← News

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 April 2024

26 April 2024

EMA's human medicines committee (CHMP) recommended eight medicines for approval at its April 2024 meeting.

News Human COVID-19 Medicines

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Eight new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended eight medicines for approval at its April 2024 meeting.

The CHMP recommended granting a marketing authorisation for **Altuvoct*** (efanesoctocog alfa), for the treatment and prophylaxis of bleeding in patients with haemophilia A, a rare inherited bleeding disorder caused by lack of factor VIII.

The committee adopted a positive opinion for **Fruzaqla** (fruquintinib), indicated for the treatment of patients with previously treated metastatic colorectal cancer.

The CHMP gave a positive opinion for **Jeraygo** (aprocitentan), for the treatment of resistant hypertension.

Obgemsa (vibegron) received a positive opinion for the treatment of adults with overactive bladder syndrome.

The CHMP gave a positive opinion for **Truqap** (capivasertib), for the treatment of locally advanced or metastatic breast cancer with one or more specific mutations.

The committee adopted positive opinions for two biosimilar medicines:

- **Tofidence** (tocilizumab), for the treatment of rheumatoid arthritis, COVID-19, polyarticular juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis.
- **Wezenla** (ustekinumab), for the treatment of plaque psoriasis, including paediatric plaque psoriasis, psoriatic arthritis and Crohn's disease.

A positive opinion was adopted for **Eribulin Baxter** (eribulin), a generic medicine indicated for the treatment of breast cancer and liposarcoma, a rare cancer that develops in fatty tissue.

Withdrawals of applications

Two applications for marketing authorisation were withdrawn: **GeGant**, a radionuclide generator which can be used by doctors to label diagnostic medicines, and **Upstelda**, a biosimilar for the treatment of plaque psoriasis, psoriatic arthritis and Crohn's disease. Upstelda is a duplicate of Wezenla.

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

Recommendations on extensions of therapeutic indication for six medicines

The committee recommended extensions of indication for six medicines that are already authorised in the European Union (EU): **Alecensa**, **Opdivo**, **Rozlytrek**, **Rybrevant**, **Sirturo** and **Triumeq**.

Other updates

The CHMP recommended new contraindications on the co-administration of **Reyataz** (Atazanavir) with encorafenib and ivosidenib, and with carbamazepine, phenobarbital, and phenytoin.

Regulatory updates

Following the appellate judgment of the Court of Justice of 14 March 2024 in Case C-291/22 P), EMA is currently considering the impact of the appellate judgment on the evaluation of Hopveus, which was the subject of the court case, as well as other regulatory procedures. On these grounds, the CHMP has decided to convene a new ad-hoc expert group (AHEG) for Syfovre and reset the evaluation procedure for this medicine from that point to day 180 of the initial assessment procedure.

The appellate judgment examined questions related to the organisation of EMA's Scientific Advisory Groups (SAGs) and ad-hoc expert groups (AHEGs). SAGs and AHEGs are groups of scientific experts that are called upon to respond to specific questions posed by EMA's committees during the evaluation of a medicine.

EMA is also currently considering the impact of the appellate judgment on the evaluation of other regulatory procedures

and will further communicate as appropriate.

Agenda and minutes

The agenda of the April 2024 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 2024 CHMP meeting are represented in the graphic below.

