18 May 2026
EMA/CHMP/93949/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 18-21 May 2026

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

18 May 2026, 09:30 – 19:30, virtual meeting/room 2C

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

20 May 2026, 08:30 – 19:30, virtual meeting/room 2C

21 May 2026, 08:30 – 15:00, virtual meeting/room 2C

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 18-21 May 2026. See May 2026 CHMP minutes (to be published post June 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 18-21 May 2026

1.3. Adoption of the minutes

Minutes from PReparatory and Organisational Matters (PROM) meeting held on 11 May 2026.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. Camizestrant - EMEA/H/C/006494

treatment of adults with locally advanced or metastatic breast cancer

Scope: Oral explanation

Third-party intervention

Action: Oral explanation to be held on 19 May 2026 at 16:00

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

2.1.2. Nerandomilast - EMEA/H/C/006405

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

Scope: Oral explanation

Action: Oral explanation to be held on 20 May 2026 at 14:00

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

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

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

Scope: Oral explanation

Action: Oral explanation to be held on 19 May 2026 at 14:00

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

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

2.3.1. WEGOVY - Semaglutide - EMA/X/0000296344

Novo Nordisk A/S

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

Scope: Oral explanation

Action: Oral explanation to be held on 20 May 2026 at 11:00

See 4.1

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Liraglutide - EMEA/H/C/006620

treatment of diabetes and weight management

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 29.01.2026. List of Questions adopted on 24.07.2025.

3.1.2. *Clostridium botulinum*, serotype E, neurotoxin (150 kDa) - EMEA/H/C/006420

temporary improvement in the appearance of moderate to severe lines between the eyebrows when these have an important psychological impact in adult patients

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.03.2026. List of Questions adopted on 13.11.2025.

3.1.3. 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: Opinion

Action: For adoption

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

3.1.4. Liraglutide - EMEA/H/C/006615

treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 29.01.2026. List of Questions adopted on 24.07.2025.

3.1.5. 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: Opinion

Action: For adoption

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

3.1.6. 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: Opinion

Action: For adoption

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

3.1.7. Ranibizumab - EMEA/H/C/006926

treatment of neovascular (wet) age-related macular degeneration (AMD); visual impairment due to diabetic macular oedema (DME); proliferative diabetic retinopathy (PDR); visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO); visual impairment due to choroidal neovascularisation (CNV)

Scope: Opinion

Action: For adoption

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

3.2.1. Azacitidine - EMEA/H/C/006695

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

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

treatment of primary hypercholesterolaemia or mixed dyslipidaemia

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 29.01.2026.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

3.2.5. Arimoclomol - Orphan - EMEA/H/C/006736

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

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

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

3.2.7. Senaparib - EMEA/H/C/006708

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

3.2.8. Ranibizumab - EMEA/H/C/006527

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

3.2.9. Tafamidis - EMEA/H/C/006711

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

3.2.10. Obicetrapib - EMEA/H/C/006516

treatment of primary hypercholesterolaemia or mixed dyslipidaemia

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

3.2.11. Trilaciclib - EMEA/H/C/006709

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

Scope: List of outstanding issues

Action: For adoption

List of Questions adopted on 11.12.2025.

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

3.3.1. Baxdrostat - EMEA/H/C/006597

treatment of hypertension in adults

Scope: List of questions

Action: For adoption

3.3.2. Orforglipron - EMEA/H/C/006632

treatment of obesity and type 2 diabetes mellitus in adults

Scope: List of questions

Action: For adoption

3.3.3. Garetosmab - Orphan - EMEA/H/C/005750

Regeneron Ireland Designated Activity Company; treatment of adult patients with fibrodysplasia ossificans progressiva (FOP)

Scope: List of questions

Action: For adoption

3.3.4. Emapalumab - Orphan - EMEA/H/C/006790

Swedish Orphan Biovitrum AB (publ); Treatment of acute or recurrent secondary haemophagocytic lymphohistiocytosis (sHLH) in adult and paediatric patients (6 months and

older)

Scope: List of questions

Action: For adoption

3.3.5. Cefepime / Zidebactam - EMEA/H/C/006799

Accelerated assessment

treatment of a number of infections in adults

Scope: List of questions

Action: For adoption

3.3.6. Temozolomide - Orphan - EMEA/H/C/006892

Orphelia Pharma; treatment of adults with glioblastoma multiforme and children with malignant glioma

