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Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 19-22 May 2025

23 May 2025

Ten new medicines recommended for approval; another four medicines recommended for extension of their therapeutic indications

[News](#)[Human](#)[Medicines](#)[Vaccines](#)



Ten new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended ten medicines for approval at its May 2025 meeting.

The committee recommended granting a conditional marketing authorisation for **Aucatzyl*** (obecabtagene autoleucel), for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukaemia, a type of cancer of the white blood cells. This medicine was supported through EMA's PRIority MEdicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support for promising medicines with a potential to address unmet medical needs. See more details in the news announcement in the grid below.

A positive opinion was adopted for **Blenrep*** (belantamab mafodotin), for the treatment of relapsed or refractory multiple myeloma, a rare and incurable disease of the plasma cells, which typically affects adults from 60 years of age.

The committee recommended granting a conditional marketing authorisation for **Ezmekly*** (mirdametinib), for the treatment of paediatric and adult patients with neurofibromatosis type 1, an inherited disease in which the patient develops benign (non-cancerous) tumours along the nerves.

Itovebi (inavolisib) received a positive opinion from the CHMP for the treatment of adults with PIK3CA-mutated, oestrogen receptor (ER)-positive, HER2-negative locally advanced and metastatic breast cancer.

The CHMP adopted a positive opinion under exceptional circumstances for **Maapliv*** (amino acids), for the treatment of maple syrup urine disease (MSUD) in patients from birth. MSUD is a rare genetic disorder where the body

cannot break down certain amino acids found in proteins. This leads to a buildup of harmful substances in the blood and urine, which can cause serious health problems.

The CHMP recommended granting a marketing authorisation for **Riulvy** (tegomil fumarate), for the treatment of adults and children from 13 years of age with relapsing remitting multiple sclerosis, a disease of the brain and spinal cord in which inflammation destroys the protective covering around nerves and the nerves themselves. This medicine was submitted in a hybrid application, which relies in part on the results of pre-clinical tests and clinical trials of an already-authorised reference product and in part on new data.

The committee adopted positive opinions for three biosimilar medicines:

- **Bomyntra** (denosumab), for the prevention of skeletal related events in adults with advanced malignancies involving bone and the treatment of adults and skeletally mature adolescents with giant cell tumour of bone.
- **Conexxence** (denosumab), for the treatment of osteoporosis, a disease that makes bones fragile, in postmenopausal women and in men at increased risk of fractures.
- **Rolcya** (denosumab), for the treatment of osteoporosis and bone loss.

A generic medicine, **Emtricitabine/Tenofovir alafenamide Viatris** (emtricitabine / tenofovir alafenamide), received a positive opinion for the treatment of adults and adolescents infected with human immunodeficiency virus type 1 (HIV-1).

Negative opinion for two medicines

The committee recommended not granting a paediatric-use marketing authorisation for **Atropine sulfate FGK** (atropine), a medicine intended for treating myopia in children aged three years and older.

Kinselby* (resminostat) received a negative opinion from the CHMP for the treatment of patients with advanced stage

mycosis fungoides and Sezary syndrome, two cancers of blood cells that affect mainly the skin.

For more information on these negative opinions, see the question-and-answer documents in the grid below.

Recommendations on extensions of therapeutic indication for four medicines

The committee recommended extensions of indication for four medicines that are already authorised in the European Union (EU): **Imfinzi**, **Rezolsta**, **Saxenda** and **Tevimbra**.

Re-examination of recommendations

On 28 June 2024, the European Commission revoked the refusal of a marketing authorisation for **Aplidin** (plitidepsin), a medicine expected to be used to treat multiple myeloma. Following the adoption of this decision, the Commission has requested EMA to re-start the re-examination of the negative opinion adopted by the CHMP in December 2017.

The marketing authorisation holder for **Winlevi** (clascoterone), a medicine intended for treating acne vulgaris, has requested a re-examination of the negative opinion adopted during the committee's April 2025 meeting.

Upon receipt of the grounds of these requests, the CHMP will re-examine its opinions and issue final recommendations.

Withdrawal of applications

An application for an initial marketing authorisation was withdrawn. **Teriparatide Ascend** (teriparatide) was intended for the treatment of osteoporosis.

An application to extend the therapeutic indication of **Lutathera** (lutetium (177Lu) oxodotreotide) in the treatment of adults with newly diagnosed tumours in the gut, known as gastroenteropancreatic neuroendocrine tumours, was also withdrawn.

Question-and-answer documents on the withdrawals of

these medicines are available in the grid below.

