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

24 July 2026

Twelve new medicines recommended for approval; another eight medicines recommended for extension of their

therapeutic indications

News Human COVID-19 Medicines

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Twelve new medicines recommended for approval

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

The committee recommended granting marketing authorisations for three medicines to treat adults with primary hypercholesterolaemia or mixed dyslipidaemia, conditions that cause high cholesterol levels in the blood: **Lyrokaul** (lerodalcibep) is an injection that patients can self-administer monthly; **Evlarco** (obicetrapib / ezetimibe) and **Ubeslo** (obicetrapib) are both oral formulations to be taken daily. All three medicines are for use in addition to diet and can be taken alone or in combination with other lipid-lowering therapies.

Susvimo (rabinizumab) received a recommendation for marketing authorisation to treat adults with neovascular (wet) age-related macular degeneration. Susvimo is delivered via a refillable implant, the first of this kind approved in the EU, inserted surgically into the eye. The implant is designed to release ranibizumab over time and is refilled every six months. Susvimo represents a new treatment option for patients. For more information read the news announcement in the grid below.

The CHMP recommended granting a marketing authorisation for **Icotyde** (icotrokinra) for the treatment of moderate-to-severe plaque psoriasis in adults and adolescents from 12 years of age. Icotyde is the first oral medicine that targets the protein interleukin-23 receptor, thereby reducing inflammation and symptoms associated with the disease. See more details in the news announcement in the grid below.

Lynavoy (linerixibat) received a positive opinion from the CHMP for the treatment of adults with cholestatic pruritus, a complication of an autoimmune disease called primary biliary cholangitis in which there is gradual destruction of the bile ducts in the liver. Patients who develop cholestatic pruritus experience intense itching due to a build-up of bile acids in the bloodstream.

The committee also recommended granting a marketing authorisation under exceptional circumstances for **Nezglyal** (leriglitazone) for the treatment of cerebral adrenoleukodystrophy, a rare genetic disorder which affects the brain, typically during childhood.

Zokovea (ensitrelvir), an antiviral medicine, received a positive opinion for the post-exposure prophylaxis of COVID-19.

The committee adopted a positive opinion for the biosimilar medicine **Cavoley** (pegfilgrastim) for the treatment of neutropenia (low levels of neutrophils, a type of white blood cell).

Three generic medicines received a positive opinion:

- **Riociguat Accord** (riociguat) for the treatment of chronic thromboembolic pulmonary hypertension in adults and treatment of pulmonary arterial hypertension in adults and children from 6 years of age;
- **Ruxolitinib Viatris** (ruxolitinib hemifumarate) for the treatment of myelofibrosis, polycythaemia vera and graft-versus-host disease;
- **Tafamidis Accord** (tafamidis) for the treatment of hereditary transthyretin amyloidosis in adult patients with cardiomyopathy.

Negative opinion for three medicines

The committee adopted negative opinions for three medicines:

- **KemSu** (sufentanil / ketamine) for the treatment of acute pain in children aged 1 to less than 18 years.
- **Meplyffa** (arimoclomol citrate) intended for treatment of Niemann-Pick disease type C, a rare, inherited, progressive neurodegenerative disorder, in patients aged 2 years and

older in combination with miglustat.
- **Qezzaqar** (catequentinib) intended for the treatment of synovial sarcoma or leiomyosarcoma, two types of soft tissue sarcomas (a type of cancer that affects the soft, supportive tissues of the body).

For more information on these negative opinions, see the question-and-answer documents in the grid below.

Recommendations on extensions of therapeutic indication for eight medicines

The CHMP recommended extensions of indication for eight medicines that are already authorised in the EU: **Enhertu**, **Jivi, Piqray**, **Repatha**, **Riltrava Aerosphere**, **Rinvoq, Trixeo Aerosphere**, and **Trodelvy**.

