Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 20-23 April 2026

24 April 2026

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

News Human COVID-19 Medicines

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Five new medicines recommended for approval

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

The committee recommended granting a marketing authorisation for **Cenrifki** (tolebrutinib), for the treatment of non-relapsing secondary progressive multiple sclerosis, a disease of the brain and spinal cord in which inflammation destroys the protective covering around nerves and the nerves themselves.

The CHMP recommended granting a marketing authorisation for the gene therapy medicine **Itvisma** (onasemnogene abeparvovec), for the treatment of spinal muscular atrophy, a rare, serious inherited disease that causes weakness and wasting of the muscles.

The CHMP adopted a positive opinion for **Redemplo** (plozasiran) to treat adults with familial chylomicronaemia syndrome, a rare inherited disease that prevents the body from

breaking down lipids (fats). This medicine provides a new treatment option for patients with a high unmet medical need. See more details in the news announcement in the grid below.

The committee recommended granting a marketing authorisation for **Rexatilux** (ranibizumab), a biosimilar medicine for the treatment of several eye diseases causing vision impairment.

A generic medicine, **Palbociclib Viatris** (palbociclib), received a positive opinion for the treatment of breast cancer.

Recommendations on extensions of therapeutic indication for nine medicines

The committee recommended extensions of indication for nine medicines that are already authorised in the European Union (EU): **Agamree**, **Aquipta**, **Crysvita**, **Comirnaty**, **Inaqovi**, **Opdivo**, **Privigen**, **S** and **Venclyxto**.

Withdrawal of applications

An application for an initial marketing authorisation was withdrawn. **Viokat** (diazoxide choline) was developed for the treatment of hyperphagia, extreme hunger that cannot be satisfied, in people with Prader-Willi syndrome, a genetic condition that affects growth, development and behaviour.

The application for a new use of **Pluvicto** (lutetium (^{177}Lu) vipivotide tetraxetan), a medicine to treat cancer of the prostate, to treat adults with PSMA-positive mCRPC who have no or mild symptoms, after their cancer has worsened despite treatment with a hormone blocking medicine, was withdrawn.

Question-and-answer documents on the withdrawal of these two applications are available in the grid below.

Other updates

The CHMP has finalised its assessment of an application to extend the use of **Opdualag** (nivolumab/relatlimab) to include the treatment of advanced melanoma, a type of skin cancer that has spread or cannot be surgically removed, with PD-L1 levels of 1% or higher. PD-L1 is a protein produced by some cancer cells. Although EMA did not recommend this use, it agreed that relevant data submitted with the application be included in the medicine's product information, so that healthcare professionals have access to up-to-date data on the effects of Opdualag in patients with advanced melanoma with PD-L1 levels below 1%.

For more information, see the question-and-answer document

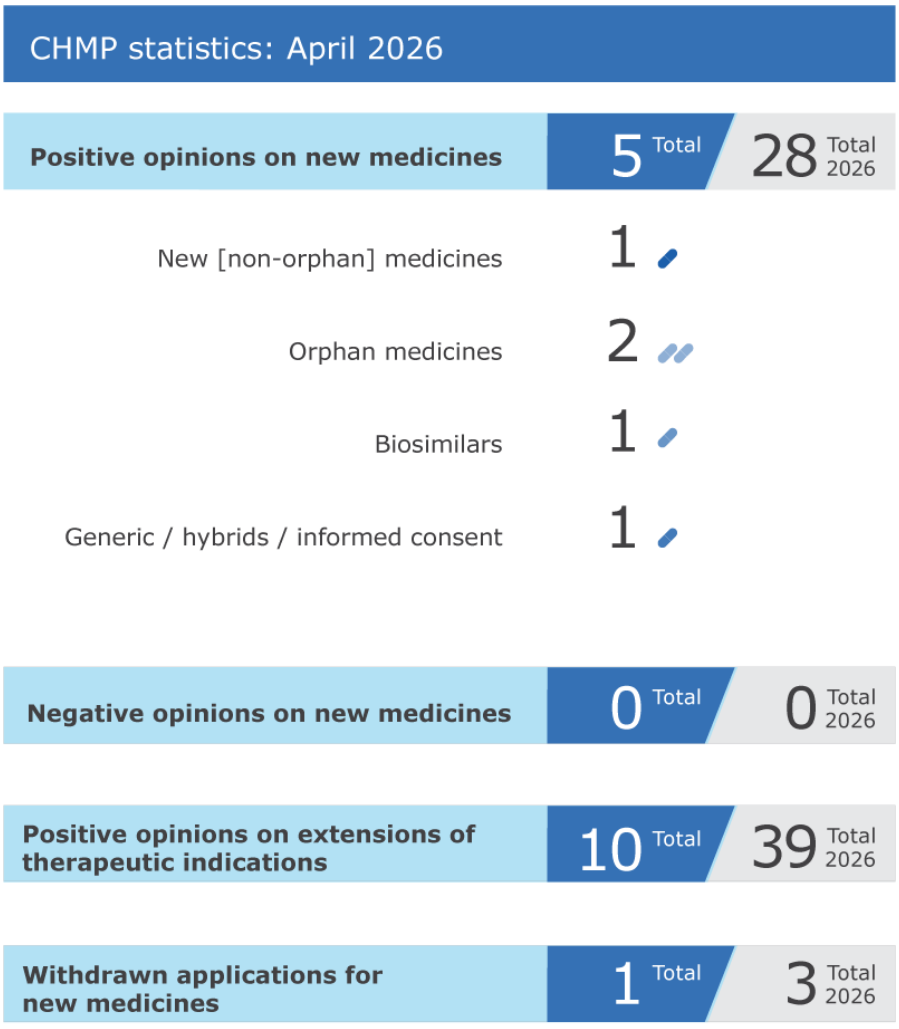
in the grid below.