Scope: List of questions

Action: For adoption

3.3.7. Influenza mRNA vaccine - EMEA/H/C/006204

immunisation for the prevention of influenza disease in adults

Scope: List of questions

Action: For adoption

3.3.8. Tanruprubart - Orphan - EMEA/H/C/006782

Sinclair Regulatory Consulting Europe Limited; treatment of Guillain-Barré syndrome in adults and children

Scope: List of questions

Action: For adoption

3.3.9. Ruxolitinib - EMEA/H/C/006793

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

Scope: List of questions

Action: For adoption

3.3.10. Sonrotoclax - EMEA/H/C/006770

treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)

Scope: List of questions

Action: For adoption

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

3.4.1. Gefurulimab - EMEA/H/C/006558

Treatment of adult patients with generalised myasthenia gravis (gMG)

Scope: Request by the Applicant for a change of timetable to respond to the list of questions adopted in April 2026.

Action: For information

List of Questions adopted on 23.04.2026.

3.4.2. Autologous melanoma-derived tumour infiltrating lymphocytes, ex vivo-expanded - ATMP - EMEA/H/C/006563

treatment of melanoma

Scope: Update on the procedure

Oral explanation held at CAT (11-13 May 2026)

Action: For information

List of Outstanding Issues adopted on 20.03.2026. List of Questions adopted on 18.07.2025.

3.4.3. Ensitrelvir - EMEA/H/C/006063

treatment of coronavirus disease 2019 (COVID-19)

Scope: Update on the procedure

Action: For information

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

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

3.5.1. Daybu - Trofinetide - Orphan - EMEA/H/C/006482

Acadia Pharmaceuticals (Netherlands) B.V.; treatment of Rett syndrome in adults and paediatric patients 2 years of age and older

Scope: List of Questions to the SAG-N

Third party intervention

Action: For adoption

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

Questions adopted on 22.05.2025.

3.5.2. Iloperidone Vanda Pharmaceuticals - Iloperidone - EMEA/H/C/006561

Vanda Pharmaceuticals Netherlands B.V.; treatment of schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder

Scope: Withdrawal of re-examination request

Action: For information

Opinion adopted on 26.02.2026. List of Outstanding Issues adopted on 13.11.2025, 18.09.2025. List of Questions adopted on 25.04.2025.

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Bevacizumab - Orphan - EMEA/H/C/006392

Laboratoires Delbert; treatment of adult patients with hereditary haemorrhagic telangiectasia

Scope: Withdrawal of marketing authorisation application

Action: For information

3.7.2. Infliximab - EMEA/H/C/006901

treatment of adults with Rheumatoid arthritis, Crohn’s disease or Ulcerative colitis

Scope: Withdrawal of marketing authorisation application

Action: For information

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. ICLUSIG - Ponatinib - EMA/X/0000296489

Incyte Biosciences Distribution B.V.;

Rapporteur: Filip Josephson, Co-Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Mari Thorn

Scope: Extension application to introduce a new pharmaceutical form associated with a new strength (5 mg hard capsule) grouped with an Extension of Indication to include treatment of paediatric patients aged 6 years and older with chronic phase chronic myeloid leukaemia (CP-CML) who are resistant or intolerant to at least one tyrosine kinase inhibitor for ICLUSIG, based on interim results from study INCB 84344-102 and a final results from early-terminated study Ponatinib-1501; the first is an ongoing open-label, single-arm, Phase 1/2 study evaluating the safety and efficacy of ponatinib MONOTHERAPY for the treatment of R/R leukaemia, lymphomas, or solid tumours in paediatric participants. The second is a Phase 1/2, single-arm, open-label, multicentre study designed to evaluate the safety, tolerability, PK, and efficacy of ponatinib when administered IN COMBINATION WITH multiagent CHEMOTHERAPY in paediatric patients with Ph+ ALL, Ph+ MPAL, or Ph-like ALL who had a relapse, were resistant or intolerant to at least 1 prior BCR-ABL1 TKI therapy, or had the T315I mutation. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.8, 5.1, 5.2, 6.1 and 6.5 of the SmPC are updated. Package Leaflet is updated accordingly. The RMP version 23.4 has also been submitted.