Conclusion of referral

The committee finalised its review of the use of **azithromycin**, an antibiotic that has been used for decades to treat a wide range of infectious diseases. The [CHMP](#) has recommended several changes, including revisions and removals of certain indications. These recommendations aim to optimise the use of this common antibiotic and minimise the development of antimicrobial resistance, the ability of microorganisms to become resistant to antimicrobials.

For more information on this recommendation see the public health communication in the grid below.

Start of referral

The [CHMP](#) started a review of all available information on the benefits and risks of medicines containing **ipidacrine**. These medicines have been authorised in several EU countries through national procedures and are used in adults to treat different conditions affecting the nervous system. The review of ipidacrine-containing medicines has been initiated at the request of the Irish medicines regulatory agency, under [Article 31 of Directive 2001/83/EC](#).

For more information, see the public health communication in the grid below.

Agenda and minutes

The agenda of the May 2025 [CHMP](#) meeting is published on EMA's website. Minutes of the meeting will be published in the coming weeks.

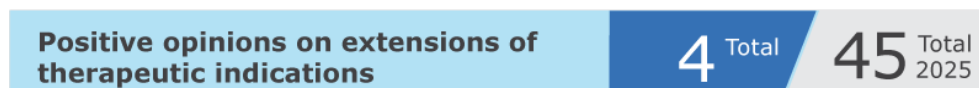
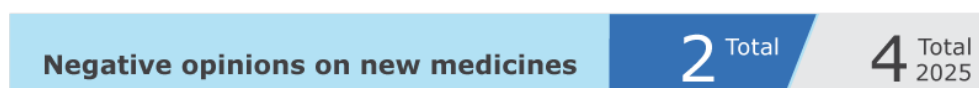
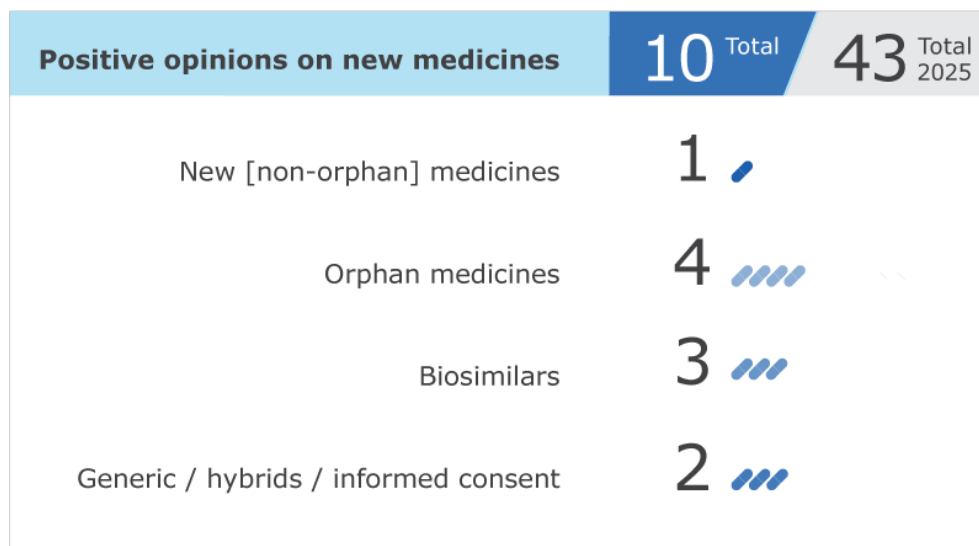
CHMP statistics

Key figures from the May 2025 [CHMP](#) meeting are represented in the graphic below.

*This product was designated as an orphan medicine during its development. [Orphan designations](#) are reviewed by EMA's [Committee for Orphan Medicinal Products \(COMP\)](#) at the time of approval to determine whether the information

available to date allows maintaining the medicine's orphan status and granting the medicine ten years of market exclusivity.

