EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 12-15 September 2022

News 16/09/2022

12 new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended 12 medicines for approval at its September 2022 meeting.

The CHMP recommended granting a marketing authorisation for **Beyfortus** (nirsevimab) intended for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants during their first RSV season (when there is a risk of RSV infection in the community). Beyfortus was supported through EMA's PRIority MEdicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support to medicines that have a particular potential to address patients' unmet medical needs. See more information in the news announcement in the grid below.

The committee adopted a positive opinion for **Enjaymo*** (sutimlimab) for the treatment of haemolytic anaemia (breakdown of red blood cells) in adult patients with cold agglutinin disease, a rare autoimmune disorder characterised by the premature destruction of red blood cells.

Livtencity* (maribavir) received a positive opinion for the treatment of adults and paediatric patients with cytomegalovirus infection and/or disease that is refractory to one or more prior therapies. Cytomegalovirus is a type of herpes virus that commonly causes infection after a stem cell or an organ transplant.

The committee adopted a positive opinion for **Melatonin Neurim** (melatonin) for the treatment of insomnia, a sleeping disorder affecting more than 10% of the European Union (EU) population.

The CHMP gave a positive opinion for **Mycapssa*** (octreotide) for the treatment of acromegaly, a rare hormonal disorder where the body produces too much growth hormone. This causes body tissues and bones to grow more quickly, leading e.g. to the enlargement of the hands, feet, forehead, jaw or nose.

The committee recommended granting a conditional marketing authorisation for **Pyrukynd*** (mitapivat) for the treatment of an inherited condition called pyruvate kinase deficiency, a rare genetic disorder characterised by the premature destruction of red blood cells.

Zynlonta * (loncastuximab tesirine) received a positive opinion from the CHMP. This medicine is intended for the treatment of adult patients with diffuse large B-cell lymphoma and high-grade B-cell lymphoma, two types of cancer that begin in the lymphatic system when abnormal white blood cells grow.

The committee adopted a positive opinion for the biosimilar medicine **Ximluci** (ranibizumab) for the treatment of neovascular age-related macular degeneration, a progressive retinal macular disease, causing gradual vision impairment, mainly in the elderly population.

The CHMP recommended granting a marketing authorisation for **Teriparatide SUN** (teriparatide) for the treatment of osteoporosis in adults. Osteoporosis affects around 22% of women over the age of 50 in the EU. The recommendation followed a hybrid application, which relies in part on the results of pre-clinical tests and clinical trials of an already authorised reference product and in part on new data.

The CHMP gave a positive opinion for the generic medicine **Sorafenib Accord** (sorafenib) for the treatment of hepatocellular carcinoma and renal cell carcinoma, two cancers that start in cells or tissues of the liver and kidney.

The committee adopted a positive opinion for the generic medicines **Teriflunomide Accord** and **Teriflunomide Mylan** (teriflunomide), indicated for the treatment of multiple sclerosis, a chronic disease affecting the central nervous system.

Recommendations on extensions of therapeutic indication for 11 medicines

The committee recommended 12 extensions of indication for medicines that are already authorised in the EU: **Adtralza** , **Biktarvy**, **Brukinsa**, **Evusheld** , **Exparel liposomal, Revolade, Skyrizi**, **Vaxneuvance**, **Veklury** (includes two extensions of indication for two paediatric populations, see the COVID-19 update below), **Xalkori** and **Yescarta**.

Withdrawals of initial applications

The application for marketing authorisation for **Exkivity** was withdrawn by the respective applicant. This medicine was indicated for the treatment of a certain type of lung cancer. A question-and-answer document on the withdrawal is available in the grid below.

The application for marketing authorisation for **Sevsury** was withdrawn by the respective applicant. This medicine was indicated for the treatment of progressive neuroendocrine tumours. A question-and-answer document on the withdrawal is available in the grid below.