Action: For adoption

4.1.2. SIALANAR - Glycopyrronium - EMA/X/0000287532

Proveca Pharma Limited;

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

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

Action: For adoption

4.1.3. VYNDAQEL - Tafamidis - EMA/X/0000287968

Pfizer Europe MA EEIG;

Rapporteur: Nicolas Beix, PRAC Rapporteur: Zoubida Amimour

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

Action: For adoption

4.1.4. 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

See 2.3

4.1.5. WEGOVY - Semaglutide - EMA/X/0000304416

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt

Scope: Extension application to add a new strength of 7.2 mg.

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

AstraZeneca AB;

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

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

Action: For adoption

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

AstraZeneca AB;

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

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

Action: For adoption

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. IMRALDI - Adalimumab - EMA/X/0000321285

Samsung Bioepis NL B.V.;

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

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

Action: For adoption

4.3.2. ZERCEPAC - Trastuzumab - EMA/X/0000321364

Accord Healthcare S.L.U.;

Rapporteur: Sol Ruiz, PRAC Rapporteur: Dirk Mentzer

Scope: Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (600 mg) and a new route of administration (subcutaneous use).

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

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

Vanda Pharmaceuticals Netherlands B.V.

Scope: Revised assessment report adopted via written procedure on 06.05.2026.

Action: For information

Opinion adopted on 16.03.2026, 11.12.2025. List of Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

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

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

5.1.1. ABIRATERONE MYLAN - Abiraterone acetate - WS - EMA/VR/0000291298

Mylan Pharmaceuticals Limited;

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

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

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

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

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

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

Action: For adoption

5.1.2. BRAFTOVI - Encorafenib - EMA/VR/0000304994

Pierre Fabre Medicament;

Rapporteur: Martin Mengel, PRAC Rapporteur: Rugile Pilviniene

Scope: Extension of indication to include, in combination with cetuximab and FOLFOX, the first line treatment of adult patients with metastatic colorectal cancer with a BRAF V600E mutation for BRAFTOVI, based on the interim results from the pivotal Study C4221015 (BREAKWATER). This is an open-label, multicentre, 3-arm, randomized Phase 3 study of encorafenib plus cetuximab (EC) alone or in combination with mFOLFOX6 versus standard of care chemotherapy in first-line participants with BRAF V600E-mutant mCRC. 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 version 3.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

Action: For adoption

5.1.3. COSENTYX - Secukinumab - EMA/VR/0000326984

Novartis Europharm Limited;

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

Scope: Extension of indication to include treatment of polymyalgia rheumatica in adults who have had an inadequate response to glucocorticoids or who experience a relapse during glucocorticoid taper for COSENTYX, based on the week 52 primary analysis results from study CAIN457C22301 as well as supportive safety data from the Phase 3 study CAIN457R12301 (GCAptAIN) in giant cell arteritis (GCA) patients. Study CAIN457C22301 is a randomized, parallel-group, double-blind, placebo-controlled, multicentre Phase 3 trial to evaluate efficacy and safety of secukinumab administered subcutaneously versus placebo, in combination with a glucocorticoid taper regimen, in patients with polymyalgia rheumatica (PMR). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 13.0 of the RMP has also been submitted. In addition, the MAH is taking this opportunity to implement updates regarding polysorbate 80 in the PI following the guidance on excipients, and to introduce minor editorial changes to the PI.

Action: For adoption

5.1.4. ELIQUIS - Apixaban - EMA/VR/0000327005

Bristol-Myers Squibb / Pfizer EEIG;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Bianca Mulder

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

Action: For adoption

5.1.5. 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/0000326482

Daiichi Sankyo Europe GmbH;

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

Scope: Extension of indication to include treatment of adult patients with HER2-positive breast cancer (IHC3+ or ISH+) who have residual invasive disease after neoadjuvant HER2 targeted treatment for ENHERTU, based on interim results from study DS8201-A-U305 (DESTINY-Breast05); this is a phase 3, multicentre, randomized, open-label, active-controlled study of trastuzumab deruxtecan (T-DXd) versus trastuzumab emtansine (T-DM1) in subjects with high-risk HER2-positive primary breast cancer who have residual invasive disease in breast or axillary lymph nodes following neoadjuvant therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.2 of the RMP has also been submitted.

