← News

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 24-27 June 2024

28 June 2024

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

News Human Medicines Referrals

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

The committee recommended granting a marketing authorisation for **Balversa** (erdafitinib), for the treatment of adult patients with unresectable or metastatic urothelial carcinoma, a cancer of the bladder and urinary system.

The CHMP adopted a positive opinion for **Eurneffy** (epinephrine), the first emergency treatment against allergic reactions that is administered as a nasal spray, not as an injection. See more details in the news announcement in the grid below.

mResvia (Respiratory Syncytial Virus (RSV) mRNA vaccine) received a positive opinion from the CHMP for prevention in adults 60 years of age and older of lower respiratory tract disease and acute respiratory disease caused by respiratory syncytial virus, a common respiratory virus that usually causes mild, cold-like symptoms but can lead to serious consequences in older adults. This is the first mRNA vaccine targeting a different pathogen than SARS-CoV-2 that receives a positive opinion from the CHMP.

The committee recommended granting a conditional marketing authorisation for **Ordspono*** (odronextamab), for the treatment of follicular lymphoma and diffuse large B-cell lymphoma, two types of blood cancer that affect the immune system.

Piasky (crovalimab) received a positive opinion from the CHMP for the treatment of paroxysmal nocturnal haemoglobinuria, a rare genetic disorder that causes the premature breakdown of red blood cells by the immune system and is potentially life-threatening.

The CHMP gave a positive opinion for **Tauvid** (flortaucipir (^{18}F)), for positron emission tomography (PET) imaging of the brain in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease.

The CHMP recommended granting a marketing authorisation for **Winrevair*** (sotatercept), to treat adult patients with pulmonary arterial hypertension, a rare, long-term, debilitating and life-threatening condition in which patients have abnormally high blood pressure in the arteries in the lungs. This medicine was supported through EMA's Priority Medicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support for promising medicines with a potential to address unmet medical needs. See more details in the news announcement in the grid below.

The committee recommended granting a marketing authorisation for **Steqeyma** (ustekinumab), a biosimilar medicine for the treatment of adult patients with moderately-to severely-active Crohn's disease, plaque psoriasis, paediatric plaque psoriasis and psoriatic arthritis.

The committee also adopted positive opinions for two generic medicines:

- **Enzalutamide Viatris** (enzalutamide) for the treatment of prostate cancer.
- **Nilotinib Accord** (nilotinib) for the treatment of Philadelphia chromosome positive chronic myelogenous leukaemia.

Negative opinions for two medicines

The CHMP recommended the refusal of marketing authorisations for **Masitinib AB Science*** (masitinib), a medicine intended for the treatment of amyotrophic lateral sclerosis, a rare disease of the nervous system leading to loss of muscle function and paralysis, and **Syfovre** (pegcetacoplan), for the treatment of geographic atrophy secondary to age-related macular degeneration, a progressive retinal macular disease causing gradual vision impairment mainly in elderly people.

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

Non-renewal of conditional marketing authorisation

The committee recommended not renewing the conditional marketing authorisation for **Translarna*** (ataluren), a medicine for treating patients with non-sense mutation Duchenne muscular dystrophy, a genetic disorder characterised by the progressive loss of muscle. This CHMP opinion will now be forwarded to the European Commission for a final legally-binding decision applicable in all European Union (EU) Member States.

For more information on the non-renewal of this conditional marketing authorisation, see the public health communication in the grid below.

Recommendations on extensions of therapeutic indication for 11 medicines

The committee recommended extensions of indication for 11 medicines that are already authorised in the EU: **Betmiga**, **Beyfortus**, **Cresemba**, **Imcivree***, **Imfinzi**, **Infanrix hexa**, **Lynparza**, **Pegasys**, **Tepkinly***, **Vabysmo** and **Xalkori**.

Withdrawal of application

One application for an initial marketing authorisation was withdrawn. **Dabigatran etexilate Teva** (dabigatran etexilate) was intended for the prevention of venous thromboembolic events.

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

Conclusion of referrals

The committee completed a review of **Havrix**, a vaccine used to protect adults and children against hepatitis A virus infection, and recommended changes to the prescribing information in order to harmonise the way the medicine is used in the EU. A question-and-answer document is available in the grid below.

The CHMP completed a review of **Lorazepam Macure**, a medicine of the benzodiazepine class, following disagreement among EU Member States about an application to update the medicine's product information to

include the control of status epilepticus in adults, adolescents and children from one month old. A question-and-answer document about this update is available in the grid below.

EMA’s human medicines committee concluded its review of **Ocaliva***, a medicine used to treat adults with a rare liver disease known as primary biliary cholangitis, and recommended that the medicine’s conditional marketing authorisation should be revoked because its benefits are no longer considered to outweigh its risks. For more information on the recommendation to revoke this conditional marketing authorisation see the public health communication in the grid below.

Other updates

The CHMP gave a positive opinion to update the composition of the mRNA vaccine **Comirnaty** to target the new SARS-CoV-2 JN.1 variant of the virus that causes COVID-19**.** The revision of this vaccine is in line with the recommendation issued by EMA’s Emergency Task Force to update COVID-19 vaccines to target the SARS-CoV-2 variant JN.1 for the 2024/2025 vaccination campaign.