Re-examination concluded

The CHMP confirmed its recommendation to suspend the marketing authorisations of several generic medicines tested by **Synchron Research Services**, a contract research organisation

(CRO) located in Ahmedabad, India. This concludes the re-examination requested by the marketing authorisation holders for some of the medicines concerned. For more information, see the public health communication in the grid below.

COVID-19 update

Since the CHMP meeting in July, several recommendations related to COVID-19 vaccines and therapeutics were made.

- Authorising use of **Nuvaxovid** as a booster dose for adults who have had Nuvaxovid, an mRNA vaccine or an adenoviral vector vaccine as their primary vaccination. (The recommendation was made on 1 September 2022)
- Authorising two vaccines adapted to provide broader protection against COVID-19. **Comirnaty Original/Omicron BA.1** and **Spikevax bivalent Original/Omicron BA.1** are for use in people aged 12 years and above who have received at least primary vaccination against COVID-19. For more information, see the news announcement. (The recommendation was made on 1 September 2022)

COVID-19 recommendations adopted during the present meeting of the CHMP:

- Authorising the adapted bivalent vaccine **Comirnaty Original/Omicron BA.4-5** for use in people aged 12 years and above who have received at least a primary course of vaccination against COVID-19. This vaccine is an adapted version of the mRNA COVID-19 vaccine Comirnaty and targets the Omicron subvariants BA.4 and BA.5 in addition to the original strain of SARS-CoV-2. For more information, see the news announcement .
- Converting the conditional marketing authorisations of the COVID-19 vaccines **Comirnaty** and **Spikevax** into standard marketing authorisations. CHMP considered that the additional studies conducted by the companies as part of their post-authorisation obligations have provided ample information on the vaccines' protection against COVID-19, as well as their quality and safety. For more information, see the news announcement.
- Approving a new manufacturing site in Dessau-Rosslau, Germany, for COVID-19 Vaccine **Valneva**.
- Authorising booster doses of **Comirnaty** for children from 5 to 11 years of age .
- Extending the use of COVID-19 therapeutic **Evusheld** for the treatment of adults and adolescents with COVID-19 who do not require supplemental oxygen.
- Extending the use of COVID-19 therapeutic **Veklury** in two paediatric populations:
    - Paediatric patients (of at least 4 weeks of age and weighing at least 3 kg) with pneumonia requiring supplemental oxygen or other non-invasive ventilation at the start of treatment.
    - Paediatric patients (weighing at least 40 kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