Action: For adoption

5.1.7. ERBITUX - Cetuximab - EMA/VR/0000326978

Merck Europe B.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include in combination with encorafenib treatment of with metastatic colorectal cancer (mCRC) with a BRAF V600E mutation, who have received prior systemic therapy for ERBITUX, based on final results from study ARRAY-818-302 (BEACON-CRC); this is a randomized, open label, 3-arm Phase 3 design that investigated the BRAF inhibitor, encorafenib in combination with cetuximab with or without the mitogen-activated protein kinase (MEK) inhibitor, binimetinib, in patients with BRAF V600E-mutated mCRC whose disease has progressed after 1 or 2 prior regimens in the metastatic setting. 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 21.1 of the RMP has also been submitted.

Action: For adoption

5.1.8. ERBITUX - Cetuximab - EMA/VR/0000327014

Merck Europe B.V.;

Rapporteur: Filip Josephson, PRAC Rapporteur: Mari Thorn

Scope: Extension of indication to include in combination with encorafenib and mFOLFOX6 treatment of metastatic colorectal cancer with a BRAF V600E mutation for ERBITUX, based on interim results from study C4221015 (BREAKWATER); this is an open-label, multicentre, 3-arm, randomized phase 3 study of EC alone or in combination with mFOLFOX6 versus standard-of-care chemotherapy in first-line participants with BRAF V600E-mutant mCR. 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 21.1 of the RMP has also been submitted.

Action: For adoption

5.1.9. FASENRA - Benralizumab - EMA/VR/0000288520

AstraZeneca AB;

Rapporteur: Paulo Paixão, PRAC Rapporteur: David Olsen

Scope: Extension of indication to include treatment of adults and adolescents with hypereosinophilic syndrome (HES) for FASENRA, based on interim results from study D3254C00001 (NATRON); this is a multicentre, randomised, double-blind, parallel-group, placebo-controlled, 24-week phase III study with an open-label extension to evaluate the efficacy and safety of benralizumab in patients with HES; 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 8 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial and administrative updates to the PI and to update the list of local representatives in the Package Leaflet. Furthermore, section 6.5 of the SmPC was updated.

Action: For adoption

5.1.10. GAZYVARO - Obinutuzumab - EMA/VR/0000327013

Roche Registration GmbH;

Rapporteur: Thalia Marie Estrup Blicher, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Mari Thorn

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

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

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

Action: For adoption

5.1.11. HETRONIFLY - Serplulimab - EMA/VR/0000290021

Accord Healthcare S.L.U.;

Rapporteur: Eva Skovlund, PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include HETRONIFLY in combination with carboplatin and nab-paclitaxel for the first-line treatment of adult patients with unresectable, locally advanced or metastatic squamous non-small cell lung carcinoma based on final results from study HLX10-004-NSCLC303; this is a randomized, double-blind, multi-centre, phase III pivotal study, to compare the clinical efficacy and safety of serplulimab combined with chemotherapy (carboplatin and nab-paclitaxel) versus placebo combined with chemotherapy (carboplatin and nab-paclitaxel). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP Version 1.3 has been submitted.

Action: For adoption

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

Bayer AG;

Rapporteur: Ewa Balkowiec Iskra, PRAC Rapporteur: Bianca Mulder

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

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

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

Version 4.1 of the RMP has also been submitted.

Action: For adoption

5.1.13. JYSELECA - Filgotinib - EMA/VR/0000325892

Alfasigma S.p.A.;

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

Scope: Extension of indication to include treatment of axial spondyloarthritis in adult patients with active radiographic axial spondyloarthritis (r-axSpA) and with active non-radiographic axial spondyloarthritis (nr-axSpA) for JYSELECA, based on interim results from study LPG0634-CL-336 (OLINGUITO); this is a Phase 3 randomized, placebo-controlled, double-blind, parallel-group program to evaluate efficacy and safety of filgotinib in adult subjects with active axial spondyloarthritis up to Week 52. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has also been submitted.

