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Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 14-17 September 2026

18 September 2026

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

indications

News

Human

Medicines



12 new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended 12 medicines for approval at its September 2026 meeting.

The committee recommended granting a marketing authorisation for **Frehemgo** (denecimig), for the prophylaxis of bleeding episodes in patients with haemophilia A, an inherited bleeding disorder caused by a lack of factor VIII, a protein that helps blood clot.

Gevalka (ensartinib) received a positive opinion from the CHMP for the treatment of adult patients with anaplastic lymphoma kinase positive advanced non-small cell lung cancer.

The CHMP recommended granting a marketing authorisation for **Klygefa** (gefurulimab) for the treatment of adult patients with generalised myasthenia gravis, a disease that leads to muscle weakness and tiredness.

The committee adopted a positive opinion for **Lifyorli** (relacorilant), for the treatment of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Povofortay (povorcitinib) received a positive opinion from the CHMP for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults. Acne inversa is a chronic inflammatory skin disease that causes lumps, abscesses (collections of pus) and scarring on the skin. Povofortay is the first oral daily treatment that can be prescribed in adults patients refractory or intolerant to anti-tumour necrosis factor therapy.

The CHMP recommended granting a marketing authorisation

for **Sepalna** (senaparib), a maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer.

The committee recommended granting a marketing authorisation for **VaxRabeo** (rabies virus (inactivated) strain WISTAR (PM/WI38 1503-3M)), a vaccine for pre-exposure and post-exposure prophylaxis against rabies in individuals of all age groups. Rabies is a rare but very serious infection caused by a virus which is usually spread through the bite or scratch of an infected animal.

Zeydovio (glepaglutide) received a positive opinion from the CHMP for the treatment of short bowel syndrome, a condition in which nutrients and fluids are not properly absorbed by the gut, usually because a large part of the intestine has been surgically removed.

The committee adopted positive opinions for two biosimilar medicines:

- **Adcomfo** (omalizumab), for the treatment of asthma, chronic rhinosinusitis with nasal polyps and chronic spontaneous urticaria.
- **Pebrilzo** (pertuzumab), for the treatment of breast cancer in adults. Pebrilzo is the first biosimilar medicine recommended for approval following the [tailored clinical approach](#).

Two generic medicines received a positive opinion:

- **Inijaq** (tofacitinib), for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis in adults, and juvenile idiopathic arthritis in children from two years of age.
- **Ruxolitinib Zentiva** (ruxolitinib), for the treatment of myelofibrosis in adults, polycythaemia vera in adults, and graft-versus-host disease in adults and children.

Recommendations on extensions of therapeutic indication for 11 medicines

The CHMP adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product **Anzupgo**, a medicine used to treat moderate to severe

chronic hand eczema in adults. The committee recommended lowering the age of administration to adolescents 12 years of age and older.

The committee recommended extensions of indication for another 10 medicines that are already authorised in the European Union (EU): **Abiraterone Mylan**, **Cosentyx**, **Enhertu**, **Jyseleca**, **Keytruda**, **Ocrevus**, **Padcev**, **Pepaxti**, **Sogroya**, and **Tecvayli**.

Withdrawal of applications

Two applications for initial marketing authorisation were withdrawn:

- **Isembyld** (apitegromab), for the treatment of 5q spinal muscular atrophy, a genetic disease that causes weakness and wasting of the muscles including the lung muscles.
- **Zinmyleo** (trilaciclib), for reducing myelosuppression (damage to the bone marrow) caused by chemotherapy in patients undergoing certain treatment for extensive-stage small-cell lung cancer.

Applications for an extension of the indications of three medicines that are already authorised in the EU were withdrawn:

- **Alhemo** (concizumab), for use in children below 12 years of age with haemophilia A or haemophilia B, with or without factor VIII or IX inhibitors.
- **Kaftrio** (ivacaftor/tezacaftor/elexacaftor), for use in children aged one year and older with cystic fibrosis, in combination with ivacaftor.
- **Kalydeco** (ivacaftor), for use in combination with a medicine containing ivacaftor/tezacaftor/elexacaftor in children aged one year and older with cystic fibrosis.

