20 April 2026
EMA/CHMP/74711/2026 Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 20-23 April 2026

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

20 April 2026, 09:00 – 19:30, virtual meeting/room 2E

21 April 2026, 08:30 – 19:30, virtual meeting/room 2E

22 April 2026, 08:30 – 19:30, virtual meeting/room 2E

23 April 2026, 08:30 – 15:00, virtual meeting/room 2E

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

Table of contents

1. Introduction 7

1.1. Welcome and declarations of interest of members, alternates and experts 7

1.2. Adoption of agenda 7

1.3. Adoption of the minutes 7

2. Oral Explanations 7

2.1. Pre-authorisation procedure oral explanations 7

2.1.1. Copper (64Cu) oxodotreotide - Orphan - EMEA/H/C/006608 7

2.1.2. Colchicine - EMEA/H/C/006653 7

2.1.3. Alpelisib - Orphan - EMEA/H/C/006539 8

2.2. Re-examination procedure oral explanations 8

2.3. Post-authorisation procedure oral explanations 8

2.3.1. OPDUALAG - Nivolumab / Relatlimab - EMA/VR/0000303785 8

2.3.2. ORLADEYO - Berotralstat - EMA/X/0000268892 8

2.3.3. REZOLSTA - Darunavir / Cobicistat - EMA/X/0000268372 8

2.4. Referral procedure oral explanations 9

3. Initial applications 9

3.1. Initial applications; Opinions 9

3.1.1. Tolebrutinib - EMEA/H/C/006386 9

3.1.2. Onasemnogene abeparvovec - Orphan - ATMP - EMEA/H/C/006498 9

3.1.3. Nerandomilast - EMEA/H/C/006405 9

3.1.4. Palbociclib - EMEA/H/C/006624 9

3.1.5. Plozasiran - Orphan - EMEA/H/C/006579 10

3.1.6. Ranibizumab - EMEA/H/C/006634 10

3.2. Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable) 10

3.2.1. Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated - EMEA/H/C/006692 10

3.2.2. Catequentinib - Orphan - EMEA/H/C/006317 10

3.2.3. Denosumab - EMEA/H/C/006626 10

3.2.4. Levodopa / Carbidopa - EMEA/H/C/006629 11

3.2.5. Leriglitazone - Orphan - EMEA/H/C/006693 11

3.2.6. Insulin efsitora alfa - EMEA/H/C/006388 11

3.2.7. Lerodalcibep - EMEA/H/C/006694 11

3.2.8. Narsoplimab - Orphan - EMEA/H/C/005247 11

3.2.9. Norucholic acid - Orphan - EMEA/H/C/006515 12

3.2.10. Ensitrelvir - EMEA/H/C/006063 12

3.3. Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable) 12
3.3.1. Anselamimab - Orphan - EMEA/H/C/006422 12
3.3.2. Bevacizumab - EMEA/H/C/005995 12
3.3.3. Fondaparinux sodium - EMEA/H/C/006824 12
3.3.4. Tofacitinib - EMEA/H/C/006698 12
3.3.5. Gefurulimab - EMEA/H/C/006558 13
3.3.6. Pertuzumab - EMEA/H/C/006844 13
3.3.7. Sintilimab - EMEA/H/C/006743 13
3.4. Update on on-going initial applications for Centralised procedure 13
3.5. Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004 13
3.6. Initial applications in the decision-making phase 13
3.7. Withdrawals of initial marketing authorisation application 13
3.7.1. Diazoxide choline - Orphan - EMEA/H/C/006576 13
4. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008 14
4.1. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion 14
4.1.1. Gardasil 9 - Human papillomavirus 9-valent Vaccine (Recombinant, adsorbed) - EMA/X/0000310883 14
4.1.2. ORLADEYO - Berotralstat - EMA/X/0000268892 14
4.1.3. REZOLSTA - Darunavir / Cobicistat - EMA/X/0000268372 14
4.1.4. SIVEXTRO - Tedizolid phosphate - EMA/X/0000282136 15
4.1.5. SKYRIZI - Risankizumab - EMA/X/0000296763 15
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. WEGOVY - Semaglutide - EMA/X/0000296344 16
4.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question 16
4.3.1. DAPIVIRINE VAGINAL RING 25 MG - Dapivirine - EMA/X/0000314697 16
4.4. Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008 16
4.5. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008 16
5. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008 17
5.1. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information 17
5.1.1. AGAMREE - Vamorolone - EMA/VR/0000293535 17