Action: For adoption

5.1.14. KEYTRUDA - Pembrolizumab - EMA/VR/0000312515

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to include in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment of adults with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin containing chemotherapy for KEYTRUDA, based on interim results from study KEYNOTE-905, an open label, randomised, interventional phase 3 study. As consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 51.1 of the RMP has also been submitted.

Action: For adoption

5.1.15. KEYTRUDA - Pembrolizumab - EMA/VR/0000316576

Merck Sharp & Dohme B.V.;

Rapporteur: Paolo Gasparini, PRAC Rapporteur: Bianca Mulder

Scope: A grouped application consisting of:

C.I.6. Extension of indication for KEYTRUDA for subcutaneous use to include treatment of melanoma for adolescents aged 12 years and older based on an extrapolation approach from adults to adolescents using pharmacokinetics modelling and simulation. 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 52.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to implement some minor editorial and formatting changes in the PI.

C.I.6. Extension of indication for KEYTRUDA for subcutaneous use to include treatment of classical Hodgkin lymphoma for adolescents aged 12 years and older based on an extrapolation approach from adults to adolescents using pharmacokinetics modelling and simulation. 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.

Action: For adoption

5.1.16. LEQVIO - Inclisiran - EMA/VR/0000293324

Novartis Europharm Limited;

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

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

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

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

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

Action: For adoption

5.1.17. MAVIRET - Glecaprevir / Pibrentasvir - EMA/VR/0000316551

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Nicolas Beix, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Extension of indication to include treatment of Acute HCV for MAVIRET, based on final results from study M20-350; this is a multicentre, single-arm prospective study to evaluate safety and efficacy of GLE/PIB 8-week treatment in adults and adolescents with acute hepatitis C virus (HCV) infection. 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 10.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder took the opportunity to update the list of local representatives in the Package Leaflet.

Action: For adoption

5.1.18. MOUNJARO - Tirzepatide - EMA/VR/0000310637

Eli Lilly Nederland B.V.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Bianca Mulder

Scope: Extension of indication to reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, or stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease for MOUNJARO, based on final results from study I8F-MC-GPGN (SURPASS-CVOT). SURPASS-CVOT was a Phase 3, event-driven, multicentre, international, randomized, double-blind, active-comparator, parallel-group study to assess the effect of tirzepatide versus dulaglutide on major adverse cardiovascular events in participants with type 2 diabetes. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the PI.

Action: For adoption

5.1.19. PADCEV - Enfortumab vedotin - EMA/VR/0000312495

Astellas Pharma Europe B.V.;

Rapporteur: Thalia Marie Estrup Blicher, PRAC Rapporteur: Eva Jirsová

Scope: Extension of indication to include PADCEV, in combination with pembrolizumab, for use as neoadjuvant treatment and continued as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle-invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy, based on interim results from study EV-303/KN-905; this is a randomized phase 3 study evaluating cystectomy with perioperative pembrolizumab and cystectomy with perioperative enfortumab, vedotin and pembrolizumab versus cystectomy alone in participants who are cisplatin-ineligible or decline cisplatin with muscle-invasive bladder cancer. 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 5.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, and to bring the PI in line with the latest QRD template version 10.4.

Action: For adoption

5.1.20. PALYNZIQ - Pegvaliase - EMA/VR/0000302032

Biomarin International Limited;

Rapporteur: Patrick Vrijlandt, Co-Rapporteur: Alexandre Moreau, PRAC Rapporteur: Rhea Fitzgerald

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

C.I.6: Extension of indication to include treatment of adolescent patients aged 12 to <16 years with phenylketonuria (PKU) for PALYNZIQ, based on interim results from study 165-306; this is a Phase 3 open label, randomized, controlled, 2-arm, multicentre study designed to evaluate the safety and efficacy of pegvaliase in adolescent participants 12 to <18 years old with PKU. As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the PI to include editorial changes and remove references to the route of administration of adrenaline (injection) to allow physicians to prescribe any approved adrenaline device.

C.I.4: Update of section 4.6 of the SmPC in order to update information on pregnancy based on a comprehensive assessment of all pregnancy and breastfeeding reports received from all sources.

The RMP version 5.0 has also been submitted.