Safety update

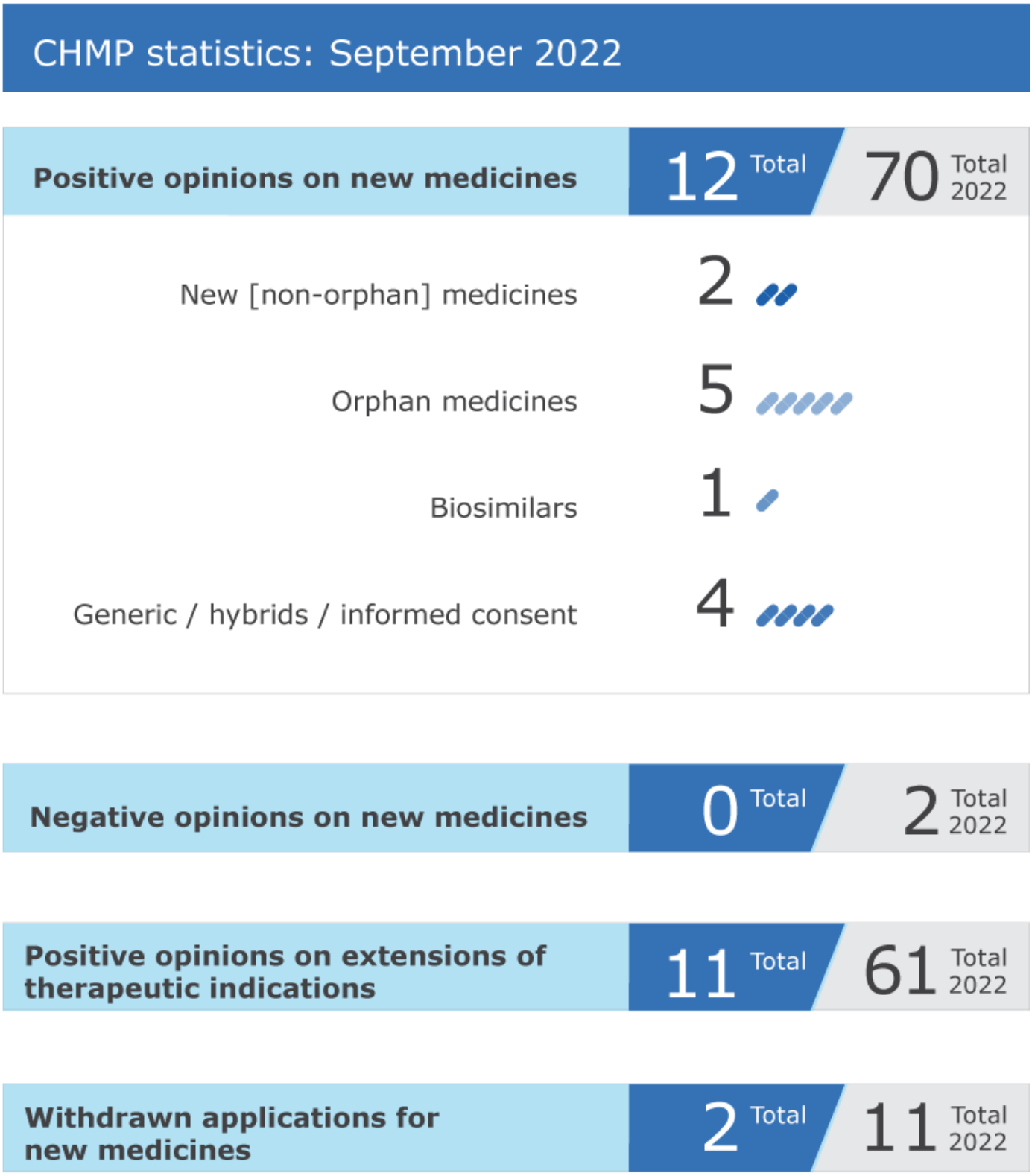
At its extraordinary meeting, on 2 September 2022, the CHMP endorsed the recommendation of the Pharmacovigilance Risk Assessment Committee (PRAC) and recommended that medicines containing high-dose nomegestrol (3.75 – 5 mg) or high-dose chlormadinone (5 – 10 mg) should be used at the lowest effective dose and for the shortest duration possible, and only when other interventions are not appropriate. In addition, low- and high-dose nomegestrol- or chlormadinone-containing medicines must not be used by patients who have, or have had, meningioma. For more information, see the news announcement .

Agenda and minutes

The agenda of the September 2022 CHMP meeting is published on EMA's website. Minutes of the September 2022 CHMP meeting will be published in the coming weeks.

CHMP statistics

Key figures from the September 2022 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

Name of medicine

Beyfortus

International non-proprietary name (INN)

nirsevimab

Marketing-authorisation applicant

AstraZeneca AB

Therapeutic indication

Prevention of respiratory syncytial virus lower respiratory tract disease in newborns and infants

More information

Beyfortus: Pending EC decision

News announcement: New medicine to protect babies and infants from respiratory syncytial virus (RSV) infection

Name of medicine

Enjaymo

INN

sutimlimab

Marketing-authorisation applicant

Genzyme Europe BV

Therapeutic indication

Treatment of haemolytic anaemia in adult patients with cold agglutinin disease

More information

Enjaymo: Pending EC decision

Name of medicine

Livtencity

INN

maribavir

Marketing-authorisation applicant

Takeda Pharmaceuticals International AG Ireland Branch

Therapeutic indication

Treatment of cytomegalovirus infection and/or disease that is refractory to one or more prior therapies