Agenda and minutes

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



CHMP statistics

Key figures from the April 2026 CHMP meeting are represented in the graphic below.

CHMP statistics: Text version

Positive recommendations on new medicines

Cenrifki

INN

tolebrutinib

Marketing authorisation applicant

Sanofi Winthrop Industrie

Therapeutic indication

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

More information

Cenrifki: pending EC decision

Itvisma

INN

onasemnogene abeparvovec

Marketing authorisation applicant

Novartis Europharm Limited

Therapeutic indication

Treatment of 5q spinal muscular atrophy (SMA)

Orphan designation

This medicine was designated an orphan medicine

More information

Itvisma: pending EC decision

Redemplo

INN

plozasiran

Marketing authorisation applicant

Arrowhead Pharmaceuticals Ireland Limited

Therapeutic indication

Treatment of familial chylomicronaemia syndrome (FCS)

Orphan designation

This medicine was designated an orphan medicine

More information

Redemplo: pending EC decision

News

New medicine to reduce triglycerides in adults with familial chylomicronaemia syndrome

Positive recommendations on new biosimilar medicine

Rexatilux

INN

ranibizumab

Marketing authorisation holder

Intas Third Party Sales 2005 S.L.

Therapeutic indication

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

More information

Rexatilux: pending EC decision

Positive recommendations on new generic medicine

Palbociclib Viatris

INN

palbociclib

Marketing authorisation holder

Viatris Limited

Therapeutic indication

Treatment of breast cancer

More information

Palbociclib Viatris: pending EC decision

Positive recommendations on extensions of therapeutic indications

Agamree

INN

vamorolone

Marketing authorisation holder

Santhera Pharmaceuticals (Deutschland) GmbH

More information

Agamree: pending EC decision

Aquipta

INN

atogepant

Marketing authorisation holder

Abbvie Deutschland GmbH & Co. KG

More information

Aquipta: pending EC decision

Comirnaty

INN

COVID-19 mRNA vaccine

Marketing authorisation holder

BioNTech Manufacturing GmbH

More information

Comirnaty: pending EC decision

Crysvita

INN

burosumab

Marketing authorisation holder

Kyowa Kirin Holdings B.V.

More information

Crysvita: pending EC decision

Inaqovi

INN

decitabine / cedazuridine

Marketing authorisation holder

Otsuka Pharmaceutical Netherlands B.V.

More information

Inaqovi: pending EC decision

Opdivo

INN

nivolumab

Marketing authorisation holder

Bristol-Myers Squibb Pharma EEIG

More information

Opdivo: pending EC decision

Privigen

INN

human normal immunoglobulin

Marketing authorisation holder

CSL Behring GmbH

More information

Privigen: pending EC decision

Skyrizi

INN

risankizumab

Marketing authorisation holder

Abbvie Deutschland GmbH & Co. KG

More information

Skyrizi: pending EC decision

Venclyxto

INN

venetoclax

Marketing authorisation holder

Abbvie Deutschland GmbH & Co. KG

More information

- Venclyxto: pending EC decision (EMA/VR/0000322237)
- Venclyxto: pending EC decision (EMA/VR/0000322240)

Withdrawal of initial marketing authorisation application

Viokat

INN

diazoxide choline

Marketing authorisation applicant

Soleno Therapeutics Europe Limited

Therapeutic indication

Treatment of adult and paediatric patients with Prader-Willi syndrome (PWS)

Orphan designation

This medicine was designated an orphan medicine

More information

Viokat: questions and answers

Withdrawal of application to change the marketing authorisation

Pluvicto

INN

lutetium (177Lu) vipivotide tetraxetan

Marketing authorisation holder

Novartis Europharm Limited

More information

Pluvicto: questions and answers

Other updates

Questions and answers on the outcome of assessment on use of Opdualag in the treatment of advanced melanoma

Adopted

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