Action: For adoption

5.1.21. RINVOQ - Upadacitinib - EMA/VR/0000312506

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include the treatment of severe alopecia areata (AA) in adult and adolescents 12 years and older for RINVOQ, based on interim results from 2 pivotal, Phase 3 studies (M23-716 Study 1 and Study 2); those are randomized, double blind, placebo-controlled, multi-centre studies of Upadacitinib evaluating the efficacy and safety of Upadacitinib 15 mg QD and 30 mg QD versus placebo for the treatment of severe AA in subjects who are at least 12 years of age. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Annex II are updated in accordance. Version 18.0 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

CHMP Request for PRAC advice.

Action: For adoption

5.1.22. RINVOQ - Upadacitinib - EMA/VR/0000325958

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Kristina Dunder, PRAC Rapporteur: Petar Mas

Scope: Extension of indication to include the treatment of non-segmental vitiligo in adults and adolescents 12 years and older who are candidates for systemic therapy, for RINVOQ, based on results from the two replicate Phase 3 studies M19-044: study 1 (R&D/25/1342) and study 2 (R&D/25/1343), as well as from integrated long-term safety data. Study 1 and study 2 are Phase 3, global, randomized, double-blind, placebo-controlled multi-centre studies that evaluate the safety and efficacy of upadacitinib in adult and adolescent patients with non-segmental vitiligo. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet has been updated in accordance. Version 19.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.23. SOGROYA - Somapacitan - EMA/VR/0000264734

Novo Nordisk A/S;

Rapporteur: Patrick Vrijlandt, PRAC Rapporteur: Dennis Lex

Scope: Grouped extension of indication application to include treatment of children born small for gestational age (SGA), Noonan syndrome (NS) and idiopathic short stature (ISS) for SOGROYA, based on interim results from the pivotal, confirmatory phase 3 study NN8640-4467 supported by the phase 3 study NN8640-4469 and the phase 2 study NN8640-4245. Study 4467 is a study comparing the effect and safety of once weekly dosing of somapacitan with daily Norditropin as well as evaluating long-term safety of somapacitan in a basket study design in children with short stature either born small for gestational age or with Turner syndrome, Noonan syndrome, or idiopathic short stature. Study 4469 is a study evaluating the safety and efficacy of once-weekly dosing of somapacitan in a basket study design in paediatric participants with short stature either born small for gestational age or with turner syndrome, Noonan syndrome or idiopathic short stature. Study 4245 is a dose-finding trial evaluating the effect and safety of once-weekly treatment of somapacitan compared to daily Norditropin in children with short stature born small for gestational age with no catch-up growth by 2 years of age or older. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.24. STELARA - Ustekinumab - EMA/VR/0000316205

Janssen Cilag International;

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

Scope: Extension of indication to include treatment of ulcerative colitis in paediatric patients from the age of 2 years and older for STELARA, based on results from study CNTO1275PUC3001; this is a Phase 3 Study of the Efficacy, Safety and Pharmacokinetics of Ustekinumab as Open-label Intravenous Induction Treatment Followed by Randomized Double-blind Subcutaneous Ustekinumab Maintenance in Paediatric Participants (2 to <18 Years of Age) with Moderately to Severely Active Ulcerative Colitis. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 32.2 of the RMP has also been submitted.

Action: For adoption

5.1.25. TEPKINLY - Epcoritamab - EMA/VR/0000311043

Abbvie Deutschland GmbH & Co. KG;

Rapporteur: Peter Mol, PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Extension of indication to include in combination with rituximab and lenalidomide treatment of patients with relapsed/refractory follicular lymphoma (FL) for Tepkinly, based on interim results from study M20-638; this is a Phase 3, open-label study to evaluate safety and efficacy of epcoritamab in combination with rituximab and lenalidomide (R2) compared to R2 in subjects with relapsed or refractory follicular lymphoma (EPCORE FL-1). 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 3.2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor changes to the PI. As part of the application, the MAH is requesting a 1-year extension of the market protection.