More information

Livtencity: Pending EC decision

Name of medicine

Melatonin Neurim

INN

melatonin

Marketing-authorisation applicant

RAD Neurim Pharmaceuticals EEC SARL

Therapeutic indication

Treatment of insomnia

More information

Melatonin Neurim: Pending EC decision

Name of medicine

Mycapssa

INN

octreotide

Marketing-authorisation applicant

Amryt Pharmaceuticals DAC

Therapeutic indication

Treatment of acromegaly

More information

Mycapssa: Pending EC decision

Name of medicine

Pyrukynd

INN

mitapivat

Marketing-authorisation applicant

Agios Netherlands B.V.

Therapeutic indication

Treatment of pyruvate kinase deficiency

More information

Pyrukynd: Pending EC decision

Name of medicine

Zynlonta

INN

loncastuximab tesirine

Marketing-authorisation holder

ADC Therapeutics (NL) B.V.

Therapeutic indication

Treatment of adult patients with diffuse large B-cell lymphoma and high-grade B-cell lymphoma

More information

Zynlonta: Pending EC decision

Positive recommendation on new biosimilar medicine

Name of medicine

Ximluci

INN

ranibizumab

Marketing-authorisation applicant

STADA Arzneimittel AG

Therapeutic indication

Treatment of neovascular age-related macular degeneration

More information

Ximluci: Pending EC decision

Positive recommendation on new hybrid medicine

Name of medicine

Teriparatide SUN

INN

teriparatide

Marketing-authorisation applicant

Sun Pharmaceutical Industries Europe B.V.

Therapeutic indication

Treatment of osteoporosis in adults

More information

Teriparatide SUN: Pending EC decision

Positive recommendations on new generic medicines

Name of medicine

Sorafenib Accord

INN

sorafenib

Marketing-authorisation applicant

Accord Healthcare S.L.U.

Therapeutic indication

Treatment of hepatocellular carcinoma and renal cell carcinoma

More information

Sorafenib Accord: Pending EC decision

Name of medicine

Teriflunomide Accord

INN

teriflunomide

Marketing-authorisation applicant

Accord Healthcare S.L.U.

Therapeutic indication

Treatment of multiple sclerosis

More information

Teriflunomide Accord: Pending EC decision

Name of medicine

Teriflunomide Mylan

INN

teriflunomide

Marketing-authorisation applicant

Mylan Pharmaceuticals Limited

Therapeutic indication

Treatment of multiple sclerosis

More information

To be published shortly

Positive recommendations on extensions of indications

Name of medicine

Adtralza

INN

tralokinumab

Marketing-authorisation holder

LEO Pharma A/S

More information

Adtralza: Pending EC decision

Name of medicine

Biktarvy

INN

bictegravir / emtricitabine / tenofovir alafenamide

Marketing-authorisation holder

Gilead Sciences Ireland UC

More information

Biktarvy: Pending EC decision

Name of medicine

Brukinsa

INN

zanubrutinib

Marketing-authorisation holder

BeiGene Ireland Ltd

More information

Brukinsa: Pending EC decision

Name of medicine

Evusheld

INN

tixagevimab / cilgavimab

Marketing-authorisation holder

AstraZeneca AB

More information

Evusheld: Pending EC decision

Name of medicine

Exparel liposomal

INN

bupivacaine

Marketing-authorisation holder

Pacira Ireland Limited

More information

Exparel liposomal: Pending EC decision

Name of medicine

Revolade

INN

eltrombopag

Marketing-authorisation holder

Novartis Europharm Limited

More information

Revolade: Pending EC decision

Name of medicine

Skyrizi

INN

risankizumab

Marketing-authorisation holder

AbbVie Deutschland GmbH & Co. KG

More information

Skyrizi: Pending EC decision

Name of medicine

Vaxneuvance

Common name

pneumococcal polysaccharide conjugate vaccine (adsorbed)

Marketing-authorisation holder

Merck Sharp & Dohme B.V.