Re-examinations of initial marketing authorisation applications

The company that applied for the authorisation of **Yartemlea** (narsoplimab), a medicine intended for the treatment of adults and children from 2 years of age with haematopoietic stem cell transplant-associated thrombotic microangiopathy, and the company that applied for the authorisation of **Xervyteg** (allogeneic faecal microbiota, pooled), a medicine developed to treat acute graft-versus-host disease, have requested re-examinations of the negative opinions adopted during the committee's June 2026 meeting.

Question-and-answer documents on the refusal of marketing authorisations for these medicines are available on EMA's website.

Withdrawal of applications

An application for initial marketing authorisation for **Azacitidine Adienne** (azacitidine), for the treatment of adults with certain disorders and cancers of the blood and bone marrow when they cannot have haematopoietic stem cell transplantation, was withdrawn. A question-and-answer document on the withdrawal of this application is available in the grid below.

Two applications for extensions of indications were withdrawn: one to extend the use of **Dupixent** (dupilumab) for the treatment of adults with moderate-to-severe bullous pemphigoid, an autoimmune skin disease that causes widespread itching and blisters affecting the skin and sometimes the inside of the mouth; and one to extend the use of **Imfinzi** (durvalumab) for the treatment of high-risk non-muscle-invasive bladder cancer, a type of cancer that affects the lining of the bladder.

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

Other updates

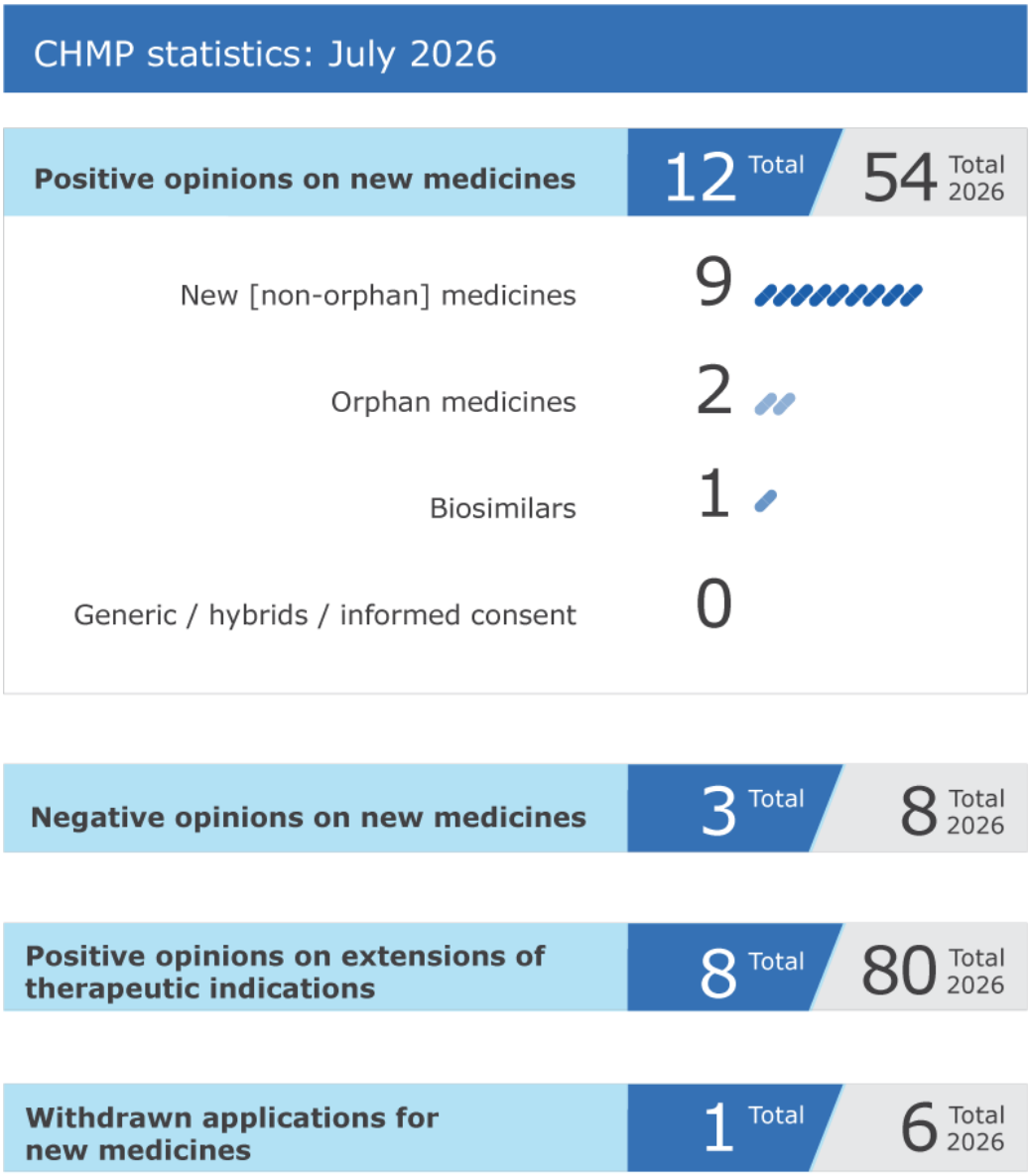
The CHMP gave a positive opinion to update the composition of the vaccines **Bimervax**, **Comirnaty, Nuvaxovid** and **Spikevax** to target the new XFG variant of the virus that causes COVID-19. The revision of these vaccines is in line with the recommendation issued by EMA's Emergency Task Force for the 2026/2027 vaccination campaign.

