Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 23-26 March 2026

27 March 2026

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

News Human Medicines

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Five new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended five medicines for approval at its March 2026 meeting.

The committee recommended granting a conditional marketing authorisation for **Adstiladrin** (nadofaragene firadenovec), for the treatment of adult patients with Bacillus Calmette-Guérin unresponsive non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumours.

The CHMP recommended granting a marketing authorisation for **Imdyltra** (tarlatamab), a new treatment for relapsed extensive-stage small cell lung cancer which addresses an unmet medical need in adults with poor prognosis and limited treatment options. See more details in the news announcement in the grid below.

Joenja (leniolisib) received a positive opinion for a marketing authorisation under exceptional circumstances for the treatment of activated phosphoinositide 3-kinase delta syndrome (APDS) in adults and adolescents 12 years of age and older and weighing 45 kg or more. APDS is a rare, inherited progressive and potentially life-threatening condition of the immune system. The incidence rate of this disease around the world is estimated to be 1 to 2 per million people.

A positive opinion was adopted for **Zepzelca** (lurbinectedin) for the maintenance treatment in patients with extensive-stage small cell lung cancer whose disease has not progressed after first-line induction therapy.

The CHMP recommended granting a paediatric-use marketing authorisation (PUMA) for **Bopediat** (furosemide) for the treatment of oedema (swelling caused by excess fluid) of

cardiac or renal origin, oedema of hepatic origin and hypertension in children from birth to under 18 years of age with chronic kidney disease. 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.

Recommendations on extensions of therapeutic indication for 13 medicines

The committee recommended extensions of indication for 13 medicines that are already authorised in the EU: **Besponsa**, **Capvaxive**, **Feraccru**, **Hetronifly** (two extensions of therapeutic indication), **Hympavzi**, **Imcivree**, **Lojuxta**, **Mekinist** (two extensions of therapeutic indication), **mResvia**, **Namuscla**, **Retsevmo**, **Sotyktu** and **Tafinlar** (two extensions of therapeutic indication).

Outcome of re-examination

After re-examining its initial opinion, the committee confirmed its recommendation to refuse a change to the marketing authorisation for **Hetlioz** (tasimelteon). The change concerned an extension of indication to include the treatment of nighttime sleep disturbance in adults and children aged 3 to 15 years with Smith-Magenis syndrome, a rare hereditary disorder characterised by developmental delay, behavioural problems and sleep disturbance.

The CHMP issued this opinion during an extraordinary meeting on 16 March 2026.

Withdrawal of application

An application for an initial marketing authorisation was withdrawn. **Blarcamesine Anavex** (blarcamesine) was developed for the treatment of Alzheimer's disease and dementia.

A question-and-answer document on the withdrawal of this application is available in the grid below.

Conclusion of referral

The committee finalised its review of **Tecovirimat SIGA**

(tecovirimat), an antiviral medicine that was authorised to treat smallpox, mpox and cowpox, three infections caused by viruses belonging to the same family (orthopoxviruses). The CHMP recommended that Tecovirimat SIGA should no longer be used for the treatment of mpox. The review of Tecovirimat SIGA was initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

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

Other updates

The committee adopted a new route of administration, subcutaneous, together with a new pharmaceutical form and a new strength for **Sarclisa**, a cancer medicine used to treat adults with multiple myeloma.