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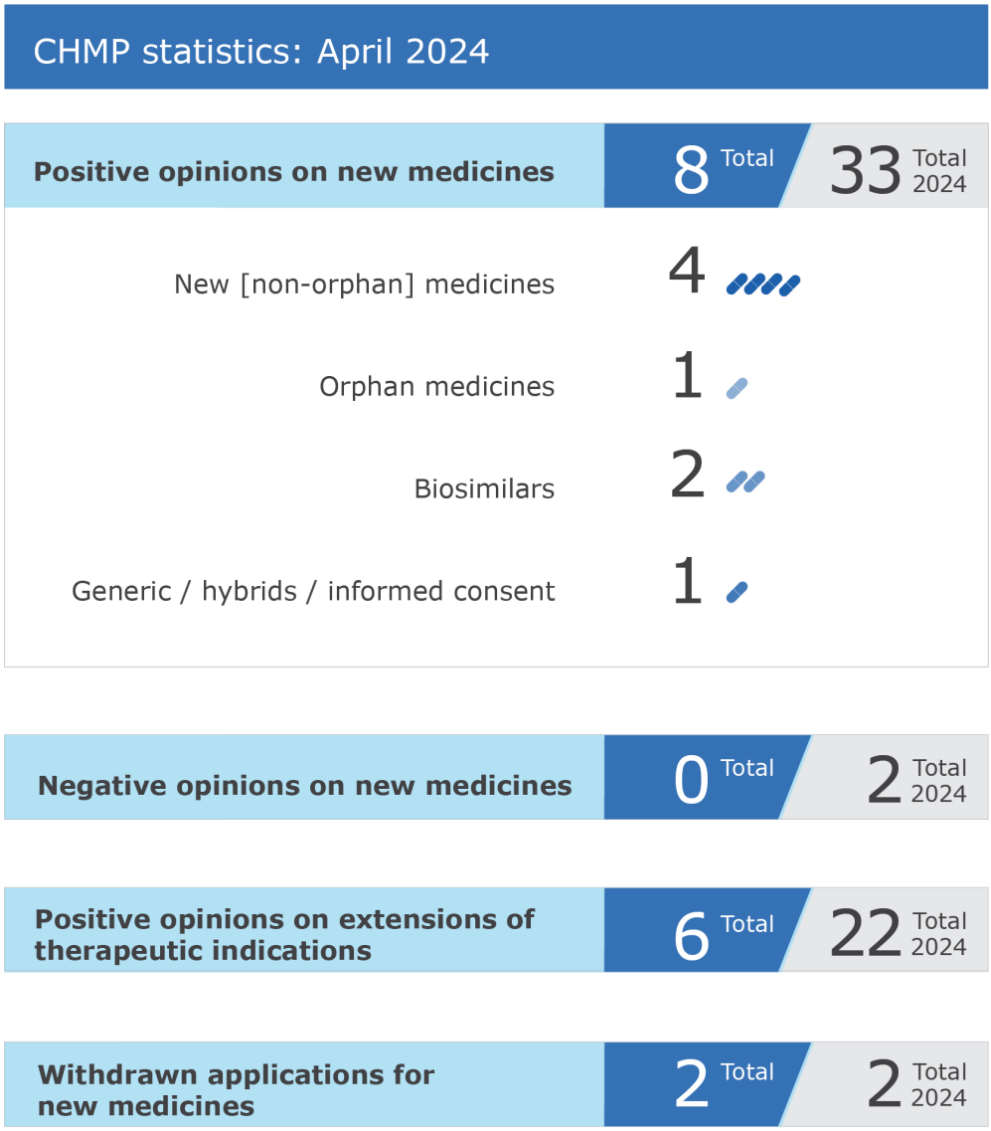
*This product was designated as an orphan medicine during its development. Orphan designations are reviewed by EMA's Committee for Orphan Medicinal Products (COMP) at the time of approval to determine whether the information available to date allows maintaining the medicine’s orphan status and granting the medicine ten years of market exclusivity.



Positive recommendations on new medicines

Altuvoct

International non-proprietary name (INN)

efanesoctocog alfa

Marketing-authorisation applicant

Swedish Orphan Biovitrum AB (publ)

Therapeutic indication

Treatment and prophylaxis of bleeding in patients with

haemophilia A.

More information

Altuvoct: Pending EC decision

Fruzaqla

International non-proprietary name (INN)

fruquintinib

Marketing-authorisation applicant

Takeda Pharmaceuticals International AG Ireland Branch

Therapeutic indication

Treatment of metastatic colorectal cancer.

