EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 20-23 June 2022

News 24/06/2022

Nine new medicines recommended for approval

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

The CHMP recommended granting a marketing authorisation for COVID-19 Vaccine (inactivated, adjuvanted) **Valneva** for use in people from 18 to 50 years of age as primary vaccination. It is the sixth vaccine recommended in the European Union (EU) for protecting against COVID-19 and, together with the vaccines already authorised, will support vaccination campaigns in EU Member States during the pandemic. See more information in the news announcement in the grid below.

The committee adopted a positive opinion for **Pepaxti*** (melphalan flufenamide) for the treatment of multiple myeloma, a rare cancer of the bone marrow that affects plasma cells, a type of white blood cell that produces antibodies.

Rayvow (lasmiditan), intended for the treatment of migraine in adults, received a positive opinion from the CHMP. It is estimated that approximately 15% of the EU population suffers from migraine.

The CHMP recommended granting a conditional marketing authorisation for **Roctavian*** (valoctocogene roxaparvovec), the first gene therapy to treat severe haemophilia A, a rare inherited bleeding disorder caused by lack of factor VIII. Roctavian 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 **Scemblix*** (asciminib), for the treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+CML-CP), previously treated with two or more tyrosine kinase inhibitors. This is a new therapeutic option for patients with this type of rare blood cancer.

The CHMP gave a positive opinion for **Sunlenca** (lenacapavir), intended for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with multidrug-resistant HIV-1 infection.

Vyvgart* (efgartigimod alfa), intended for the treatment of anti-acetylcholine receptor (AChR) antibody positive generalised myasthenia gravis, received a positive opinion from the committee. Myasthenia gravis is a chronic autoimmune neuromuscular condition that causes muscle weakness in different parts of the body.

The CHMP gave a positive opinion for the biosimilar medicine **Vegzelma** (bevacizumab), intended for the treatment of carcinoma of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, and carcinoma of the cervix.

The biosimilar medicine **Ranivisio** (ranibizumab) received a positive opinion for the treatment of adults with neovascular (wet) age-related macular degeneration, visual impairment due to macular oedema or choroidal neovascularisation, and proliferative diabetic retinopathy.

Recommendations on extensions of therapeutic indication for eight medicines

The Committee recommended eight extensions of indication for medicines that are already authorised in the
EU: **Crysvita**, **Enhertu**, **Imbruvica**, **Lonquex**, **Lynparza**, **Rinvoq** and **Zerbaxa**. It also includes an extension of the use of the COVID-19 vaccine **Nuvaxovid** in adolescents from 12-17 years of age. More information on this extension of indication is available in the news announcement in the grid below.

Re-examination of recommendations

The applicant for **Tuznue and Hervelous** has requested a re-examination of the Committee's negative opinion for these medicines adopted at its May 2022 meeting. Upon receipt of the grounds of the request, the Agency will re-examine its opinion and issue a final recommendation.

A group of companies that contracted **Synchron Research Services** has requested a re-examination of EMA's May 2022 opinion. Upon receipt of the grounds of the request, the Agency will re-examine its opinion and issue a final recommendation.

Agenda and minutes

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

CHMP statistics

Key figures from the June 2022 CHMP meeting are represented in the graphic below.