5.1.2. AQUIPTA - Atogepant - EMA/VR/0000310717 17
5.1.3. COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000320534 17
5.1.4. CRYSVITA - Burosumab - EMA/VR/0000263400 18
5.1.5. ENHERTU - Trastuzumab deruxtecan - EMA/VR/0000293327 18
5.1.6. ENHERTU - Trastuzumab deruxtecan - EMA/VR/0000322236 19
5.1.7. INAQOVI - Decitabine / Cedazuridine - EMA/VR/0000304730 19
5.1.8. KYINSU - Insulin icodec / Semaglutide - EMA/VR/0000322527 19
5.1.9. OPDIVO - Nivolumab - EMA/VR/0000304938 20
5.1.10. OPDUALAG - Nivolumab / Relatlimab - EMA/VR/0000303785 20
5.1.11. PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA - Pandemic influenza vaccine (H5N1) (live attenuated, nasal) - EMA/VR/0000321324 20
5.1.12. PIQRAY - Alpelisib - EMA/VR/0000317159 21
5.1.13. PRIVIGEN - Human normal immunoglobulin - EMA/VR/0000304719 21
5.1.14. REPATHA - Evolocumab - EMA/VR/0000322435 21
5.1.15. TECVAYLI - Teclistamab - EMA/VR/0000322279 22
5.1.16. TRODELVY - Sacituzumab govitecan - EMA/VR/0000320818 22
5.1.17. TRUQAP - Capivasertib - EMA/VR/0000293735 23
5.1.18. VENCLYXTO - Venetoclax - EMA/VR/0000322237 23
5.1.19. VENCLYXTO - Venetoclax - EMA/VR/0000322240 23
5.1.20. ZERBAXA - Ceftolozane / Tazobactam - EMA/VR/0000320716 24
5.2. Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008 24
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
6.2. Ancillary medicinal substances – post-consultation update 25
6.3. Companion diagnostics - initial consultation 25
6.3.1. In vitro diagnostic medical device - EMEA/H/D/006933 25
6.4. Companion diagnostics – follow-up consultation 25

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use) 25
7.1. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use) 25

8. Pre-submission issues 26
8.1. Pre-submission issue 26
8.1.1. Lunsotogene parvec – H006802 26
8.2. Priority Medicines (PRIME) 26

9. Post-authorisation issues 26

9.1. Post-authorisation issues 26

9.1.1. Avotzma – Tocilizumab – EMEA/H/C/006196 26

9.1.2. FLUENZ - Influenza vaccine (live, nasal) - EMA/VR/0000302352 26

9.1.3. KISQALI - Ribociclib - EMA/VR/0000325484 27

9.1.4. WEGOVY - Semaglutide - EMA/VR/0000327359 27

9.1.5. Qoyvolma – Ustekinumab – EMEA/H/C/006649 27

10. Referral procedures 27

10.1. Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004 27

10.2. Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004 . 27

10.3. Procedure under Articles 5(2) and 10 of Regulation (EC) No 726/2004 28

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 28

10.5. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC.... 28

10.6. Community Interests - Referral under Article 31 of Directive 2001/83/EC 28

10.7. Re-examination Procedure under Article 32(4) of Directive 2001/83/EC..... 28

10.8. Procedure under Article 107(2) of Directive 2001/83/EC 28

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 28

10.10. Procedure under Article 29 of Regulation (EC) 1901/2006..... 28

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 28

11. Pharmacovigilance issue 29

11.1. Early Notification System 29

12. Inspections 29

12.1. GMP inspections 29

12.2. GCP inspections 29

12.3. Pharmacovigilance inspections..... 29

12.4. GLP inspections 29

13. Innovation Task Force 29

13.1. Minutes of Innovation Task Force..... 29

13.2. Innovation Task Force briefing meetings..... 29

13.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004 30

13.3.1. EC Request for EMA scientific opinion 30

13.4. Nanomedicines activities 30

14. Organisational, regulatory and methodological matters 30

14.1. Mandate and organisation of the CHMP 30

14.1.1. Vote by Proxy 30

14.1.2. CHMP membership 30

14.2. Coordination with EMA Scientific Committees 30

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC) 30

14.2.2. Paediatric Committee (PDCO) 30

14.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups 31

14.3.1. Biologics Working Party (BWP) 31

14.3.2. Name Review Group (NRG) 31

14.3.3. Scientific Advice Working Party (SAWP) 31

14.4. Cooperation within the EU regulatory network 31

14.5. Cooperation with International Regulators 31

14.6. Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee 31

14.7. CHMP work plan 31

14.8. Planning and reporting 31

14.9. Others 32

15. Any other business 32

15.1. AOB topic 32

15.1.1. GIREX rules 32

Explanatory notes 33

1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 20-23 April 2026. See April 2026 CHMP minutes (to be published post May 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 20-23 April 2026

1.3. Adoption of the minutes

CHMP minutes for 08-11 December 2025 meeting.

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

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

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

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

Scope: Oral explanation

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

List of Outstanding Issues adopted on 26.02.2026, 11.12.2025. List of Questions adopted on 24.07.2025.

2.1.2. Colchicine - EMEA/H/C/006653

indicated to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in patients with atherosclerotic disease or with multiple risk factors for cardiovascular disease.