More information

Vaxneuvance: Pending EC decision

Name of medicine

Veklury

INN

remdesivir

Marketing-authorisation holder

Gilead Sciences Ireland UC

More information

Veklury: Pending EC decision

Name of medicine

Xalkori

INN

crizotinib

Marketing-authorisation holder

Pfizer Europe MA EEIG

More information

Xalkori: Pending EC decision

Name of medicine

Yescarta

INN

axicabtagene ciloleucel

Marketing-authorisation holder

Kite Pharma EU B.V.

More information

Yescarta: Pending EC decision

Withdrawals of initial marketing authorisation applications

Name of medicine

Exkivity

INN

mobocertinib

Marketing-authorisation applicant

Takeda Pharma A/S

More information

Exkivity: Withdrawn application

Name of medicine

Sevsury

INN

surufatinib

Marketing-authorisation applicant

Hutchmed Europe B.V.

More information

Sevsury: Withdrawn application

Outcome of referral re-examination

Name of medicine

Synchron Research Services

More information

Synchron

Other updates

Scientific advice and protocol assistance adopted during the CHMP meeting 12-15 September 2022 (PDF/230.36 KB) (new)

Adopted

First published: 16/09/2022
EMA/CHMP/SAWP/769857/2022

Related content

- Adtralza: EPAR
- Biktarvy: EPAR
- Brukinsa: EPAR
- Evusheld: EPAR
- Exparel liposomal: EPAR
- Revolade: EPAR
- Skyrizi: EPAR
- Vaxneuvance: EPAR
- Veklury: EPAR
- Xalkori: EPAR
- Yescarta: EPAR
- Zynlonta : Pending EC decision
- Exparel liposomal: Pending EC decision
- Pyrukynd: Pending EC decision
- Veklury: Pending EC decision
- Mycapssa: Pending EC decision
- Skyrizi: Pending EC decision
- Melatonin Neurim: Pending EC decision
- Xalkori: Pending EC decision
- Exkivity: Withdrawn application
- Teriparatide Sun: Pending EC decision
- Vaxneuvance: Pending EC decision
- Sorafenib Accord : Pending EC decision
- Adtralza: Pending EC decision
- Biktarvy: Pending EC decision
- Livtencity: Pending EC decision
- Enjaymo: Pending EC decision
- Revolade: Pending EC decision
- Beyfortus: Pending EC decision
- Ximluci: Pending EC decision
- Evusheld: Pending EC decision
- Yescarta: Pending EC decision
- Teriflunomide Accord: Pending EC decision
- Brukinsa: Pending EC decision

- Revolade: Paediatric investigation plan
- Revolade: Paediatric investigation plan
- Revolade: Paediatric investigation plan
- Exparel liposomal: Paediatric investigation plan
- Xalkori: Paediatric investigation plan
- Xalkori: Paediatric investigation plan
- Biktarvy: Paediatric investigation plan
- Skyrizi: Paediatric investigation plan
- Yescarta: Paediatric investigation plan
- Veklury: Paediatric investigation plan
- Livtencity: Orphan designation
- Mycapssa: Orphan designation
- Yescarta: Orphan designation
- Yescarta: Orphan designation
- Yescarta: Orphan designation
- Enjaymo: Orphan designation
- Pyrukynd: Orphan designation
- Zynlonta : Orphan designation
- Synchron: Article 31 referrals

Related content

- EMA recommends standard marketing authorisations for Comirnaty and Spikevax COVID-19 vaccines (16/09/2022)
- New medicine to protect babies and infants from respiratory syncytial virus (RSV) infection (16/09/2022)
- Adapted vaccine targeting BA.4 and BA.5 Omicron variants and original SARS-CoV-2 recommended for approval (12/09/2022)
- Committee for Medicinal Products for Human Use (CHMP): 12-15 September 2022
- CHMP: Agendas, minutes and highlights

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