More information

Fruzaqla: Pending EC decision

Jeraygo

INN

aprocitentan

Marketing-authorisation applicant

Idorsia Pharmaceuticals Deutschland GmbH

Therapeutic indication

Treatment of resistant hypertension.

More information

Jeraygo: Pending EC decision

Obgemsa

INN

vibegron

Marketing-authorisation applicant

Pierre Fabre Medicament

Therapeutic indication

Treatment of micturition frequency and/or urgency incontinence as may occur in adult patients with Over Active Bladder (OAB) syndrome.

More information

Obgemsa: Pending EC decision

Truqap

INN

capivasertib

Marketing-authorisation applicant

AstraZeneca AB

Therapeutic indication

Indicated in combination with fulvestrant for the treatment of adult patients with oestrogen receptor (ER)-positive, HER2 negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following recurrence or progression on or after an endocrine-based regimen.

More information

Truqap: Pending EC decision

Positive recommendation on new biosimilar medicines

Tofidence

INN

tocilizumab

Marketing-authorisation applicant

Biogen Netherlands B.V.

Therapeutic indication

Treatment of rheumatoid arthritis (RA), coronavirus disease 2019 (COVID-19), polyarticular juvenile idiopathic arthritis (pJIA), and systemic juvenile idiopathic arthritis (sJIA).

More information

Tofidence: Pending EC decision

Wezenla

INN

ustekinumab

Marketing-authorisation applicant

Amgen Technology (Ireland) Unlimited Company

Therapeutic indication

Treatment of moderate to severe plaque psoriasis in adults, children and adolescents, active psoriatic arthritis in adults and Crohn’s Disease.

More information

Wezenla: Pending EC decision

Positive recommendation on new generic medicine

Eribulin Baxter

INN

eribulin

Marketing-authorisation applicant

Baxter Holding B.V.

Therapeutic indication

Treatment of breast cancer and liposarcoma.

More information

Eribulin Baxter: Pending EC decision

Positive recommendations on extensions of indications

Alecensa

INN

alectinib

Marketing-authorisation holder

Roche Registration GmbH

More information

Alecensa: Pending EC decision

Opdivo

INN

nivolumab

Marketing-authorisation holder

Bristol-Myers Squibb Pharma EEIG

More information

Opdivo: Pending EC decision

Rozlytrek

INN

entrectinib

Marketing-authorisation holder

Roche Registration GmbH

More information

Rozlytrek: Pending EC decision

Rybrevant

INN

amivantamab

Marketing-authorisation holder

Janssen-Cilag International N.V.

More information

Rybrevant: Pending EC decision

Sirturo

INN

bedaquiline

Marketing-authorisation holder

Janssen-Cilag International N.V.

More information

Sirturo: Pending EC decision

Triumeq

INN

dolutegravir / abacavir / lamivudine

Marketing-authorisation holder

ViiV Healthcare B.V.

More information

Triumeq: Pending EC decision

Recommendation on new contraindication

Reyataz

INN

atazanavir sulfate

Marketing-authorisation holder

Bristol-Myers Squibb Pharma EEIG

More information

Reyataz: Pending EC decision

Withdrawal of initial marketing authorisation application

GeGant

INN

germanium (68Ge) chloride / gallium (68Ga) chloride

Marketing-authorisation applicant

ITM Medical Isotopes GmbH

More information

GeGant: Withdrawn application

Other updates

Scientific advice and protocol assistance adopted during the CHMP meeting 22-25 April 2024

Adopted

Reference Number: EMA/CHMP/SAWP/179086/2024

English (EN) (234.12 KB - PDF)

First published: 26/04/2024

View

Recommendations on eligibility to PRIME scheme adopted at the CHMP meeting of 22-25 April 2024

Reference Number: EMA/156631/2024

English (EN) (133.58 KB - PDF)

First published: 07/05/2024

View

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