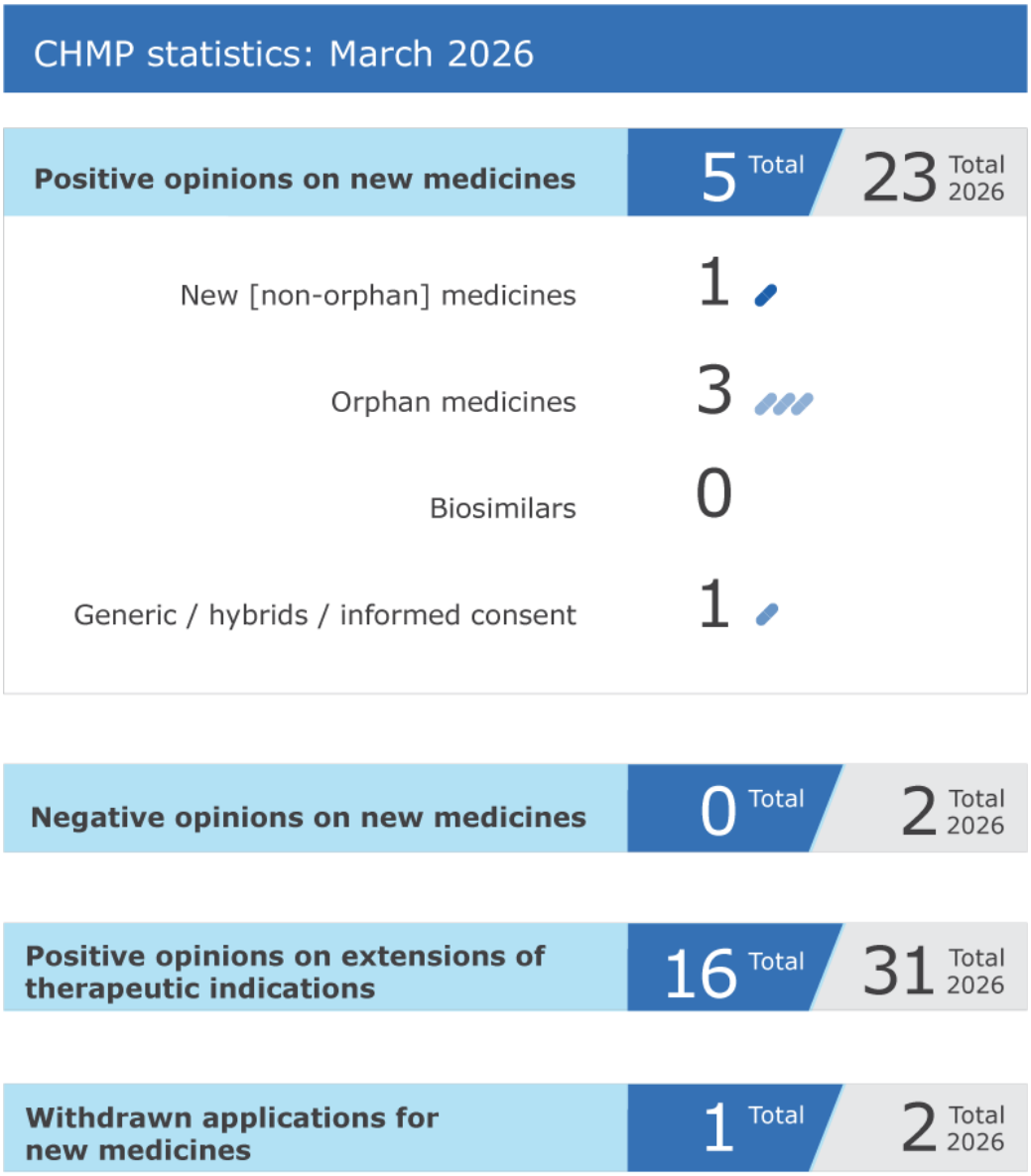
The committee adopted a **reflection paper on a tailored clinical approach in biosimilar development,** which aims to reduce the amount of clinical data required for the development and approval of certain biosimilar medicines in the EU. A biosimilar is a biological medicine highly similar to another already approved biological medicine (the 'reference medicine'). Biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines.

Agenda and minutes

The agenda of the March 2026 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 March 2026 CHMP meeting are represented in the graphic below.



CHMP statistics: Text version

Positive recommendations on new medicines

Adstiladrin

INN

nadofaragene firadenovec

Marketing authorisation applicant

Ferring Pharmaceuticals A/S

Therapeutic indication

Treatment of adult patients with high-grade (HG), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC).

More information

Adstiladrin : pending EC decision

Imdylltra

INN

tarlatamab

Marketing authorisation applicant

Amgen Europe B.V

Therapeutic indication

Treatment of extensive-stage small cell lung cancer.

More information

Imdylltra : pending EC decision

Orphan designation

This medicine was designated an orphan medicine.

News

New treatment for relapsed extensive-stage small cell lung cancer

Joenja

INN

leniolisib

Marketing authorisation applicant

Pharming Technologies B.V.

Therapeutic indication

Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS).

More information

Joenja : pending EC decision

Orphan designation

This medicine was designated an orphan medicine.

Zepzelca

INN

lurbinectedin

Marketing authorisation applicant

Pharma Mar S.A.