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

Start of re-examination

The applicants of **Kemsu** (sufentanil / ketamine), **Meplyffa** (arimoclomol) and **Qezzaqar** (catequentinib) have requested a re-examination of the negative opinions that were issued in

July 2026.

Upon receipt of the grounds of these requests, the [CHMP](#) will re-examine these opinions and issue final recommendations.

Outcome of re-examination

Following a [re-examination](#) of its initial opinion, the committee has confirmed its recommendation to refuse [marketing authorisation](#) for the medicine **Xervyteg** (allogeneic faecal microbiota, pooled). The medicine was intended for the treatment of acute graft-versus-host disease (aGvHD), a serious, life-threatening condition where the donor cells of a bone marrow or stem cell transplant attack the host body shortly after the transplant.

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

Conclusion of referral

The [CHMP](#) has finalised its review of medicines containing **ipidacrine**, which are used in adults to treat different conditions affecting the nervous system. The committee recommended several changes, including restricting and better defining the approved uses of the medicine. The aim of the recommendations was to align uses to the available data and the current standard of care. Following a review, the committee also concluded that the benefits of **sodium oxybate** syrup and oral solution (175 mg/ml) continue to outweigh their risks when used to treat acute alcohol withdrawal syndrome and to support long term abstinence in people with alcohol dependency. However additional studies are required to further characterise the efficacy of the medicines in these uses.

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

Agenda and minutes

The agenda of the September 2026 [CHMP](#) meeting is published on EMA's website. Minutes of the meeting will be published in the coming weeks.

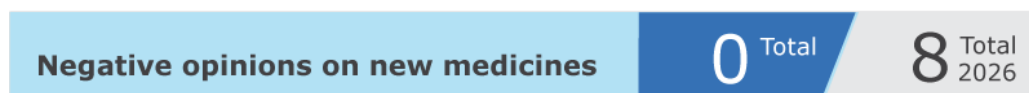
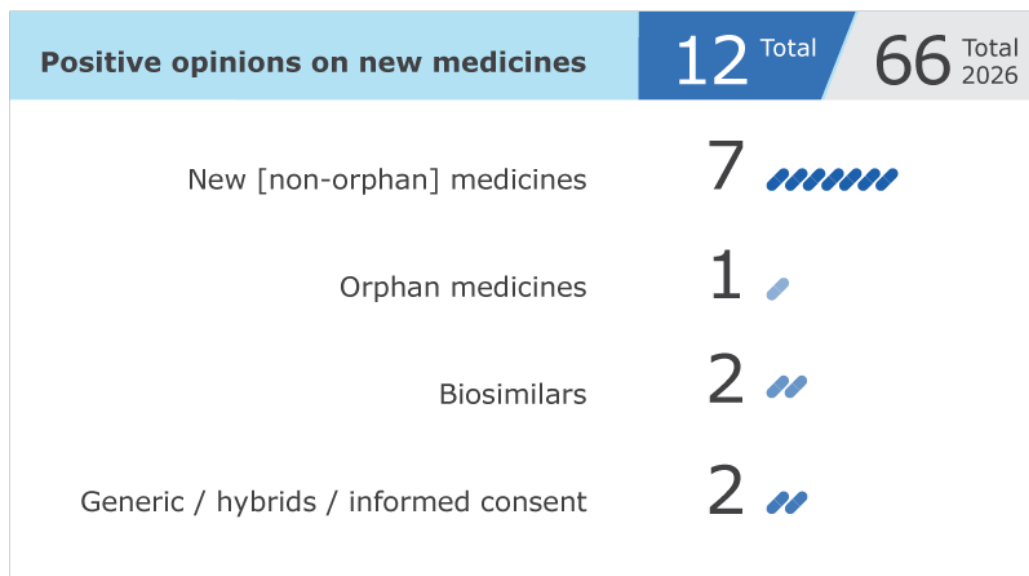
[CHMP statistics](#)

Key figures from the September 2026 [CHMP](#) meeting are represented in the graphic below.