Action: For adoption

5.1.26. TRIMBOW - Beclometasone / Formoterol / Glycopyrronium bromide - EMA/VR/0000315173

Chiesi Farmaceutici S.p.A.;

Rapporteur: Janet Koenig, PRAC Rapporteur: Jan Neuhauser

Scope: Extension of indication to include treatment of asthma for TRIMBOW 88/5/9 mcg DPI, based on existing data from the development of Trimbow 87/5/9 mcg pressurised metered dose inhaler in COPD and Asthma, Trimbow 172/5/9 mcg pressurised metered dose inhaler in Asthma and Trimbow 88/5/9 mcg Dry powder inhaler in COPD, as well as on new data coming from the PK 2 study (CLI-05993BB1-01) and on the interim results of the ongoing PASS (TRIBE) study in COPD. As a consequence, sections 4.1, 4.2, 4.4, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 11.1 of the RMP has also been submitted.

Action: For adoption

5.1.27. TRODELVY - Sacituzumab govitecan - EMA/VR/0000312649

Gilead Sciences Ireland Unlimited Company;

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

Scope: Extension of indication for treatment of adult patients with PD-L1-negative metastatic triple- negative breast cancer or PD-L1-positive metastatic triple-negative breast cancer previously treated with an anti-PD-(L)1 agent in the curative setting for Trodelvy, based on results from study GS-US-592-6238 (ASCENT-03), which is a phase 3 study of sacituzumab govitecan (IMMU-132) versus treatment of physician's choice (TPC) in Patients With Previously Untreated, Locally Advanced, Inoperable or Metastatic Triple-Negative Breast Cancer Whose Tumours Do Not Express PD-L1 or in Patients Previously Treated With Anti-PD-(L)1 Agents in the Early Setting Whose Tumours Do Express PD-L1. As a consequence, sections 4.1, 4.4, 4.5, 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

5.1.28. WELIREG - Belzutifan - EMA/VR/0000326853

Merck Sharp & Dohme B.V.;

Rapporteur: Peter Mol, PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include in combination with lenvatinib, treatment of adult patients with advanced clear cell renal cell carcinoma that progressed following a PD-1 or PD-

L1 inhibitor for WELIREG, based on interim results from study P011V01MK6482 (LITESPARK-011); this is an open-label, randomized, Phase 3 study of belzutifan in combination with lenvatinib vs cabozantinib for treatment in participants with advanced renal cell carcinoma (RCC) who have progressed after prior anti-PD-1/L1 Therapy. As a consequence, sections 4.1, 4.2, 4.8, and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted.

Action: For adoption

5.1.29. WELIREG/ Keytruda – Belzutifan/ Pembrolizumab - WS - EMA/VR/0000313634

Merck Sharp & Dohme B.V.;

Rapporteur: Peter Mol, PRAC Rapporteur: Dennis Lex

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

Action: For adoption

5.2. 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/006973

detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) to include use as an aid in identifying epithelial ovarian, fallopian tube, or primary peritoneal carcinoma patients for treatment with KEYTRUDA

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

No items

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. Natpar - Parathyroid hormone – EMEA/H/C/003861

Takeda Pharmaceuticals; treatment of hypoparathyroidism

Rapporteur: Karin Janssen van Doorn, Co-Rapporteur: Beata Maria Jakline Ullrich

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.2. Inflectra – Infliximab - EMEA/H/C/002778

Pfizer Europe MA EEIG; treatment of Rheumatoid arthritis, Adult and Paediatric Crohn's disease, Ulcerative colitis, Ankylosing spondylitis, Psoriatic arthritis, Psoriasis

Rapporteur: Outi Mäki-Ikola, Co-Rapporteur: Kristina Dunder

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.3. Pritor – Telmisartan – EMEA/H/C/000210

Bayer AG; treatment of hypertension and reduction of cardiovascular morbidity

Rapporteur: Paolo Gasparini, Co-Rapporteur: Janet Koenig

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.4. Kinzalmono - Telmisartan - EMEA/H/C/000211

Bayer AG; treatment of hypertension and reduction of cardiovascular morbidity

Rapporteur: Paolo Gasparini, Co-Rapporteur: Janet Koenig

Scope: Withdrawal of marketing authorisation

Action: For information

9.1.5. Darzalex – Daratumumab - EMA/VR/0000293615

Janssen Cilag International

Rapporteur: Boje Kvorning Pires Ehmsen

Update of sections 4.2, 4.8, 5.1, and 5.2 of the SmPC in order to update the product information based on final results from study 54767414ALL2005; this is an open-label,

multicentre, phase 2 study evaluating the efficacy and safety of daratumumab in paediatric and young adult participants ⩾1 and ⩽30 years of age with relapsed/refractory precursor B-cell or T-cell acute lymphoblastic leukaemia or lymphoblastic lymphoma; the Package Leaflet is updated accordingly.