Scope: Oral explanation

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

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

2.1.3. Alpelisib - Orphan - EMEA/H/C/006539

Novartis Europharm Limited; treatment of adult and paediatric patients aged 2 years and older with severe or life-threatening manifestations of PIK3CA-related overgrowth spectrum (PROS)

Scope: Oral explanation

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

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

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. OPDUALAG - Nivolumab / Relatlimab - EMA/VR/0000303785

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Peter Mol

Scope: Oral explanation

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

See 5.1

2.3.2. ORLADEYO - Berotralstat - EMA/X/0000268892

Biocryst Ireland Limited

Rapporteur: Finbarr Leacy, Co-Rapporteur: Margareta Bego, PRAC Rapporteur: Julia Pallos

Scope: Oral explanation

Action: Oral explanation to be held on 22 April 2026 at 09:00

See 4.1

2.3.3. REZOLSTA - Darunavir / Cobicistat - EMA/X/0000268372

Janssen Cilag International

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli

Scope: Oral explanation

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

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Tolebrutinib - EMEA/H/C/006386

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 29.01.2026, 11.12.2025, 16.10.2025. List of Questions adopted on 19.06.2025.

3.1.2. Onasemnogene abeparvovec - Orphan - ATMP - EMEA/H/C/006498

Novartis Europharm Limited; treatment of 5q spinal muscular atrophy (SMA)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 20.02.2026. List of Questions adopted on 12.09.2025.

3.1.3. Nerandomilast - EMEA/H/C/006405

treatment of adult patients with Idiopathic Pulmonary Fibrosis (IPF) and adult patients with Progressive Pulmonary Fibrosis (PPF).

Scope: Opinion

Action: For adoption

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

3.1.4. Palbociclib - EMEA/H/C/006624

treatment of breast cancer

Scope: Opinion

Action: For adoption

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

3.1.5. Plozasiran - Orphan - EMEA/H/C/006579

Arrowhead Pharmaceuticals Ireland Limited; treatment of familial chylomicronaemia syndrome (FCS).

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.02.2026. List of Questions adopted on 17.06.2025.

3.1.6. Ranibizumab - EMEA/H/C/006634

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

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.02.2026. List of Questions adopted on 16.10.2025.

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

3.2.1. Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated - EMEA/H/C/006692

prophylaxis of influenza

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 13.11.2025.

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

CATS Consultants GmbH; treatment of synovial sarcoma or leiomyosarcoma

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 13.11.2025.

3.2.3. Denosumab - EMEA/H/C/006626

Prevention of skeletal related events and treatment of giant cell tumour of bone

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 13.11.2025.

3.2.4. Levodopa / Carbidopa - EMEA/H/C/006629

treatment of adult patients with Parkinson’s disease

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 13.11.2025.

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

Minoryx Therapeutics S.L.; treatment of adrenoleukodystrophy

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 13.11.2025.

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

treatment of type 2 diabetes mellitus

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

3.2.7. Lerodalcibep - EMEA/H/C/006694

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

Scope: List of outstanding issues

Action: For adoption

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

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 13.11.2025.

3.2.9. Norucholic acid - Orphan - EMEA/H/C/006515

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 13.11.2025.

3.2.10. Ensitrelvir - EMEA/H/C/006063

treatment of coronavirus disease 2019 (COVID-19)

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 April 2026.

Action: For adoption

List of Questions adopted on 13.11.2025.

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

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

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

Scope: List of questions

Action: For adoption

3.3.2. Bevacizumab - EMEA/H/C/005995

treatment of adult patients with advanced or metastatic cancers

Scope: List of questions

Action: For adoption

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

treatment of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), prevention of venous thromboembolic events (VTE) and treatment of unstable angina and myocardial infarction in adults

Scope: List of questions

Action: For adoption

3.3.4. 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: List of questions

Action: For adoption

3.3.5. Gefurulimab - EMEA/H/C/006558

Treatment of adult patients with generalised myasthenia gravis (gMG)

Scope: List of questions

Action: For adoption

3.3.6. Pertuzumab - EMEA/H/C/006844

treatment of breast cancer in adults

Scope: List of questions

Action: For adoption

3.3.7. Sintilimab - EMEA/H/C/006743

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

Scope: List of questions

Action: For adoption

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

No items

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

No items

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

No items

3.7.1. Diazoxide choline - Orphan - EMEA/H/C/006576

Soleno Therapeutics Europe Limited; treatment of adult and paediatric patients with Prader-Willi syndrome (PWS)

Scope: Withdrawal of marketing authorisation application

Action: For information

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

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. Gardasil 9 - Human papillomavirus 9-valent Vaccine (Recombinant, adsorbed) - EMA/X/0000310883

Merck Sharp & Dohme B.V.