Agenda and minutes

The July 2026 CHMP meeting agenda is published on EMA's website. Minutes of the meeting will be published in the coming weeks.

CHMP statistics

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



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CHMP statistics: Text version

Positive recommendations on new medicines

Evlarco

International non-proprietary name (INN)

obicetrapib / ezetimibe

Marketing authorisation applicant

A. Menarini International Licensing S.A.

Therapeutic indication

Treatment of primary hypercholesterolaemia or mixed dyslipidaemia

More information

Evlarco : pending EC decision

Icotyde

INN

icotrokinra hydrochloride

Marketing authorisation applicant

Janssen-Cilag International N.V.

Therapeutic indication

Treatment of moderate to severe plaque psoriasis in adults, and adolescents 12 years of age and older and weighing at least 40 kg

More information

Icotyde : pending EC decision

News

First oral medicine targeting interleukin-23 receptor recommended for plaque psoriasis

Lynavoy

INN

linerixibat

Marketing authorisation applicant

Glaxosmithkline Trading Services Limited

Therapeutic indication

Treatment of cholestatic pruritus in adult patients with primary biliary cholangitis

More information

Lynavoy : pending EC decision

Orphan medicine

This medicine was designated as an orphan medicine.

Lyrokaul

INN

lerodalcibep

Marketing authorisation applicant

LIB Therapeutics B.V.

Therapeutic indication

Treatment of adults with primary hypercholesterolaemia (heterozygous familial (HeFH) and non-familial) or mixed dyslipidaemia as an adjunct to diets

More information

Lyrokaul : pending EC decision

Nezglyal

INN

leriglitazone

Marketing authorisation applicant

Minoryx Therapeutics S.L.

Therapeutic indication

Treatment of cerebral adrenoleukodystrophy

More information

Nezglyal : pending EC decision

Orphan medicine

This medicine was designated as an orphan medicine.

Susvimo

INN

ranibizumab

Marketing authorisation applicant

Roche Registration GmbH

Therapeutic indication

Treatment of adults with neovascular (wet) age-related macular degeneration

More information

Susvimo : pending EC decision

News

New treatment option for neovascular age-related macular degeneration

Ubeslo

INN

obicetrapib

Marketing authorisation applicant

A. Menarini International Licensing S.A.

Therapeutic indication

Treatment of primary hypercholesterolaemia or mixed dyslipidaemia

More information

Ubeslo : pending EC decision

Zokovea

INN

ensitrelvir

Marketing authorisation applicant

Shionogi B.V.