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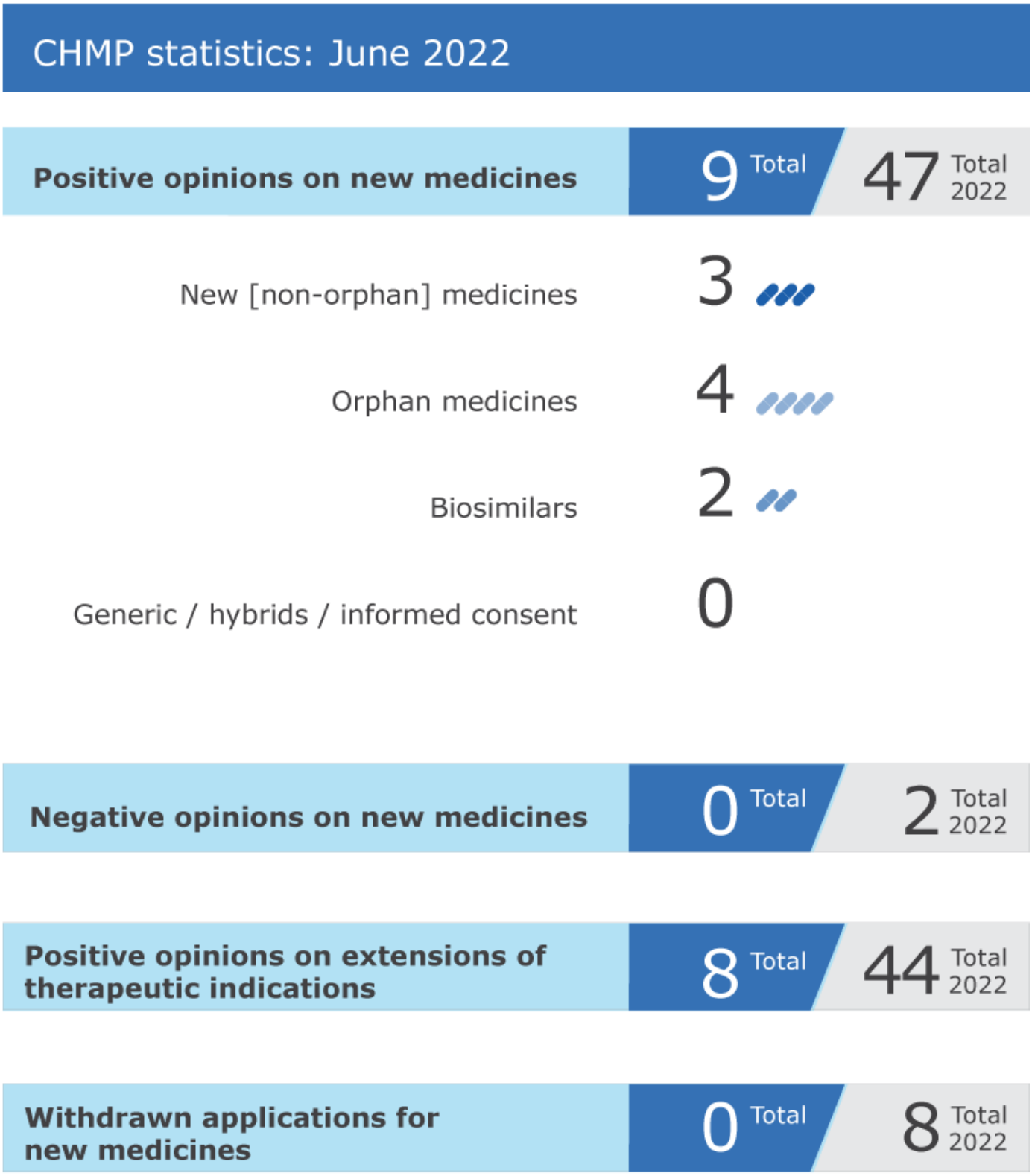
*This product was designated as an orphan medicine during its development. Orphan designations are reviewed by EMA's Committee for Orphan Medicinal Products (COMP) at the time of approval to determine whether the information available to date allows maintaining the medicine's orphan status and granting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



Positive recommendations on new medicines

Name of medicine

COVID-19 Vaccine (inactivated, adjuvanted) Valneva

Common name

COVID-19 vaccine (inactivated, adjuvanted, adsorbed)

Marketing-authorisation applicant

Valneva Austria GmbH

Therapeutic indication

Active immunisation against coronavirus disease 2019 (COVID-19)

More information

COVID-19 Vaccine (inactivated, adjuvanted) Valneva: Pending EC decision

News announcement: EMA recommends Valneva's COVID-19 vaccine for authorisation in the EU

Name of medicine

Pepaxti

INN

melphalan flufenamide

Marketing-authorisation applicant

Oncopeptides AB

Therapeutic indication

Treatment of multiple myeloma

More information

Pepaxti: Pending EC decision

Name of medicine

Rayvow

International non-proprietary name (INN)

lasmiditan

Marketing-authorisation applicant

Eli Lilly Nederland B.V.

Therapeutic indication

Treatment of migraine

More information

Rayvow: Pending EC decision

Name of medicine

Roctavian

INN

valoctocogene roxaparvovec

Marketing-authorisation applicant

BioMarin International Limited

Therapeutic indication

Treatment of severe haemophilia A

More information

Roctavian: Pending EC decision

News announcement: First gene therapy to treat severe haemophilia A

Name of medicine

Scemblix

INN

asciminib

Marketing-authorisation applicant

Novartis Europharm Limited

Therapeutic indication

Treatment of Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+CML-CP)

More information

Scemblix: Pending EC decision

Name of medicine

Sunlenca

INN

lenacapavir

Marketing-authorisation applicant

Gilead Sciences Ireland Unlimited Company

Therapeutic indication

Treatment of human immunodeficiency virus type 1 (HIV-1) infection

More information

Sunlenca: Pending EC decision

Name of medicine

Vyvgart

INN

efgartigimod alfa

Marketing-authorisation applicant

Argenx

Therapeutic indication

Treatment of anti acetylcholine receptor (AChR) antibody positive generalised myasthenia gravis

More information

Vyvgart: Pending EC decision

Positive recommendations on new biosimilar medicines

Name of medicine

Ranivisio

INN

ranibizumab

Marketing-authorisation applicant

Midas Pharma GmbH

Therapeutic indication

Treatment of neovascular (wet) age-related macular degeneration, visual impairment due to macular oedema or choroidal neovascularisation, and proliferative diabetic retinopathy

More information

Ranivisio: Pending EC decision

Name of medicine

Vegzelma

INN

bevacizumab

Marketing-authorisation applicant

Celltrion Healthcare Hungary Kft

Therapeutic indication

Treatment of carcinoma of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, and carcinoma of the cervix

