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Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 16-19 June 2025

20 June 2025

13 new medicines recommended for approval; another six medicines recommended for extension of their therapeutic indications

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13 new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended 13 medicines for approval at its June 2025 meeting.

The committee recommended granting a marketing authorisation for **Austedo** (deutetrabenazine), for the treatment of adults with moderate-to-severe tardive dyskinesia, a disorder in which predisposed patients experience abnormal involuntary movements resulting from chronic or even episodic exposure to dopamine receptor antagonists.

Imreplys (sargramostim) received a positive opinion from the CHMP for a marketing authorisation under exceptional circumstances for the treatment of people with haematopoietic acute radiation syndrome, when the bone marrow produces fewer blood cells leading to a higher risk of infection and bleeding, following acute exposure to radiation.

A positive opinion was adopted for **Ogsiveo*** (nirogacestat), for the treatment of adults with progressing desmoid tumours, a type of soft tissue tumours that form in fibrous tissue, most commonly in the abdomen, arms and legs, that do not spread to other locations.

The committee recommended granting a conditional marketing authorisation for **Rezdiffra** (resmetirom), for the treatment of adults with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), a serious disease where fat cells accumulate in the liver causing chronic inflammation. Currently, there is no authorised treatment for metabolic dysfunction-associated steatohepatitis in the European Union (EU). See more details in the news announcement in the grid below.

The CHMP recommended granting a conditional marketing authorisation for **Zemcelpro*** (dorocubicel / unexpanded umbilical cord cells), a stem cell therapy to treat patients with haematological malignancies (blood cancers). This medicine provides an option for patients with blood cancer who need a blood stem cell transplant and have no suitable donor. It 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.

The committee adopted positive opinions for six biosimilar medicines:

- **Mynzepli** (aflibercept), and its duplicate **Afiveg** (aflibercept), **Vgenfli** (aflibercept), and its duplicate **Eiyzey** (aflibercept), for the treatment of age-related macular degeneration and visual impairment.
- **Usymro** (ustekinumab), for the treatment of plaque psoriasis, arthritis psoriatic and Crohn's Disease.
- **Vivlipeg** (pegfilgrastim), to reduce the duration of neutropenia and the incidence of febrile neutropenia after cytotoxic chemotherapy.

Two generic medicines received a positive opinion:

- **Emtricitabine/Rilpivirine/Tenofovir Alafenamide Viatris** (emtricitabine / rilpivirine / tenofovir alafenamide), for the treatment of adults and adolescents infected with human immunodeficiency virus type 1 (HIV-1).
- **Nintedanib Viatris** (nintedanib), for the treatment of idiopathic pulmonary fibrosis, other chronic fibrosing interstitial lung diseases with a progressive phenotype, and systemic sclerosis associated with interstitial lung disease.

Recommendations on extensions of therapeutic indication for six medicines

The committee recommended extensions of indication for six medicines that are already authorised in the EU: **Benlysta**, **Cabometyx**, **Darzalex***, **Imbruvica**, **Nubeqa**, and

Sarclisa.

Recommendations on extensions of therapeutic indication for one medicine intended for use outside the EU

The CHMP recommended an extension of indication for one medicine intended for use outside the EU. **Dapivirine Vaginal Ring 25 mg** (dapivirine) is a vaginal ring originally approved in July 2020 and used to reduce the risk of women 18 years and older getting infected with human immunodeficiency virus type 1 (HIV-1) through vaginal intercourse. The CHMP's opinion extends the indication for this medicine to include its use in women from 16 years of age.

This medicine was submitted under a regulatory procedure known as [EU-Medicines for all \(EU-M4All\)](#) that enables EMA to support global regulatory capacity building and contribute to the protection and promotion of public health beyond the EU.

Start of re-examination of recommendations

The marketing authorisation holder for **Atropine sulfate FGK** (atropine), a medicine intended to slow myopia progression in children aged 6 to 10 years with spherical equivalent refraction (SER) in the range of -0.50 to -6.00 diopter (D), has requested a re-examination of the negative opinion adopted during the committee's May 2025 meeting.

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

The CHMP started a re-examination of its March 2025 recommendation not to grant a marketing authorisation for **Kisunla** (donanemab), a medicine intended for the treatment of early Alzheimer's disease. The re-examination started on 2 June following a request from the applicant.