CHMP statistics: May 2025



Positive recommendations on new medicines

Aucatzyl

International non-proprietary name (INN)

obecabtagene autoleucel

Marketing-authorisation applicant

Autolus GmbH

Therapeutic indication

Treatment of patients with relapsed or refractory B cell precursor acute lymphoblastic leukaemia

More information

[Aucatzyl: pending EC decision](#)

[New treatment for adults with acute lymphoblastic leukaemia](#)

Blenrep

INN

belantamab mafodotin

Marketing-authorisation applicant

Glaxosmithkline Trading Services Limited

Therapeutic indication

Treatment of multiple myeloma

More information

[Blenrep: pending EC decision](#)

Ezmeckly

INN

mirdametinib

Marketing-authorisation applicant

Springworks Therapeutics Ireland Limited

Therapeutic indication

Treatment of neurofibromatosis type 1

More information

[Ezmekly: pending EC decision](#)

Itovebi

INN

inavolisib

Marketing-authorisation applicant

Roche Registration GmbH

Therapeutic indication

Treatment of adult patients with PIK3CA mutated, oestrogen receptor (ER) positive, HER2 negative, locally advanced or metastatic breast cancer

More information

[Itovebi: pending EC decision](#)

Maapliv

INN

amino acids

Marketing-authorisation applicant

Recordati Rare Diseases

Therapeutic indication

Treatment of decompensation episodes in MSUD patients

More information

[Maapliv: pending EC decision](#)

Positive recommendations on new biosimilar medicines

Bomyntra

INN

denosumab

Marketing-authorisation applicant

Fresenius Kabi Deutschland GmbH

Therapeutic indication

Prevention of skeletal related events in adults with advanced malignancies involving bone

More information

[Bomyntra: pending EC decision](#)

Conexxence

INN

denosumab

Marketing-authorisation applicant

Fresenius Kabi Deutschland GmbH

Therapeutic indication

Treatment of osteoporosis and bone loss

More information

[Conexxence: pending EC decision](#)

Rolcya

INN

denosumab

Marketing-authorisation applicant

Sandoz GmbH

Therapeutic indication

Treatment of osteoporosis and bone loss

More information

[Rolcyra: pending EC decision](#)

Positive recommendation on new
hybrid medicine

Riulvy

INN

tegomil fumarate

Marketing-authorisation applicant

Neuraxpharm Pharmaceuticals S.L.

Therapeutic indication

Treatment of multiple sclerosis

More information

[Riulvy: pending EC decision](#)

Positive recommendation on new
generic medicine

Emtricitabine/Tenofovir alafenamide Viatrix

INN

emtricitabine / tenofovir alafenamide

Marketing-authorisation holder

Viartis Limited

Therapeutic indication

Treatment of human immunodeficiency virus type 1 (HIV-1)

More information

[Emtricitabine / Tenofovir alafenamide Viartis: pending EC decision](#)

Withdrawal of initial marketing authorisation application

Teriparatide Ascend

INN

teriparatide

Marketing-authorisation applicant

Ascend GmbH

Therapeutic indication

Treatment of osteoporosis

More information

[Teriparatide Ascend: withdrawn application](#)

Negative opinion of initial marketing authorisation application

Atropine sulfate FGK

INN

atropine

Marketing-authorisation applicant

FGK Representative Service GmbH

Therapeutic indication

Treatment of myopia in children aged 3 years and older

More information

[Atropine sulfate FGK: pending EC decision](#)

Kinselby

INN

resminostat mesilate

Marketing-authorisation applicant

4Sc AG

More information

Kinselby: Pending EC decision (to be published shortly)

Positive recommendations on
extensions of therapeutic
indications

Imfinzi

INN

durvalumab

Marketing-authorisation holder

Astra Zeneca AB

More information

Imfinzi: [pending EC decision](#)

Rezolsta

INN

darunavir / cobicistat

Marketing-authorisation holder

Janssen-Cilag International N.V.

More information

Rezolsta: [pending EC decision](#)

Saxenda

INN

liraglutide

Marketing-authorisation holder

Novo Nordisk A/S

More information

Saxenda : [pending EC decision](#)

Tevimbra

INN

tislelizumab

Marketing-authorisation holder

BeiGene Ireland Ltd

More information

Tevimbra: [pending EC decision](#)

Withdrawal of extension of

indication

Lutathera

INN

lutetium

Marketing-authorisation applicant

Advanced Accelerator Applications

More information

[Lutathera: application withdrawn](#)

Re-examination of recommendations

Aplidin

INN

plitidepsin

More information

[Aplidin: pending EC decision](#)

Winlevi

INN

clascoterone

More information

[Winlevi: pending EC decision](#)

Start of referral procedure

Ipidacrine

INN

ipidacrine

More information

[EMA starts review of ipidacrine-containing medicines](#)

[Ipidacrine-containing medicinal products - referral](#)

Outcome of referral procedure

Azithromycin containing medicinal products for systemic use

INN

various

More information

[Azithromycin-containing medicinal products for systemic use - referral](#)

[Changes to the use of antibiotic azithromycin](#)

Other updates



Start of Union reviews adopted during the CHMP meeting of 19-22 May 2025

Adopted

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