Rapporteur: Kristina Dunder

Scope: Extension application to introduce a new pharmaceutical form suspension for injection. Additionally, product information includes an update to the polysorbate excipient statement in the SmPC and package leaflet, in accordance with the Annex of the Excipients Guideline (Version 4), ensuring alignment with current regulatory standards.

Action: For adoption

4.1.2. ORLADEYO - Berotralstat - EMA/X/0000268892

Biocryst Ireland Limited

Rapporteur: Finbarr Leacy, Co-Rapporteur: Margareta Bego, PRAC Rapporteur: Julia Pallos

Scope: Extension application to introduce a new pharmaceutical form associated with new strengths (78 mg, 96 mg, 108 mg and 132 mg film - coated granules). The new presentations are indicated to include treatment for paediatric patients aged 2 to less than 12 years. The extension application is grouped with a type II clinical variation (C.I.4). 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 and Labelling are updated in accordance. Version 2.1 of the RMP has also been submitted.

Action: For adoption

See 2.3

4.1.3. REZOLSTA - Darunavir / Cobicistat - EMA/X/0000268372

Janssen Cilag International

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Amelia Cupelli

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (600 mg darunavir/90 mg cobicistat dispersible tablet). The new presentation is

indicated to include treatment for paediatric patients aged ≥ 3 years and older weighing at least 15 kg and less than 25 kg. The extension application is grouped with a type II clinical variation (C.I.4) to update sections 4.2, 4.4, 4.8, 5.1 and 5.2 in order to add efficacy and PK data in children based on final results from study GS-US-215-0128; this is a Phase 2/3, Multicentre, Open-label, Multicohort Study Evaluating Pharmacokinetics (PK), Safety, and Efficacy of Cobicistat-boosted Atazanavir (ATV/co) or Cobicistat-boosted Darunavir (DRV/co) and Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 Infected, Virologically Suppressed Paediatric Participants. The Package Leaflet and Labelling are updated in accordance. Version 7.2 of the RMP has also been submitted.

Action: For adoption

See 2.3

4.1.4. SIVEXTRO - Tedizolid phosphate - EMA/X/0000282136

Merck Sharp & Dohme B.V.

Rapporteur: Fátima Ventura, PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension application to introduce a new pharmaceutical form (powder for oral suspension, 200 mg). The RMP (version 8.1) is updated in accordance. Additionally, the marketing authorisation holder took the opportunity to align the PI with the latest QRD template.

Action: For adoption

4.1.5. SKYRIZI - Risankizumab - EMA/X/0000296763

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Finbarr Leacy

Scope: Extension application to introduce a new strength of 55 mg solution for injection grouped with a type II variation C.I.6.a to include treatment of paediatric plaque psoriasis (6 to < 18 years) for Skyrizi, based on final results from study M19-977 and interim results from study M19-973. M19-977 is a randomized, active-controlled, efficacy assessor-blinded study to evaluate pharmacokinetics, safety, and efficacy of risankizumab in patients from 6 to less than 18 years of age with moderate to severe plaque psoriasis; M19-973 is a phase 3 multicentre, single-arm, open-label extension study to assess the safety, tolerability, and efficacy of risankizumab in subjects with moderate to severe plaque psoriasis who have completed participation in study M19-977. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.1, 6.4, 6.5, 6.6, and 8 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.0 of the RMP has also been submitted.

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. WEGOVY - Semaglutide - EMA/X/0000296344

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Mari Thorn

Scope: Extension application to introduce a new pharmaceutical form (tablet), associated with four new strengths (1.5 mg, 4 mg, 9mg and 25 mg) and a new route of administration (oral use).

Action: For adoption

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

4.3.1. 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 The RMP (version 2.1) is updated in accordance.

Action: For adoption

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

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. AGAMREE - Vamorolone - EMA/VR/0000293535

Santhera Pharmaceuticals (Deutschland) GmbH

Rapporteur: Janet Koenig, PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of 2 to <4 year olds for AGAMREE, based on final results from study VBP15-006; this is a phase II open-label, multiple dose study to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and exploratory efficacy of vamorolone in boys ages 2 to <4 years and 7 to <18 years with Duchenne Muscular Dystrophy (DMD) and an updated paediatric extrapolation report referencing 4 to <7-year-old subjects with DMD from Study VBP15-004, compared to the 2 to <4-year-old population from Study VBP15-006. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to make some editorial corrections to SmPC.

Action: For adoption

5.1.2. AQUIPTA - Atogepant - EMA/VR/0000310717

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Janet Koenig, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Rugile Pilviniene

Scope: A grouped application comprised of 1 Type II variation and 3 Type I Quality variations, as follows:

Type II (C.I.6): Extension of indication to include acute treatment of migraine with or without aura in adults, based on interim results from study M24-305; this is a 24-week, global, Phase 3, multicentre, randomized, double blind, placebo-controlled, multiple-migraine attack study with an open label period to evaluate the safety and efficacy of atogepant in adult participants for the acute treatment of migraine (ECLIPSE). 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 2.2 of the RMP has also been submitted.