Scope: Withdrawal of type II variation

Action: For information

Opinion adopted on 13.11.2025.

9.1.6. NINLARO – Ixazomib - EMA/VR/0000301996

Takeda Pharma A/S

Rapporteur: Paolo Gasparini

Update of sections 4.2, 4.8, 5.1, and 5.2 of the SmPC based on final results from study T2017-002; this is an open-label, single arm study designed to assess the pharmacokinetics and safety (in phase 1) and efficacy (in phase 2) of ixazomib as a treatment option for children and adolescents with relapsed/refractory acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LLy) with or without extramedullary disease. In addition, the MAH requested a PIP compliance statement and an extension to the orphan exclusivity period.

Scope: Withdrawal of type II variation

Action: For information

Opinion adopted on 11.12.2025.

9.1.7. Otulfi – Ustekinumab - EMA/VR/0000296289

Fresenius Kabi Deutschland GmbH

Rapporteur: Ruth Kieran, PRAC Rapporteur: Rhea Fitzgerald

Scope: Revised opinion adopted via written procedure on 30.04.2026

Action: For information

Opinion adopted on 12.02.2026.

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

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

Action: For information

12. Inspections

12.1. GMP inspections

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

12.2. GCP inspections

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

12.3. Pharmacovigilance inspections

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

12.4. GLP inspections

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

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

No items

13.2. Innovation Task Force briefing meetings

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

No items

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

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Vote by Proxy

No items

14.1.2. CHMP membership

No items

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

Agenda of the upcoming SRLM.

CHMP: Emilia Mavrokordatou

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 May 2026.

Action: For adoption

14.2.2. Paediatric Committee (PDCO)

PIPs reaching D30 at May 2026 PDCO.

Action: For information

Agenda of the PDCO meeting held on 19-22 May 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. Scientific Advice Working Party (SAWP)

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

Report from the SAWP meeting held on 04-07 May 2026. Table of conclusions

Action: For information

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

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

Scope: Amended EU recommendations for the seasonal influenza vaccine composition for the season 2026/2027 adopted via written procedure on 05.05.2026.

Action: For information

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

Scope: Second amended EU recommendations for the seasonal influenza vaccine composition for the season 2026/2027.

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

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)*

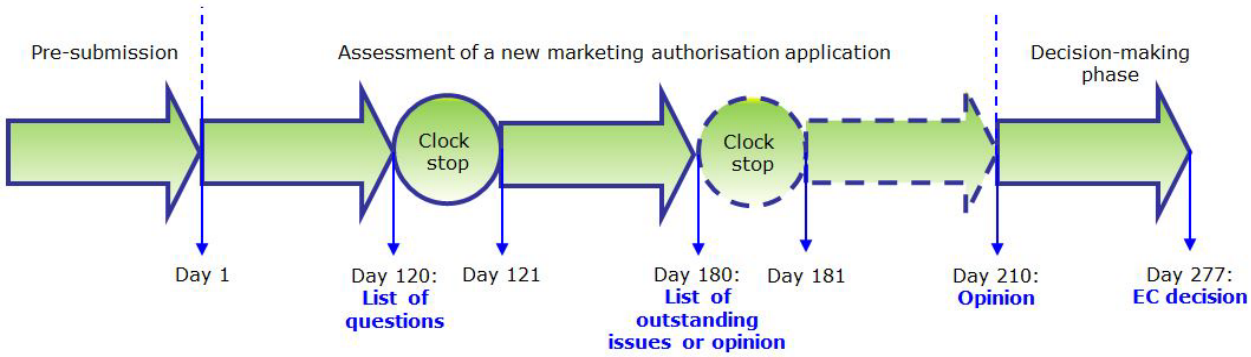
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

18 May 2026
EMA/CHMP/95175/2026

Annex to 18-21 May 2026 CHMP Agenda

Pre-submission and post-authorisations issues

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A. PRE-SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

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

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

Final Outcome of Rapporteurship allocation for May 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 04-07 May 2026

None

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.