year co-opted member mandate of Jan Mueller-Berghaus comes to an end on 13 November 2026. The Committee agreed that a co-opted member should be appointed in the following area of expertise: Quality, safety and efficacy of biological medicinal products, including advanced therapies, and with specific emphasis on vaccines.

A call for nomination of a co-opted member was launched on 02 October 2026.

Nomination(s) received

Action: For election

14.1.3. Stakeholder engagement at CHMP

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 November 2026

Action: For adoption

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

14.3.1. Scientific Advice Working Party (SAWP)

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

Report from the SAWP meeting held on 26-29 October 2026. Table of conclusions

Action: For information

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

14.3.2. Joint 3Rs Replacement, Reduction and Refinement Working Party (3RsWP) Vice-chair election

The 3RsWP Vice-chair has stepped down on 30 June 2026, a call for nominations was launched at the October PROM meeting.

Nominations received

Action: For election

14.3.3. BWP Vice-chairs election

The vice-chair of the CHMP Biologics Working Party (BWP) has been appointed Chair of the BWP following election by the CHMP plenary on 14 October 2026. CHMP agreed at the time, in view of the expansion of responsibilities for the BWP, to the introduction of a second vice-chair for BWP. A call for nominations was launched at the November PROM meeting.

Nominations received

Action: For election

14.3.4. BWP Vaccines Quality Operational Expert Group (BV-OEG)

Third amended EU recommendations for the seasonal influenza vaccine composition for the season 2026/2027. This amendment reflects an update for mRNA influenza vaccines.

Action: For adoption

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

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

Action: For discussion

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)*

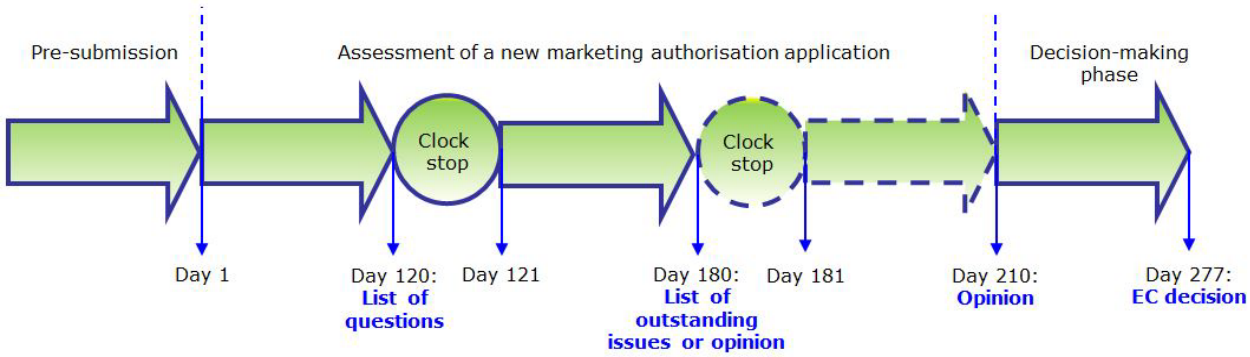
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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