Start of referral

The CHMP started a review of medicines containing **sodium oxybate** used in people with alcohol dependency to treat

alcohol withdrawal syndrome and to support long term abstinence. The review has been initiated at the request of the French Medicines Agency under [Article 31 of Directive 2001/83/EC](#).

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

Agenda and minutes

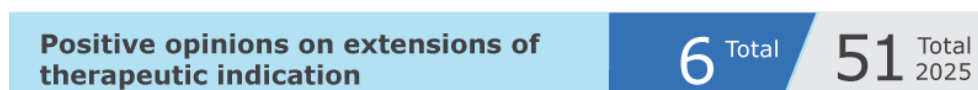
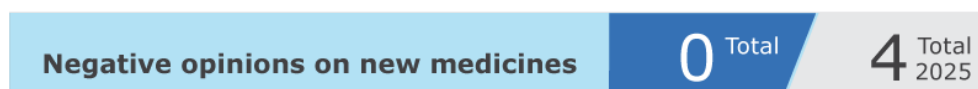
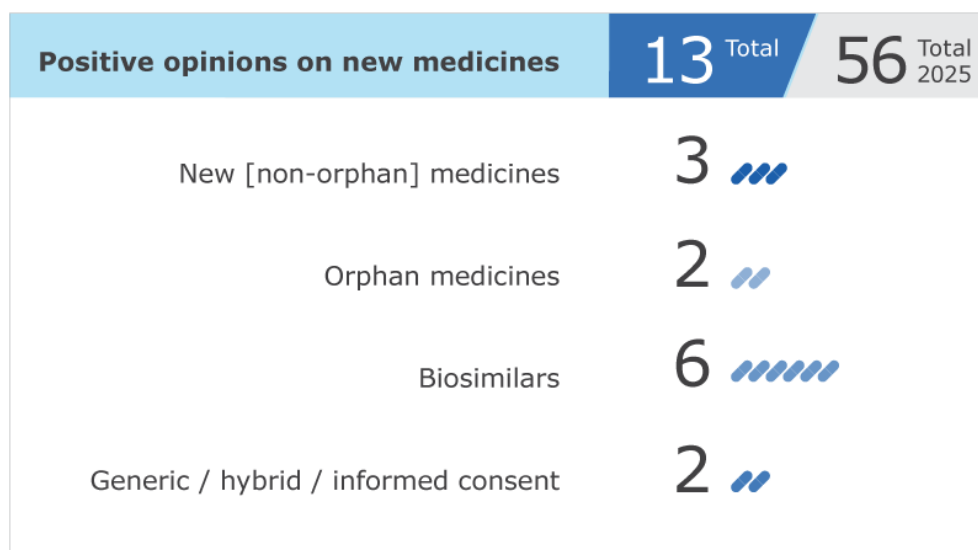
The agenda of the June 2025 CHMP meeting is published on EMA's website. Minutes of the meeting will be published in the coming weeks.

*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

Key figures from the June 2025 CHMP meeting are represented in the graphic below.

CHMP statistics: June 2025



CHMP statistics: Text version

Positive recommendations on new medicines

Austedo

International non-proprietary name (INN)

deutetrabenazine

Marketing-authorisation applicant

Teva GmbH

Therapeutic indication

Treatment of tardive dyskinesia

More information

[Austedo: pending EC decision](#)

Imreplys

INN

sargramostim

Marketing-authorisation applicant

Partner Therapeutics Limited

Therapeutic indication

Treatment for exposure to myelosuppressive doses of radiation

More information

[Imreplys: pending EC decision](#)

Ogsiveo

INN

nirogacestat

Marketing-authorisation applicant

SpringWorks Therapeutics Ireland Limited

Therapeutic indication

Treatment of desmoid tumours

More information

[Ogsiveo: pending EC decision](#)

Rezdiffra

INN

resmetirom

Marketing-authorisation applicant

Madrigal Pharmaceuticals EU Limited

Therapeutic indication

Treatment of adults with nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis

More information

[Rezdiffra: pending EC decision](#)

News announcement

[First treatment against liver scarring caused by a type of 'fatty liver disease'](#)

Zemcelpro

INN

Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded

Marketing-authorisation applicant

Cordex Biologics International Limited

Therapeutic indication

Orphan designation for treatment in haematopoietic stem cell transplantation

More information

[Zemcelpro: pending EC decision](#)