Therapeutic indication

Post-exposure prophylaxis of COVID-19

More information

Zokovea : pending EC decision

Positive recommendation on new biosimilar medicine

Cavoley

INN

pegfilgrastim

Marketing authorisation applicant

CuraTeQ Biologics s.r.o

Therapeutic indication

Reduction of neutropenia in adults

More information

Cavoley : pending EC decision

Positive recommendations on new generic medicines

Riociguat Accord

INN

riociguat

Marketing authorisation applicant

Accord Healthcare S.L.U.

Therapeutic indication

Treatment of Chronic thromboembolic pulmonary hypertension (CTEPH) in adults and treatment of Pulmonary arterial hypertension (PAH) in adults and children from 6 years of age

More information

Riociguat Accord : pending EC decision

Ruxolitinib Viatris

INN

ruxolitinib hemifumarate

Marketing authorisation applicant

Viatris Limited

Therapeutic indication

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

More information

Ruxolitinib Viatris : pending EC decision

Tafamidis Accord

INN

tafamidis

Marketing authorisation applicant

Accord Healthcare S.L.U.

Therapeutic indication

Treatment of hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTRh-CM)

More information

Tafamidis Accord : pending EC decision

Negative recommendations on new medicines

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 : pending EC decision

Meplyffa

INN

arimoclomol citrate

Marketing authorisation applicant

Zevra Denmark A/S

Therapeutic indication

Treatment of Niemann-Pick disease type C in patients aged 2 years and older in combination with miglustat

More information

Meplyffa : pending EC decision

Orphan designation

This medicine was designated an orphan medicine.

Qezzaqar

INN

catequentinib

Marketing authorisation applicant

CATS Consultants GmbH

Therapeutic indication

Treatment of synovial sarcoma or leiomyosarcoma

More information

Qezzaqar : pending EC decision

Orphan medicine

This medicine was designated as an orphan medicine.

Positive recommendations on extensions of therapeutic indications

Enhertu

INN

trastuzumab deruxtecan

Marketing authorisation holder

Daiichi Sankyo Europe GmbH

More information

Enhertu : pending EC decision

Jivi

INN

damoctocog alfa pegol

Marketing authorisation holder

Bayer AG

More information

Jivi : pending EC decision - to be published shortly

Piqray

INN

alpelisib

Marketing authorisation holder

Novartis Europharm Limited

More information

Piqray : pending EC decision

Repatha

INN

evolocumab

Marketing authorisation holder

Amgen Europe B.V.

More information

Repatha : pending EC decision

Rinvoq

INN

upadacitinib

Marketing authorisation holder

Abbvie Deutschland GmbH & Co. KG.

More information

Rinvoq : pending EC decision

Riltrava Aerosphere

INN

formoterol / glycopyrronium bromide / budesonide

Marketing authorisation holder

AstraZeneca AB

More information

Riltrava Aerosphere : pending EC decision

Trixeo Aerosphere

INN

formoterol / glycopyrronium bromide / budesonide

Marketing authorisation holder

AstraZeneca AB

More information

Trixeo Aerosphere : pending EC decision

Trodelvy

INN

sacituzumab govitecan

Marketing authorisation holder

Gilead Sciences Ireland Unlimited Company

More information

Trodelvy : pending EC decision

Withdrawal of application for recommendation on new medicine

Azacitidine Adienne

INN

azacitidine

More information

Azacitidine Adienne : Withdrawal

Withdrawal of applications for recommendations on extensions of indications

Dupixent

INN

dupilumab

More information

Dupixent : Withdrawal

Imfinzi

INN

durvalumab

More information

Imfinzi : Withdrawal

Other updates

Overview of (invented) names reviewed in June 2026 by the Name Review Group (NRG) - Adopted at the CHMP meeting of 23 July 2026

Adopted

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English (EN) (170.16 KB - PDF)

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Committee for Medicinal Products for Human Use (CHMP): 20-23 July 2026

Committee for Medicinal Products for Human Use (CHMP)

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