CHMP statistics

Key figures from the September 2026 [CHMP](#) meeting are represented in the graphic below.

CHMP statistics: September 2026



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Positive recommendations on new

medicines

Frehemgo

International non-proprietary name (INN)

denecimig

Marketing authorisation applicant

Novo Nordisk A/S

Therapeutic indication

Treatment of prophylaxis of bleeding episodes in patients with haemophilia A

More information

[Frehemgo : pending EC decision](#)

Gevalka

INN

ensartinib

Marketing authorisation applicant

SFL Pharmaceuticals Deutschland GmbH

Therapeutic indication

The treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)

More information

[Gevalka : pending EC decision](#)

Klygefa

INN

gefurulimab

Marketing authorisation applicant

Alexion Europe

Therapeutic indication

Treatment of adult patients with generalised myasthenia gravis (gMG)

More information

[Klygefa: pending EC decision](#)

Lifyorli

INN

relacorilant

Marketing authorisation applicant

Corcept Therapeutics Netherlands B.V

Therapeutic indication

Lifyorli in combination with nab-paclitaxel is indicated for the treatment of adult patients with platinum-resistant high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens

More information

[Lifyorli : pending EC decision](#)

Orphan medicine

This medicine was designated as an orphan medicine.

Povofortay

INN

povorcitinib

Marketing authorisation applicant

Incyte Biosciences Distribution B.V

Therapeutic indication

Treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults

More information

[Povofortay : pending EC decision](#)

Sepalna

INN

senaparib

Marketing authorisation applicant

SFL Pharmaceuticals Deutschland GmbH

Therapeutic indication

Maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer

More information

[Sepalna : pending EC decision](#)

VaxRabeo

INN

Rabies vaccine (inactivated) for human use

Marketing authorisation applicant

Sanofi Winthrop Industrie

Therapeutic indication

Pre-exposure and post-exposure prophylaxis against rabies in all age groups

More information

[VaxRabeo : pending EC decision](#)

Zeydovio

INN

glepaglutide

Therapeutic indication

Treatment of adults with Short Bowel Syndrome

More information

[Zeydovio : pending EC decision](#)

Positive recommendation on new biosimilar medicine

Adcomfo

INN

omalizumab

Marketing authorisation applicant

Advanz Pharma Limited

Therapeutic indication

Treatment of asthma, chronic rhinosinusitis with nasal polyps (CRSwNP) and chronic spontaneous urticaria (CSU)

More information

[Adcomfo : pending EC decision](#)

Pebrilzo

INN

pertuzumab

Marketing authorisation applicant

Biosimilar Collaborations Ireland Limited

Therapeutic indication

Treatment of breast cancer in adults

More information

[Pebrilzo : pending EC decision](#)

Positive recommendations on new generic medicines

Inijaq

INN

tofacitinib

Marketing authorisation applicant

Gedeon Richter Plc.

Therapeutic indication

Treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis in adults, and juvenile idiopathic arthritis (JIA) in children from 2 years old

More information

[Inijaq : pending EC decision](#)

Ruxolitinib Zentiva

INN

ruxolitinib

Marketing authorisation applicant

Zentiva k.s.

