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Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 9-12 November 2026

13 November 2026

Seven new medicines recommended for approval; another 11 medicines recommended for extension of their therapeutic indications

News Human Medicines

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Seven new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended

seven medicines for approval at its November 2026 meeting.

The committee recommended granting a marketing authorisation for **Aumseqa** (aumolertinib), for the treatment of non-small cell lung cancer.

The CHMP recommended granting a marketing authorisation for **Baxfendy** (baxdrostat), for the treatment of insufficiently controlled hypertension.

Zybrivo (sintilimab) received a positive opinion from the CHMP for the treatment of non-squamous non-small cell lung cancer in adults.

The committee adopted positive opinions for two biosimilar medicines, **Garzulys** (insulin aspart) and **Donrafylix** (insulin aspart), for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.

Two generic medicines received a positive opinion:

- **Fondaparinux sodium Evumed** (fondaparinux sodium), for the prevention of venous thromboembolic events, and the treatment of deep vein thrombosis, pulmonary embolism, unstable angina and myocardial infarction in adults.
- **Ruxolitinib Krka** (ruxolitinib), for the treatment of myelofibrosis and polycythaemia vera in adults, and treatment of Graft-versus-host disease in adults and children.

Recommendations on extensions of therapeutic indication for 11 medicines

The CHMP recommended extending the use of **Gazyvaro** (obinutuzumab) to treat adults with moderate-to-severe active systemic lupus erythematosus, an autoimmune disease predominantly affecting women that occurs when the immune system attacks the body's own tissues, causing inflammation that can damage organs. Gazyvaro addresses needs of patients whose disease is not adequately controlled by standard treatment. It reduces disease activity while allowing patients to reduce their corticosteroid use and the associated risk of side effects. See more details in the news announcement in the grid below.

The committee also adopted a positive opinion to extend the therapeutic indication of **Isturisa** (osilodrostat), to include the treatment of endogenous Cushing's syndrome in adolescents and children aged 6 years and older. Cushing syndrome is a rare disease characterised by an excess production of the hormone cortisol by the adrenal glands, two glands situated above the kidneys.

The committee recommended extensions of indication for another nine medicines that are already authorised in the European Union (EU): **Bexsero**, **Cosentyx**, **Dovato**, **Enflonsia**, **Steglatro**, **Sunlenca**, **Talzenna**, **Tivic**

Positive opinions for medicines intended for use outside the EU

The CHMP recommended a new strength (100mg) for **Dapivirine Vaginal Ring** (dapivirine), used to reduce the risk of women 16 years and older getting infected with human immunodeficiency virus type 1 (HIV-1) through vaginal intercourse. The new strength allows the ring to be replaced every three months, instead of every month.

This medicine was assessed 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. Experts from the World Health Organization and national regulators from Kenia, South Africa and Zambia also participated in the assessment.

Outcome of re-examination

Following a re-examination of its initial opinion, the committee has confirmed its recommendation to refuse a marketing authorisation for two medicines:

- **KemSu** (sufentanil / ketamine), intended for the treatment of acute pain in children and adolescents.
- **Meplyffa** (arimoclomol citrate), intended for treatment of Niemann-Pick disease type C, a rare, inherited, progressive neurodegenerative disorder, in patients aged two years and older in combination with miglustat.

For more information, see the question-and-answer documents in the grid below.

Withdrawal of applications

Applications for initial marketing authorisation for two medicines were withdrawn:

- **Amlypave** (anselamimab), for the treatment of kappa light chain amyloidosis that seriously affects the heart. Kappa light chain amyloidosis is a disease in which proteins (kappa light chains) form clumps called amyloids that build up in tissues and organs, such as the heart, and prevent them from working properly.
- **Qezzaqar** (catequentinib), a cancer medicine for two types of soft tissue sarcoma, a type of cancer that affects the soft, supportive tissues of the body.

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

Other updates

The CHMP has adopted a direct healthcare professional communication (DHPC) about the potential effect of **Mounjaro** (tirzepatide) on the reliability of oral contraceptives. The DHPC reminds healthcare professionals that contraception is recommended for women who can become pregnant and are

using Mounjaro. It also states that limited information is available on the effect of tirzepatide on the pharmacokinetics and efficacy of oral contraceptives in women with obesity, overweight or type 2 diabetes mellitus. Women using an oral contraceptive are now advised to either:

- add a barrier method of contraception for 4 weeks after starting tirzepatide and for 4 weeks after each dose increase, or;
- switch to a non-oral method of contraception.