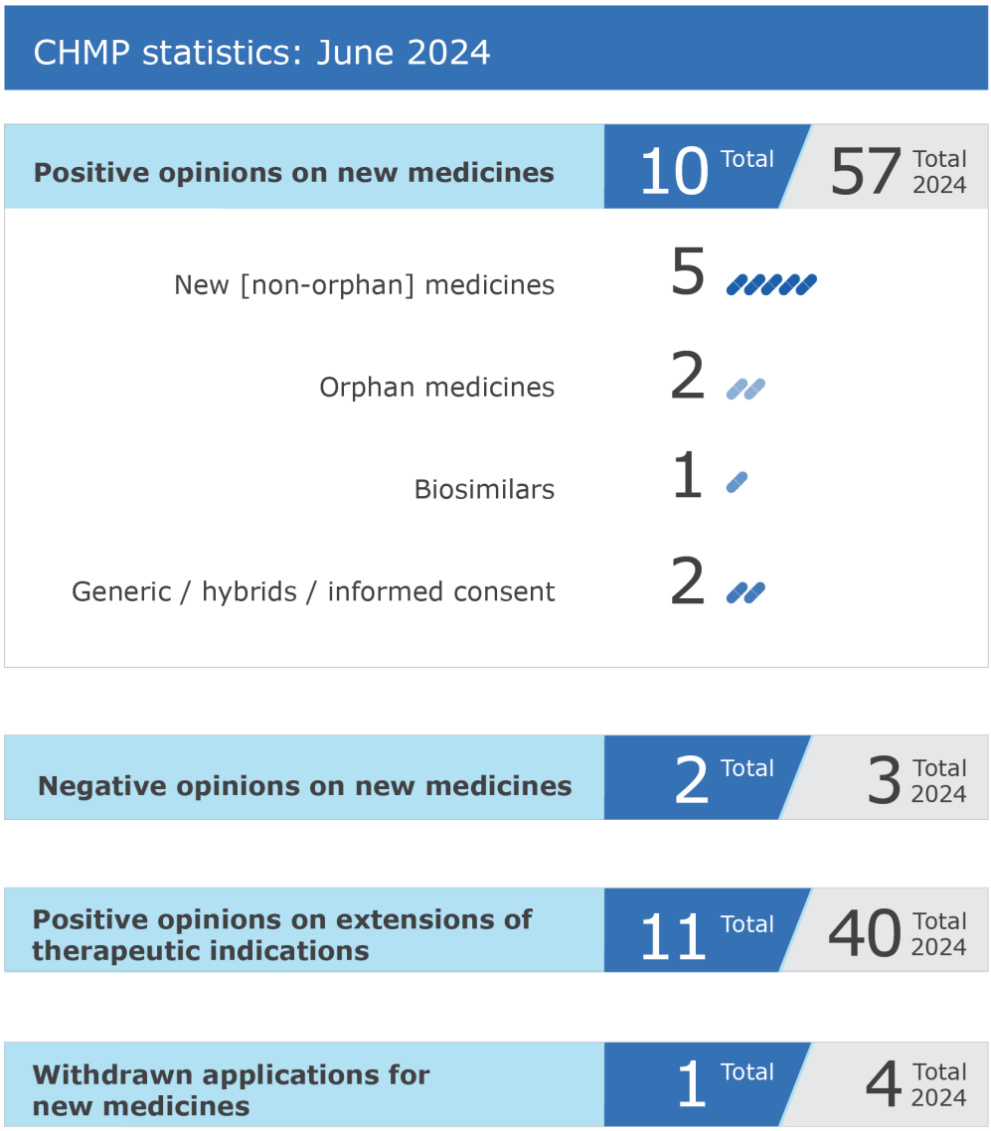
Agenda and minutes

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

*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

Balversa

Common name

erdafitinib

Marketing-authorisation applicant

Janssen-Cilag International N.V.

Therapeutic indication

Treatment of adult patients with locally

advanced unresectable or metastatic urothelial carcinoma

More information

Balversa: Pending EC decision

Eurneffy

INN

epinephrine

Marketing-authorisation applicant

Ars Pharmaceuticals Irl Limited

Therapeutic indication

Treatment of allergic reactions (anaphylaxis) and idiopathic or exercise induced anaphylaxis

More information

Eurneffy: Pending EC decision

News

First nasal adrenaline spray for emergency treatment against allergic reactions

mResvia

INN

Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation

Marketing-authorisation applicant

Moderna Biotech Spain S.L.

Therapeutic indication

Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults 60 years of

age and older

More information

mResvia: Pending EC decision

Ordspono

INN

odronextamab

Marketing-authorisation applicant

Regeneron Ireland Designated Activity Company

Therapeutic indication

Treatment of blood cancers (follicular lymphoma (FL) or diffuse large B cell lymphoma (DLBCL) and large B cell lymphoma)

More information

Ordspono: Pending EC decision

Piasky

Common name

crovalimab

Marketing-authorisation applicant

Roche Registration GmbH

Therapeutic indication

Treatment of paroxysmal nocturnal haemoglobinuria

More information

Piasky: Pending EC decision

Tauvid

INN

Flortaucipir (18F)

Marketing-authorisation applicant

Eli Lilly Nederland B.V.