News announcement

[New stem cell therapy to treat patients with blood cancers](#)

Positive recommendations on new biosimilar medicines

Afiveg

INN

aflibercept

Marketing-authorisation applicant

Stada Arzneimittel AG

Therapeutic indication

Treatment of age-related macular degeneration (AMD) and visual impairment

More information

[Afiveg: pending EC decision](#)

Eiyzey

INN

aflibercept

Marketing-authorisation applicant

Zakłady Farmaceutyczne Polpharma S.A

Therapeutic indication

Treatment of age-related macular degeneration (AMD) and visual impairment

More information

[Eiyzey: pending EC decision](#)

Mynzepli

INN

aflibercept

Marketing-authorisation applicant

Advanz Pharma Limited

Therapeutic indication

Treatment of age-related macular degeneration (AMD) and visual impairment

More information

[Mynzepli: pending EC decision](#)

Usymro

INN

ustekinumab

Marketing-authorisation applicant

Elc Group s.r.o

Therapeutic indication

Treatment of plaque psoriasis arthritis psoriatic and Crohn's Disease

More information

[Usymro: pending EC decision](#)

Vgenfli

INN

aflibercept

Marketing-authorisation applicant

Zakłady Farmaceutyczne Polpharma S.A

Therapeutic indication

Treatment of age-related macular degeneration (AMD) and visual impairment

More information

[Vgenfli: pending EC decision](#)

Vivlipeg

INN

pegfilgrastim

Marketing-authorisation applicant

Biosimilar Collaborations Ireland Limited

Therapeutic indication

To reduce the duration of neutropenia and the incidence of febrile neutropenia after cytotoxic chemotherapy

More information

[Vivlipeg: pending EC decision](#)

Positive recommendations on new generic medicines

Emtricitabine/Rilpivirine/Tenofovir
Alafenamide Viatris

INN

emtricitabine / rilpivirine / tenofovir alafenamide

Marketing-authorisation applicant

Viatriis Limited

Therapeutic indication

Treatment of HIV-1

More information

[Emtricitabine/Rilpivirine/Tenofovir Alafenamide Viatriis: pending EC decision](#)

Nintedanib Viatriis

INN

nintedanib

Marketing-authorisation applicant

Viatriis Limited

Therapeutic indication

Treatment of idiopathic pulmonary fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) and systemic sclerosis associated interstitial lung disease (SSc-ILD)

More information

[Nintedanib Viatriis: pending EC decision](#)

Positive recommendations on extensions of therapeutic indications

Benlysta

INN

belimumab

Marketing-authorisation holder

GlaxoSmithKline

More information

[Benlysta: pending EC decision](#)

Cabometyx

INN

cabozantinib

Marketing-authorisation holder

Ipsen Pharma

More information

[Cabometyx: pending EC decision](#)

Darzalex

INN

daratumumab

Marketing-authorisation holder

Janssen-Cilag International N.V.

More information

[Darzalex: pending EC decision](#)

Imbruvica

INN

ibrutinib

Marketing-authorisation holder

Janssen-Cilag International N.V.

More information

[Imbruvica: pending EC decision](#)

Nubeqa

INN

darolutamide

Marketing-authorisation holder

Bayer AG

More information

[Nubeqa: pending EC decision](#)

Sarclisa

INN

isatuximab

Marketing-authorisation holder

Sanofi Winthrop Industrie

More information

[Sarclisa: pending EC decision](#)

Start of re-examination of initial applications

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 (to be published shortly)

Kisunla

INN

donanemab

Marketing authorisation applicant

Eli Lilly Nederland B.V.

Therapeutic indication

To slow disease progression in adult patients with Alzheimer's disease (AD).

More information

Kisunla: pending EC decision (to be published shortly)

Start of referral

Sodium oxybate-containing syrup and oral solution for alcohol dependence

Marketing authorisation applicant

Various – Article 31

More information

[Sodium oxybate-containing syrup and oral solution for](#)

[alcohol dependence - referral](#)

Recommendations on extension of therapeutic indication for one medicine intended for use outside the EU

Dapivirine Vaginal Ring 25 mg

INN

dapivirine

Marketing authorisation applicant

International Partnership for Microbicides Belgium AISBL

More information

[Dapivirine Vaginal Ring 25 mg](#)

Other updates



Start of Union reviews adopted during the CHMP meeting of 16-19 June 2025

Adopted

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