Action: For adoption

5.1.3. COMIRNATY - COVID-19 mRNA vaccine - EMA/VR/0000320534

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson, PRAC Rapporteur: Liana Martirosyan

Scope: A grouped application consisting of:

C.I.6.a. To modify the approved therapeutic indication by extending from COMIRNATY concentrate for dispersion for injection formulation to Comirnaty dispersion for injection formulation as well as the overall change of posology from 3mcg to 10mcg and dosing regimen simplification (i.e. from 3-dose to a 2-dose primary course for 6 months to <2 years of age and to a single dose for 2 years to <5 years of age) for the active immunization to prevent COVID-19 caused by SARS-CoV-2 in infants and children from 6 months to <5 years without history of completion of COVID-19 primary series based on sub-study A (SSA) phase 2/3 Groups 1-5 of study C4591048 as well as to support the approved 10mcg single dose simplified posology in vaccine-naïve children from 5 to 11 years of age based on sub study E (SSE) of study C4591048, listed as a category 3 study in the RMP. As consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 6.5, 6.6 and 8 of the SmPC and sections 1, 2, 3, 4 and 6 of the PL are updated accordingly. Study C4591048 is a master phase 1/2/3 protocol to investigate the safety, tolerability, and immunogenicity of variant adapted BNT162b2 RNA – based vaccine candidate(s) in healthy children. The updated RMP version 15.2 has also been submitted. In addition, the MAH took the opportunity to implement minor editorial changes in the PI.

C.I.7.b. To delete the 3mcg strength from the Comirnaty Marketing authorisation (EU/1/20/1528/035-036, EU/1/20/1528/042, EU/1/20/1528/050).

Action: For adoption

5.1.4. CRYSVITA - Burosumab - EMA/VR/0000263400

Kyowa Kirin Holdings B.V.

Rapporteur: Kristina Dunder

Scope: Extension of indication to include treatment of X-linked hypophosphataemia (XLH) in paediatric patients from birth to less than 1 year of age for CRYSVITA, based on final results from study BUR-CL207; this is a phase 1/2 Open-label, Multicentre, Non-randomized Study to Evaluate Safety, Pharmacodynamics, Pharmacokinetics and Effect of Burosumab in Paediatric Patients from Birth to Less than 1 Year of Age with XLH; 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.

Action: For adoption

5.1.5. ENHERTU - Trastuzumab deruxtecan - EMA/VR/0000293327

Daiichi Sankyo Europe GmbH

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Peter Mol, PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumours who have received prior treatment and who have no satisfactory alternative treatment options for Enhertu, based on pooled pop-PK analysis and interim results from study D967VC00001 (DESTINY-PanTumor02); this is a

Phase II, Multicentre, Open-label Study to Evaluate the Efficacy and Safety of Trastuzumab Deruxtecan (T-DXd, DS-8201a) for the Treatment of Selected HER2-expressing Tumours; As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI.

Action: For adoption

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

Daiichi Sankyo Europe GmbH

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Carla Torre

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

Action: For adoption

5.1.7. INAQOVI - Decitabine / Cedazuridine - EMA/VR/0000304730

Otsuka Pharmaceutical Netherlands B.V.

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

Scope: Extension of indication to include treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy for INAQOVI in combination with venetoclax, based on interim results from study ASTX727-07; this is a single-arm, open-label pharmacokinetic, safety, and efficacy study of ASTX727 in combination with venetoclax in adult patients with acute myeloid leukaemia; 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 1.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and bring editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

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

Novo Nordisk A/S

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise for KYINSU, based on results from the Phase 3b study NN1535-4988 (COMBINE 4); this is a 40-week study comparing the efficacy and safety of once weekly IcoSema and daily insulin glargine 100 units/mL in

participants with type 2 diabetes inadequately controlled on oral anti-diabetic drugs. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.1.9. OPDIVO - Nivolumab - EMA/VR/0000304938

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Peter Mol, PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include OPDIVO for the treatment of adults and adolescents 12 years of age and older with previously untreated Stage III or IV classical Hodgkin Lymphoma (cHL), based on results from the pivotal study CA2098UT (SWOG 1826), a Phase 3, randomized, open-label study of nivolumab (Opdivo) + AVD (N-AVD) versus brentuximab vedotin (Adcetris) + AVD (Bv-AVD) in patients (age ≥12 years) with newly diagnosed, advanced stage cHL. 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 51.0 of the RMP has also been submitted.