Mounjaro is a medicine used together with diet and physical activity to treat adults with type 2 diabetes which is not satisfactorily controlled. It is also used together with diet and physical activity to help people with obesity (BMI of 30 kg/m2 or more) or who are overweight (BMI between 27 and 30 kg/m2) and who have weight-related health problems lose weight and keep their weight under control.

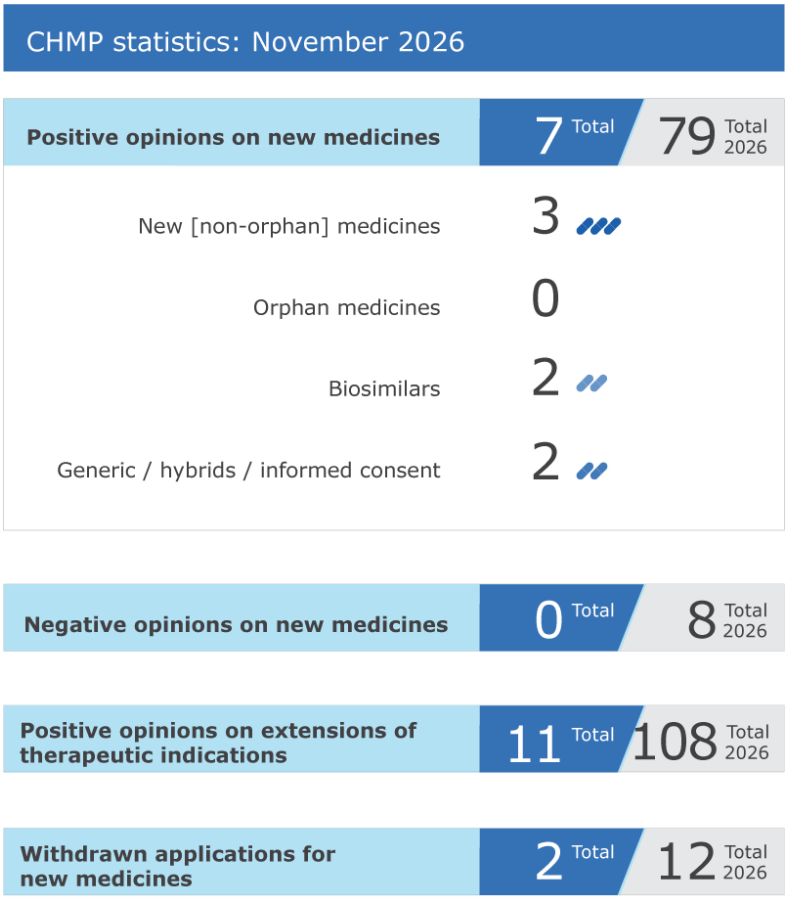
Following a decision by the European Commission, the DHPC will be disseminated to healthcare professionals by the marketing authorisation holder and published on the EMA website and in national registers in EU Member States.

Agenda and minutes

The agenda of the November 2026 CHMP meeting is published. Minutes of the meeting will be published in the coming weeks.

CHMP statistics

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



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CHMP statistics: Text version

Positive recommendations on new medicines

Aumseqa

International non-proprietary name (INN)

aumolertinib

Marketing authorisation applicant

SFL Pharmaceuticals Deutschland GmbH

Therapeutic indication

Treatment of non-small cell lung cancer in adults

More information

Aumseqa : pending EC decision

Baxfendy

INN

baxdrostat

Marketing authorisation applicant

AstraZeneca AB

Therapeutic indication

Treatment of hypertension in adults

More information

Baxfendy : pending EC decision

Zybrivo

INN

sintilimab

Marketing authorisation applicant

Fortvita Biologics (Ireland) Limited

Therapeutic indication

Treatment of non-squamous non-small cell lung cancer in adults

More information

Zybrivo : pending EC decision

Positive recommendations on new biosimilar medicines

Garzulys

INN

insulin aspart

Marketing authorisation applicant

Sciencepharma Sp. z o.o.