Therapeutic indication

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

More information

[Ruxolitinib Zentiva : pending EC decision](#)

Start of re-examinations

KemSu

INN

sufentanil / ketamine - PUMA

Marketing authorisation holder

Proveca Pharma Limited

Therapeutic indication

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

More information

[KemSu : refusal Q&A](#)

Meplyffa

INN

arimoclomol

Marketing authorisation holder

Zevra Denmark A/S

More information[Meplyffa : refusal Q&A](#)

Qezzaqar

INN

catequentinib

Marketing authorisation holder

CATS Consultants GmbH

Therapeutic indication

Treatment of synovial sarcoma or leiomyosarcoma

More information[Qezzaqar : refusal Q&A](#)**Orphan medicine**

This medicine was designated as an orphan medicine

Outcome of re-examination

Xervyteg

Therapeutic indication

Treatment of allogeneic faecal microbiota, pooled

More information[Xervyteg : refusal Q&A](#)**Orphan medicine**

This medicine was designated as an orphan medicine

Withdrawal of applications for initial

application procedures

Zinmyleo

INN

trilaciclib

Market authorisation applicant

Pharmacosmos A/S

More information

[Zinmyleo : Withdrawal](#)

Isembyld

INN

apitegromab

Market authorisation applicant

Scholar Rock Netherlands B.V.

More information

[Isembyld : Withdrawal](#)

Positive recommendations on extensions of therapeutic indications

Abiraterone Mylan

INN

abiraterone acetate

Marketing authorisation holder

Mylan Pharmaceuticals Limited

More information

[Abiraterone Mylan : pending EC decision](#)

Anzupgo

INN

delgocitinib

Marketing authorisation holder

Leo Pharma A/S

More information

[Anzupgo : pending EC decision](#)

Cosentyx

INN

secukinumab

Marketing authorisation holder

Novartis Europharm Limited

More information

[Cosentyx : pending EC decision](#)

Enhertu

INN

trastuzumab deruxtecan

Marketing authorisation holder

Daiichi Sankyo Europe GmbH

More information

[Enhertu : pending EC decision](#)

Jyseleca

INN

filgotinib

Marketing authorisation holder

Alfasigma S.p.A.

More information

[Jyseleca : pending EC decision](#)

Keytruda

INN

pembrolizumab

Marketing authorisation holder

Merck Sharp & Dohme B.V.

More information

[Keytruda : pending EC decision](#)

Ocrevus

INN

ocrelizumab

Marketing authorisation holder

Roche Registration GmbH

More information

[Ocrevus : pending EC decision](#)

Padcev

INN

enfortumab vedotin

Market authorisation holder

Astellas Pharma Europe B.V.

More information

[Padcev : pending EC decision](#)

Pepaxti

INN

melphalan flufenamide

Marketing authorisation applicant

Oncopeptides AB

More information

[Pepaxti : pending EC decision](#)

Sogroya

INN

somapacitan

Marketing authorisation applicant

Novo Nordisk A/S

More information

[Sogroya : pending EC decision](#)

Tecvayli

INN

teclistamab

Marketing authorisation holder

Janssen Cilag International

More information

[Tecvayli : pending EC decision](#)

Withdrawal of applications for recommendations on extensions of indications

Alhemo

INN

concizumab

Market authorisation applicant

Novo Nordisk A/S

More information

[Alhemo : Withdrawal](#)

Kaftrio

INN

ivacaftor / tezacaftor / elexacaftor

Market authorisation applicant

Vertex Pharmaceuticals (Ireland) Limited

More information

[Kaftrio : Withdrawal](#)

Kalydeco

INN

Ivacaftor

Market authorisation applicant

Vertex Pharmaceuticals (Ireland) Limited

More information

[Kalydeco : Withdrawal](#)

Conclusion of Referrals

Ipidacrine-containing medicinal products

INN

ipidacrine

More information

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

News

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

Sodium oxybate syrup and oral solution for alcohol dependence

INN

sodium oxybate

More information

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

News

[Benefits of sodium oxybate continue to outweigh risks in people with alcohol dependency](#)

Other updates

Pradaxa

INN

dabigatran etexilate

Marketing authorisation applicant

Boehringer Ingelheim International GmbH

More information

[Pradaxa : pending EC decision](#)

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