More information

Vegzelma: Pending EC decision

Re-examination of recommendations for new medicines

Name of medicine

Hervelous

INN

trastuzumab

Marketing-authorisation applicant

Prestige Biopharma Belgium

Therapeutic indication

Treatment of certain forms of breast cancer and gastric (stomach) cancer

More information

Hervelous: Pending EC decision

Name of medicine
Tuznue
INN
trastuzumab
Marketing-authorisation applicant
Prestige Biopharma Belgium
Therapeutic indication
Treatment of certain forms of breast cancer and gastric (stomach) cancer
More information
Tuznue: Pending EC decision

Positive recommendations on extensions of indications

Name of medicine
Crysvita
INN
burosumab
Marketing-authorisation holder
Kyowa Kirin Holdings B.V.
More information
Crysvita: Pending EC decision

Name of medicine
Enhertu
INN
trastuzumab deruxtecan
Marketing-authorisation holder
Daiichi Sankyo Europe GmbH
More information

Enhertu: Pending EC decision

Name of medicine

Imbruvica

INN

ibrutinib

Marketing-authorisation holder

Janssen-Cilag International NV

More information

Imbruvica: Pending EC decision

Name of medicine

Lonquex

INN

lipegfilgrastim

Marketing-authorisation holder

Teva B.V.

More information

Lonquex: Pending EC decision

Name of medicine

Lynparza

INN

olaparib

Marketing-authorisation holder

AstraZeneca AB

More information

Lynparza: Pending EC decision

Name of medicine

Nuvaxovid

Common name

COVID-19 Vaccine (recombinant, adjuvanted)

Marketing-authorisation holder

Novavax CZ, a.s.

More information

Nuvaxovid: Pending EC decision

News announcement: EMA recommends authorisation of Nuvaxovid for adolescents aged 12 to 17

Name of medicine

Rinvoq

INN

upadacitinib

Marketing-authorisation holder

AbbVie Deutschland GmbH & Co. KG

More information

Rinvoq: Pending EC decision

Name of medicine

Zerbaxa

INN

ceftolozane / tazobactam

Marketing-authorisation holder

Merck Sharp & Dohme B.V.

More information

Zerbaxa: Pending EC decision

Re-examination of public-health recommendation

Name of referral

Synchron

More information

Synchron Research Service: suspension of medicines over flawed studies

Other updates

Scientific advice and protocol assistance adopted during the CHMP meeting 20-23 June 2022 (PDF/248.67 KB) (new)

First published: 24/06/2022
EMA/CHMP/SAWP/603443/2022

Start of union reviews adopted during the CHMP meeting of 20-23 June 2022 (PDF/106.55 KB) (new)

Adopted

First published: 24/06/2022
EMA/598738/2022

Related content

- Crysvita: EPAR
- Enhertu: EPAR
- Imbruvica: EPAR
- Lynparza: EPAR
- Nuvaxovid: EPAR
- Rinvoq: EPAR
- Zerbaxa: EPAR
- Rayvow: Pending EC decision
- Zerbaxa: Pending EC decision
- Sunlenca: Pending EC decision
- Rinvoq: Pending EC decision
- Vyvgart: Pending EC decision

- Vegzelma: Pending EC decision
- Tuznue: Pending EC decision
- Crysvita: Pending EC decision
- Nuvaxovid: Pending EC decision
- Enhertu: Pending EC decision
- Pepaxti: Pending EC decision
- Rinvoq: Pending EC decision
- COVID-19 Vaccine (inactivated, adjuvanted) Valneva: Pending EC decision
- Lynparza: Pending EC decision
- Scemblix: Pending EC decision
- Imbruvica: Pending EC decision
- Roctavian: Pending EC decision
- Ranivisio: Pending EC decision
- Hervelous: Pending EC decision
- Zerbaxa: Paediatric investigation plan
- Zerbaxa: Paediatric investigation plan
- Imbruvica: Paediatric investigation plan
- Imbruvica: Paediatric investigation plan
- Imbruvica: Paediatric investigation plan
- Imbruvica: Paediatric investigation plan
- Crysvita: Paediatric investigation plan
- Rinvoq: Paediatric investigation plan
- Rinvoq: Paediatric investigation plan
- Lynparza: Paediatric investigation plan
- Vyvgart: Orphan designation
- Crysvita: Orphan designation
- Pepaxti: Orphan designation
- Roctavian: Orphan designation
- Scemblix: Orphan designation
- Janus Kinase inhibitors (JAKi): Article 20 procedures
- Synchron: Article 31 referrals

Related content

- First gene therapy to treat severe haemophilia A (24/06/2022)
- EMA recommends Valneva's COVID-19 vaccine for authorisation in the EU (23/06/2022)
- EMA recommends authorisation of Nuvaxovid for adolescents aged 12 to 17 (23/06/2022)
- Committee for Medicinal Products for Human Use (CHMP): 20-23 June 2022
- CHMP: Agendas, minutes and highlights

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