Action: For adoption

5.1.10. OPDUALAG - Nivolumab / Relatlimab - EMA/VR/0000303785

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Peter Mol, PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include patients with tumour cell PD-L1 expression ≥ 1% in the first-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older for OPDUALAG, based on updated descriptive 4-year data from pivotal Study CA224047; this is a randomized, double-blind phase 2/3 study of relatlimab combined with nivolumab versus nivolumab in participants with previously untreated metastatic or unresectable melanoma; As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to remove Annex IV from the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

See 2.3

5.1.11. PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA - Pandemic influenza vaccine (H5N1) (live attenuated, nasal) - EMA/VR/0000321324

AstraZeneca AB

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

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

Action: For adoption

5.1.12. PIQRAY - Alpelisib - EMA/VR/0000317159

Novartis Europharm Limited

Rapporteur: Carolina Prieto Fernandez, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

5.1.13. PRIVIGEN - Human normal immunoglobulin - EMA/VR/0000304719

CSL Behring GmbH

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

Scope: A grouped application consisting of a quality variation together with a C.I.6: Extension of indication to include treatment of patients with measles pre/post-exposure prophylaxis in whom active immunisation is contraindicated or not advised, for PRIVIGEN, in alignment with the IVIg core SmPC (EMA/CHMP/BPWP/94038/2007 Rev); As a consequence, sections 2, 4.1, 4.2 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. The RMP version 9 has also been submitted.

Action: For adoption

5.1.14. REPATHA - Evolocumab - EMA/VR/0000322435

Amgen Europe B.V.

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

Scope: Extension of indication to extend the indication for REPATHA to include adults at high risk for a first cardiovascular event, based on the final results from study 20170625 (VESALIUS); this is a Phase 3, double-blind, randomized, placebo-controlled, multicentre study to evaluate the impact of evolocumab on major cardiovascular events in patients at high cardiovascular risk without prior myocardial infarction or stroke. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, some typographical errors were corrected, and the PI is brought in line with the latest QRD template version.

Action: For adoption

5.1.15. TECVAYLI - Teclistamab - EMA/VR/0000322279

Janssen Cilag International

Rapporteur: Johanna Lähteenvuo, PRAC Rapporteur: Veronika Macurova

Scope: Extension of indication to include in combination with daratumumab treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy for TECVAYLI, based on interim analysis data from the pivotal study MajesTEC-3 (64007957MMY3001). This is an on-going multicentre, randomised, open-label, Phase 3 study to determine whether adding teclistamab to daratumumab (Tec-Dara) is more efficacious than adding pomalidomide/dexamethasone (DPd) or bortezomib/dexamethasone (DVd) to daratumumab in participants with multiple myeloma who previously received 1 to 3 prior line(s) of therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.7, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated accordingly. References to the conditional MA have been removed throughout the document. Additionally, the MAH took the opportunity to update the latest renewal date in section 9 of the SmPC, the list of local representatives in the Package Leaflet and made editorial changes throughout. An updated RMP version 6.1 has been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.16. TRODELVY - Sacituzumab govitecan - EMA/VR/0000320818

Gilead Sciences Ireland Unlimited Company

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

Scope: Extension of indication to include Trodelvy, in combination with pembrolizumab, for the treatment of adult patients with unresectable locally advanced or metastatic TNBC who have not received prior systemic therapy for metastatic disease and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10, based on results from study GS-US-592-6173 (ASCENT-04), which is a phase 3 study of sacituzumab govitecan (IMMU-132) and Pembrolizumab versus treatment of physician’s choice and Pembrolizumab in patients with previously untreated, locally advanced inoperable or metastatic triple-negative breast cancer, whose tumours express PD-L1. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.2 of the RMP has also been submitted.

Action: For adoption

5.1.17. TRUQAP - Capivasertib - EMA/VR/0000293735

AstraZeneca AB

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

Scope: Extension of indication to include Truqap in combination with abiraterone for the treatment of metastatic castration-sensitive prostate cancer characterized by PTEN deficient tumours based on non-clinical and clinical dataset, including interim results from the pivotal study D361BC00001 (CAPItello-281); this is a Phase III double-blind, randomised, placebo-controlled study assessing the efficacy and safety of capivasertib + abiraterone versus placebo + abiraterone as treatment for patients with de novo metastatic hormone-sensitive prostate cancer (mHSPC) characterised by PTEN deficiency; As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.18. VENCLYXTO - Venetoclax - EMA/VR/0000322237

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Filip Josephson, PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include, in combination with ibrutinib, the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) for VENCLYXTO based on the results of the phase 3 study 54179060CLL3011 (GLOW) and phase 2 study PCYC-1142-CA (CAPTIVATE). GLOW is a randomized, open-label, phase 3 study of the combination of ibrutinib plus venetoclax versus chlorambucil plus obinutuzumab for the first-line treatment of subjects with chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL). CAPTIVATE study is a phase 2, multicentre, international, efficacy and safety study assessing treatment with venetoclax plus ibrutinib in subjects with chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL). 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 11.2 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI and to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.19. VENCLYXTO - Venetoclax - EMA/VR/0000322240

Abbvie Deutschland GmbH & Co. KG

Rapporteur: Filip Josephson, PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include, in combination with acalabrutinib with or without obinutuzumab, the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) for VENCLYXTO based on the results from the pivotal study ACE-CL-311/D8221C00001 (AMPLIFY); this is a randomized, multicentre, open-label, Phase 3 study to compare the efficacy and safety of acalabrutinib (ACP-196) in combination with venetoclax with and without obinutuzumab compared to investigator's choice of chemoimmunotherapy in subjects with previously untreated chronic lymphocytic leukaemia without del(17p) or TP53 mutation. 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. The RMP version 11.1 has also been submitted.