Therapeutic indication

Indicated for Positron Emission Tomography (PET) imaging of the brain

More information

Tauvid: Pending EC decision

Winrevair

Common name

sotatercept

Marketing-authorisation applicant

Merck Sharp & Dohme B.V.

Therapeutic indication

Treatment of pulmonary arterial hypertension in adults

More information

Winrevair: Pending EC decision

News

Positive CHMP opinion on first-in-class medicine to treat pulmonary arterial hypertension

Positive recommendation on new biosimilar medicine

Steqeyma

INN

ustekinumab

Marketing-authorisation applicant

Celltrion Healthcare Hungary Kft.

Therapeutic indication

Treatment of adult patients with moderately to severely active Crohn’s disease, plaque psoriasis, paediatric plaque psoriasis and Psoriatic arthritis (PsA)

More information

Steqeyma: Pending EC decision

Positive recommendations on new generic medicines

Enzalutamide Viatris

INN

enzalutamide

Marketing-authorisation applicant

Viatris Limited

Therapeutic indication

Treatment of prostate cancer

More information

Enzalutamide Viatris: Pending EC decision

Nilotinib Accord

INN

nilotinib

Marketing-authorisation applicant

Accord Healthcare S.L.U.

Therapeutic indication

Treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (CML)

More information

Nilotinib Accord: Pending EC decision

Negative recommendations on new medicines

Masitinib AB Science

INN

masitinib

Marketing-authorisation applicant

AB Science

Therapeutic indication

In combination with riluzole for the treatment of adult patients with amyotrophic lateral sclerosis (ALS)

More information

Masitinib AB Science: Pending EC decision

Syfovre

INN

pegcetacoplan

Marketing-authorisation applicant

Apellis Europe B.V.

Therapeutic indication

Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

More information

Syfovre: Pending EC decision

Non-renewal of conditional marketing authorisation

Translarna

INN

ataluren

Marketing authorisation applicant

PTC Therapeutics International Limited

More information

EMA recommends non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna

Positive recommendations on extensions of indications

Betmiga

INN

mirabegron

Marketing-authorisation holder

Astellas Pharma Europe B.V.

More information

Betmiga: Pending EC decision

Beyfortus

INN

nirsevimab

Marketing-authorisation holder

Sanofi Winthrop Industrie

More information

Beyfortus: Pending EC decision

Cresemba

INN

isavuconazole

Marketing-authorisation holder

Basilea Pharmaceutica Deutschland GmbH

More information

Cresemba: Pending EC decision

Imcivree

INN

setmelanotide

Marketing-authorisation holder

Rhythm Pharmaceuticals Netherlands B.V.

More information

Imcivree: Pending EC decision

Imfinzi

INN

durvalumab

Marketing-authorisation holder

AstraZeneca AB

More information

Imfinzi: Pending EC decision

Infanrix hexa

INN

diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and haemophilus type B conjugate vaccine (adsorbed)

Marketing-authorisation holder

GlaxoSmithkline Biologicals SA

More information

Infanrix hexa: Pending EC decision

Lynparza

INN

olaparib

Marketing-authorisation holder

AstraZeneca AB

More information

Lynparza: Pending EC decision

Pegasys

INN

peginterferon alfa-2a

Marketing-authorisation holder

Pharmaand GmbH

More information

Pegasys: Pending EC decision

Tepkinly

INN

epcoritamab

Marketing-authorisation holder

AbbVie Deutschland GmbH & Co. KG

More information

Tepkinly: Pending EC decision

Vabysmo

INN

faricimab

Marketing-authorisation holder

Roche Registration GmbH

More information

Vabysmo: Pending EC decision

Xalkori

INN

crizotinib

Marketing-authorisation holder

Pfizer Europe MA EEIG

More information

Xalkori: Pending EC decision

Withdrawal of initial marketing authorisation application

Dabigatran etexilate Teva

INN

dabigatran etexilate

Marketing-authorisation holder

TEVA GmbH

More information

Dabigatran etexilate Teva: Withdrawn application

Outcome of referrals

Havrix

INN

Hepatitis A virus (inactivated, adsorbed)

Marketing-authorisation holder

GlaxoSmithKline Biologicals

More information

Havrix

Lorazepam Macure

INN

lorazepam

Marketing-authorisation holder

Macure Pharma ApS

More information

Lorazepam Macure

Ocaliva

INN

obeticholic acid

Marketing-authorisation holder

Advanz Pharma Limited

More information

Ocaliva

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- EMA recommends non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna
- EMA recommends revoking conditional marketing authorisation for Ocaliva
- First nasal adrenaline spray for emergency treatment against allergic reactions
- Positive CHMP opinion on first-in-class medicine to treat pulmonary arterial hypertension
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Media enquiries
Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu

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European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
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Tel: +31 (0)88 781 6000

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