Therapeutic indication

Treatment of diabetes mellitus from 1 year of age

More information

Garzulys : pending EC decision

Donrafylix

INN

insulin aspart

Marketing authorisation applicant

Kuraci

Therapeutic indication

Treatment of diabetes mellitus from 1 year of age

More information

Donrafylix : pending EC decision

Positive recommendation on new generic medicines

Fondaparinux sodium Evumed

INN

fondaparinux sodium

Marketing authorisation applicant

Evumed Limited

Therapeutic indication

Prevention of venous thromboembolic events (VTE), treatment of deep vein thrombosis (DVT), treatment of pulmonary embolism, treatment of unstable angina and myocardial infarction in adults

More information

Fondaparinux sodium Evumed : pending EC decision

Ruxolitinib Krka

INN

ruxolitinib

Marketing authorisation applicant

KRKA tovarna zdravil d.d. Novo mesto

Therapeutic indication

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

More information

Ruxolitinib Krka : pending EC decision

Positive recommendations on extensions of therapeutic indications

Bexsero

Common name

meningococcal group b vaccine (rDNA, component, adsorbed)

Marketing authorisation holder

Glaxosmithkline Vaccines S.r.l.

More information

Bexsero : pending EC decision

Cosentyx

INN

secukinumab

Marketing authorisation holder

Novartis Europharm Limited

More information

Cosentyx : pending EC decision

Dovato

INN

dolutegravir / lamivudine

Marketing authorisation holder

ViiV Healthcare B.V.

More information

Dovato : pending EC decision

Enflonsia

INN

clesrovimab

Marketing authorisation holder

Merck Sharp & Dohme B.V.

More information

Enflonsia : pending EC decision

Gazyvaro

INN

obinutuzumab

Marketing authorisation holder

Roche Registration GmbH

More information

Gazyvaro : pending EC decision

News announcement

EMA recommends extending Gazyvaro’s use to systemic lupus erythematosus

Isturisa

INN

osilodrostat

Marketing authorisation holder

Recordati Rare Diseases

More information

Isturisa : pending EC decision

Steglatro

INN

ertugliflozin

Marketing authorisation holder

Merck Sharp & Dohme B.V.

More information

Steglatro : pending EC decision

Sunlenca

INN

lenacapavir

Marketing authorisation holder

Gilead Sciences Ireland Unlimited Company

More information

Sunlenca : pending EC decision

Talzenna

INN

talazoparib

Marketing authorisation holder

Pfizer Europe MA EEIG

More information

Talzenna : pending EC decision

Tivicay

INN

dolutegravir

Marketing authorisation holder

ViiV Healthcare BV

More information

Tivicay : pending EC decision

Welireg

INN

belzutifan

Marketing authorisation holder

Merck Sharp & Dohme B.V.

More information

Welireg : pending EC decision

Outcome of re-examination

KemSu

INN

sufentanil / ketamine

Marketing authorisation applicant

Proveca Pharma Limited

Therapeutic indication

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

More information

KemSu : questions and answers

Meplyffa

INN

arimoclomol

Marketing authorisation applicant

Zevra Denmark A/S

Therapeutic indication

Treatment of Niemann-Pick disease type C, a rare, inherited, progressive neurodegenerative disorder, in patients aged two years and older in combination with miglustat

Orphan designation

This medicine was designated an orphan medicine.

More information

Meplyffa : questions and answers

Withdrawals of initial marketing authorisation applications

Amlypave

INN

anselamimab

Marketing authorisation applicant

Alexion Europe

Therapeutic indication

Treatment of adult patients with kappa light chain amyloidosis

Orphan designation

This medicine was designated an orphan medicine.

More information

Amlypave : questions and answers

Qezzaqar

INN

catequentinib

Marketing authorisation applicant

CATS Consultants GmbH

Therapeutic indication

Treatment of leiomyosarcoma and synovial sarcoma

Orphan designation

This medicine was designated an orphan medicine.

More information

Qezzaqar : withdrawn application

Positive opinions for medicines intended for use outside EU

Dapivirine Vaginal Ring

INN

dapivirine

Marketing authorisation holder

International Partnership For Microbicides

More information

Dapivirine Vaginal Ring

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Committee for Medicinal Products for Human Use (CHMP): 9-12 November 2026

Committee for Medicinal Products for Human Use (CHMP)

EMA recommends extending Gazyvaro’s use to systemic lupus erythematosus

Medicines for use outside the European Union

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