Therapeutic indication

Maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

More information

Zepzelca : pending EC decision

Orphan designation

This medicine was designated an orphan medicine.

Positive recommendations on new hybrid medicines

Bopediat

INN

furosemide

Marketing authorisation holder

Proveca Pharma Limited

Therapeutic indication

Treatment of all conditions requiring diuresis due to mechanical obstruction or venous insufficiency.

More information

Bopediat : pending EC decision

Positive recommendations on extensions of therapeutic indications

Besponsa

INN

inotuzumab ozogamicin

Marketing authorisation holder

Pfizer Europe MA EEIG

More information

Besponsa : pending EC decision

Capvaxive

INN

pneumococcal polysaccharide conjugate vaccine (21-valent)

Marketing authorisation holder

Merck Sharp & Dohme B.V.

More information

Capvaxive : pending EC decision

Feraccru

INN

ferric maltol

Marketing authorisation holder

Norgine B.V.

More information

Feraccru : pending EC decision

Hetronifly

INN

serplulimab

Marketing authorisation holder

Accord Healthcare S.L.U.

More information

Hetronifly: pending EC decision (EMA/VR/0000284402)
Hetronifly: pending EC decision (EMA/VR/0000282407)

Hympavzi

INN

marstacimab

Marketing authorisation holder

Pfizer Europe MA EEIG

More information

Hympavzi : pending EC decision

Imcivree

INN

setmelanotide

Marketing authorisation holder

Rhythm Pharmaceuticals Netherlands B.V.

More information

Imcivree : pending EC decision

Lojuxta

INN

lomitapide

Marketing authorisation holder

Chiesi Farmaceutici SpA

More information

Lojuxta : pending EC decision

Mekinist

INN

trametinib

Marketing authorisation holder

Novartis Europharm Limited

More information

Mekinist : pending EC decision (EMAVR0000271728)
Mekinist : pending EC decision (EMAVR0000278305)

Mresvia

INN

respiratory syncytial virus mRNA vaccine (nucleoside modified)

Marketing authorisation holder

Moderna Biotech Spain, S.L.

More information

Mresvia : pending EC decision

Namuscla

INN

mexiletine hcl

Marketing authorisation holder

Lupin Europe GmbH

More information

Namuscla : pending EC decision

Retsevmo

INN

selpercatinib

Marketing authorisation holder

Eli Lilly Nederland B.V.

More information

Retsevmo : pending EC decision

Sotyktu

INN

seucravacitinib

Marketing authorisation holder

Bristol-Myers Squibb Pharma EEIG

More information

Sotyktu : pending EC decision

Tafinlar

INN

dabrafenib

Marketing authorisation holder

Novartis Europharm Limited

More information

Tafinlar : pending EC decision (EMAVR0000271728)
Tafinlar : pending EC decision (EMAVR0000278305)

Outcome of re-examination

Hetlioz

INN

tasimelteon

Marketing authorisation holder

Vanda Pharmaceuticals Netherlands B.V.

More information

Hetlioz

Withdrawal of application

Blarcamesine Anavex

INN

blarcamesine

Marketing authorisation applicant

Anavex Germany GmbH

Therapeutic indication

Treatment of Alzheimer’s disease and dementia.

More information

Blarcamesine Anavex

Referral procedures

Tecovirimat SIGA

INN

tecovirimat

More information

Tecovirimat SIGA

Other updates

Sarclisa

INN

isatuximab

Marketing authorisation holder

Sanofi Winthrop Industrie

More information

Sarclisa : pending EC decision

Reflection paper on a tailored clinical approach in biosimilar development

Adopted

Reference Number: EMA/CHMP/BMWP/60916/2025

English (EN) (327.07 KB - PDF)

First published: 27/03/2026

View

Overview of (invented) names reviewed in February 2026 by the Name Review Group (NRG) adopted at the CHMP meeting of 24 March 2026

Adopted

Reference Number: EMA/52722/2026

English (EN) (169.74 KB - PDF)

First published: 01/04/2026

View

Scientific advice and protocol assistance adopted during the CHMP meeting 23-26 March 2026

Adopted

Reference Number: EMA/78459/2026

English (EN) (253.93 KB - PDF)

First published: 01/04/2026

View

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News

New treatment for relapsed extensive-stage small cell lung cancer

EMA recommends restricting use of Tecovirimat SIGA

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Lojuxta

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Tecovirimat SIGA - referral

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