Action: For adoption

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

Merck Sharp & Dohme B.V.

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

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

C.I.6: Extension of indication to include treatment of hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP), in paediatric patients from birth to less than 18 years of age for ZERBAXA, based on the final results from study MK-7625A-036. This is a Phase 1, open-label, non-comparative, multicentre clinical study to evaluate the safety, tolerability, and pharmacokinetics of ceftolozane/tazobactam in paediatric participants with nosocomial pneumonia. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated accordingly.

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

Version 4.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, section 5.1 "Susceptibility testing breakpoints" in the SmPC has been brought in line with the Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections.

Action: For adoption

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

No items

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

No items

6. Medical devices

6.1. Ancillary medicinal substances - initial consultation

No items

6.2. Ancillary medicinal substances – post-consultation update

No items

6.3. Companion diagnostics - initial consultation

6.3.1. In vitro diagnostic medical device - EMEA/H/D/006933

detection of the programmed death ligand 1 (PD-L1) by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissues

Scope: Opinion

Action: For adoption

6.4. Companion diagnostics – follow-up consultation

No items

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

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

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. Lunsotogene parvec – H006802

is indicated for the treatment of patients with biallelic OTOF variant-associated hearing loss

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

Action: For adoption

8.2. Priority Medicines (PRIME)

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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Avotzma – Tocilizumab – EMEA/H/C/006196

Celltrion Healthcare Hungary Kft.; treatment of rheumatoid arthritis (RA), treatment of moderate to severe active RA, treatment of active systemic juvenile idiopathic arthritis (sJIA), treatment of juvenile idiopathic polyarthritis (pJIA)

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Beata Maria Jakline Ullrich

Scope: DHPC and Communication Plan adopted via written procedure on 31.03.2026.

Action: For information

9.1.2. FLUENZ - Influenza vaccine (live, nasal) - EMA/VR/0000302352

AstraZeneca AB

Rapporteur: Christophe Focke, PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of sections 4.2 and 4.4 of the SmPC in order to introduce self-administration instructions based on postmarketing data and literature. The Package Leaflet and Labelling updated accordingly. The RMP version 13.1 has also been submitted. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

9.1.3. KISQALI - Ribociclib - EMA/VR/0000325484

Novartis Europharm Limited

Rapporteur: Filip Josephson

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

Action: For adoption

9.1.4. WEGOVY - Semaglutide - EMA/VR/0000327359

Novo Nordisk A/S

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Mari Thorn

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

9.1.5. Qoyvolma – Ustekinumab – EMEA/H/C/006649

Celltrion Healthcare Hungary Kft.; treatment of Crohn's disease and ulcerative colitis

Rapporteur: Ruth Kieran, Co-Rapporteur: Simona Badoi

Scope: Withdrawal of marketing authorisation

Action: For information

10. Referral procedures

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

No items

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

No items

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

No items

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

No items

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

No items

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

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

April 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

13.3.1. EC Request for EMA scientific opinion

Scope: CHMP scientific opinion; Third-party intervention

Action: For adoption

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by Proxy

No items

14.1.2. CHMP membership

No items

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for April 2026

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at April 2026 PDCO

Action: For information

Agenda of the PDCO meeting held on 20-23 April 2026

Action: For information

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

14.3.1. Biologics Working Party (BWP)

Chair: Sean Barry, Vice-Chair: Andreea Barbu

Action: For adoption

14.3.2. Name Review Group (NRG)

Table of Decisions of the NRG meeting held on 15-16 April 2026.

Action: For adoption

14.3.3. Scientific Advice Working Party (SAWP)

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

Report from the SAWP meeting held on 07-10 April 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.

14.4. Cooperation within the EU regulatory network

No items

14.5. Cooperation with International Regulators

No items

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

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

15. Any other business

15.1. AOB topic

15.1.1. GIREX rules

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

Action: For discussion

Explanatory notes

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

Oral explanations *(section 2)*

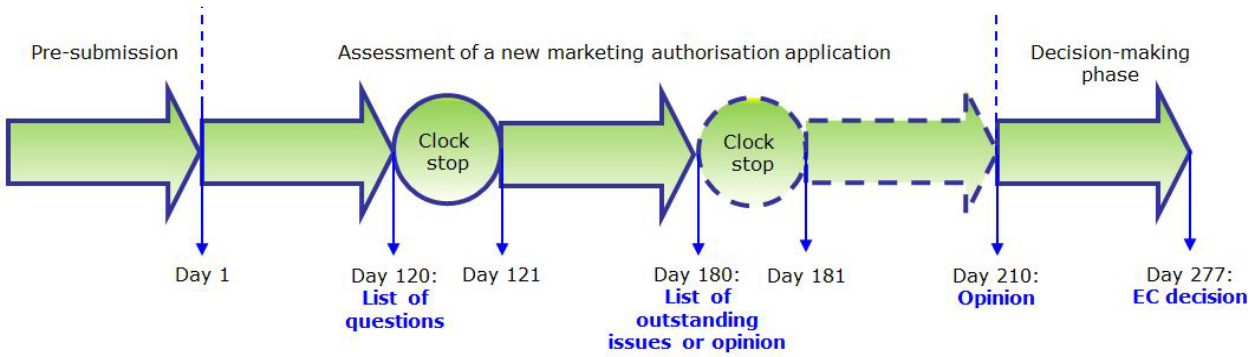
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

Initial applications *(section 3)*

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

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

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



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

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

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

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

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

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

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

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

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

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

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

Re-examination procedures *(section5.3)*

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

Withdrawal of application *(section 3.7)*

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

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

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

Pre-submission issues *(section 8)*

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

Post-authorisation issues *(section 9)*

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

Referral procedures *(section 10)*

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

Pharmacovigilance issues *(section 11)*

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

Inspections Issues *(section 12)*

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

Innovation task force *(section 13)*

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

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

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

Satellite groups / other committees *(section 14.2)*

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

Invented name issues *(section 14.3)*

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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 April 2026
EMA/CHMP/74745/2026

Annex to 20-23 April 2026 CHMP Agenda

Pre-submission and post-authorisations issues

A. PRE-SUBMISSION ISSUES 2
A.1. ELIGIBILITY REQUESTS 2
A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications 2

B. POST-AUTHORISATION PROCEDURES OUTCOMES 2
B.1. Annual re-assessment outcomes 2
B.1.1. Annual reassessment for products authorised under exceptional circumstances 2
B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES 2
B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal 2
B.2.2. Renewals of Marketing Authorisations for unlimited validity 2
B.2.3. Renewals of Conditional Marketing Authorisations 2
B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES 2
B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES 3
B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects 4
B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects 4
B.5.3. CHMP-PRAC assessed procedures 4
B.5.4. PRAC assessed procedures 4
B.5.5. CHMP-CAT assessed procedures 4
B.5.6. CHMP-PRAC-CAT assessed procedures 4
B.5.7. PRAC assessed ATMP procedures 4
B.5.8. Unclassified procedures and worksharing procedures of type I variations 4

D. Annex D - Post-Authorisation Measures (PAMs), (Details on PAMs including description and conclusion, for adoption by CHMP in that given month, or finalised ones with PRAC recommendation and no adoption by CHMP needed) 4

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES 4
E.1. PMF Certification Dossiers 4
E.2. Timetables – starting & ongoing procedures: For information 4

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

F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver 4

G. ANNEX G 4

G.1. Final Scientific Advice (Reports and Scientific Advice letters): 4

G.2. PRIME 4

A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for April 2026: **For adoption**

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

Final Outcome of Rapporteurship allocation for April 2026: **For adoption**

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

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

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

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

B.2.2. Renewals of Marketing Authorisations for unlimited validity

B.2.3. Renewals of Conditional Marketing Authorisations

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection

PRAC recommendations on signals adopted at the PRAC meeting held on 07-10 April 2026

Signal of increased risk of brain oedema in primary mediastinal large B-cell lymphoma (PMBCL) patients

YESCARTA, BREYANZI (CAP) **-** Axicabtagene ciloleucel, lisocabtagene maraleucel

Rapporteur: various, Co-Rapporteur: Claire Beuneu, PRAC Rapporteur: various
PRAC recommendation on a variation for YESCARTA only
Action: For adoption

Signal of congenital megacolon, maternal exposure during pregnancy

ICLUSIG (CAP) - Ponatinib

Rapporteur: Filip Josephson, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Mari Thorn
PRAC recommendation on a variation
Action: For adoption

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

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

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

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

B.5.3. CHMP-PRAC assessed procedures

B.5.4. PRAC assessed procedures

B.5.5. CHMP-CAT assessed procedures

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

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

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

E. Annex E - EMA CERTIFICATION OF PLASMA MASTER FILES

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

E.1. PMF Certification Dossiers

E.2. Timetables – starting & ongoing procedures: For information

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

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

G. ANNEX G

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

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

G.2. PRIME

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