EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 10-13 October 2022

News 14/10/2022

10 new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended 10 medicines for approval at its October 2022 meeting.

The CHMP recommended granting a marketing authorisation for **Dengue Tetravalent Vaccine** (Live, Attenuated) **Takeda** for the prevention of dengue virus serotypes 1, 2, 3 and 4 in people from four years of age. Dengue is a mosquito-borne tropical disease caused by the dengue virus, leading to mild flu-like symptoms in most people. However, a small number of patients develop severe disease, with potentially fatal bleeding and organ damage. The global estimated death rate is 20,000 to 25,000 per year, primarily in children. Dengue tetravalent vaccine prevents fever, severe disease and hospitalisation caused by any of the four serotypes of the dengue virus. This vaccine received an EMA recommendation under the EU Medicines for all (EU-M4All) programme, a mechanism that allows the CHMP to assess medicines that are intended for use in low- and middle-income countries outside of the European Union (EU). Simultaneously, the vaccine has also received a positive opinion for use in the EU, under the trade name **Qdenga**. See more information in the news announcement in the grid below.

The committee adopted a positive opinion for a marketing authorisation under exceptional circumstances for the advanced therapy medicinal product (ATMP) **Ebvallo*** (tabelecleucel) for the treatment of Epstein-Barr virus positive post-transplant lymphoproliferative disease. This ATMP is intended for adult and paediatric patients who experience a serious complication following solid organ transplantation or bone marrow transplantation. Ebvallo 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.

Eladynos (abaloparatide) received a positive opinion for the treatment of osteoporosis in postmenopausal women at increased risk of fractures.

The committee recommended granting a marketing authorisation under exceptional circumstances for **Livmarli*** (maralixibat chloride) intended for the treatment of cholestatic pruritus (itching) in adult and paediatric patients from two months of age with Alagille syndrome, an inherited condition in which bile builds up in the liver.

The CHMP gave a positive opinion for **Locametz** (gozetotide), which is intended for the diagnosis of prostate cancer.

The committee adopted a positive opinion for **Pluvicto** (lutetium (^{177}Lu) vipivotide tetraxetan) for the treatment of prostate cancer.

Spevigo (spesolimab) received a positive opinion for a conditional marketing authorisation for the treatment of flares in adult patients with generalised pustular psoriasis, a skin disorder that consists of pus spots surrounded by areas of red skin.

The committee adopted positive opinions for three generic medicines:

Dimethyl fumarate Teva (dimethyl fumarate), indicated for the treatment of adult and paediatric patients aged 13 years and older with multiple sclerosis, a chronic disease affecting the central nervous system.

Pemetrexed Baxter (pemetrexed) for the treatment of malignant pleural mesothelioma, a rare cancer of the lining around the lungs, and non-small cell lung cancer.

Plerixafor Accord (plerixafor) for the treatment of adults and children with lymphoma and multiple myeloma, two types of white blood cells cancers.

Recommendations on extensions of therapeutic indication for four medicines

The committee recommended four extensions of indication for medicines that are already authorised in the EU: **Brukinsa**, **Libtayo**, **Lyumjev** and **Xydalba**.

Withdrawals of initial applications

The applications for marketing authorisation for biosimilar medicines **Tuznue** and **Hervelous** were withdrawn by the applicant during the re-examination of the negative opinions that the committee adopted at its May 2022 meeting. These medicines were intended for the treatment of certain forms of breast cancer and gastric (stomach) cancer. A question-and-answer document on the withdrawals is available in the grid below.

COVID-19 update

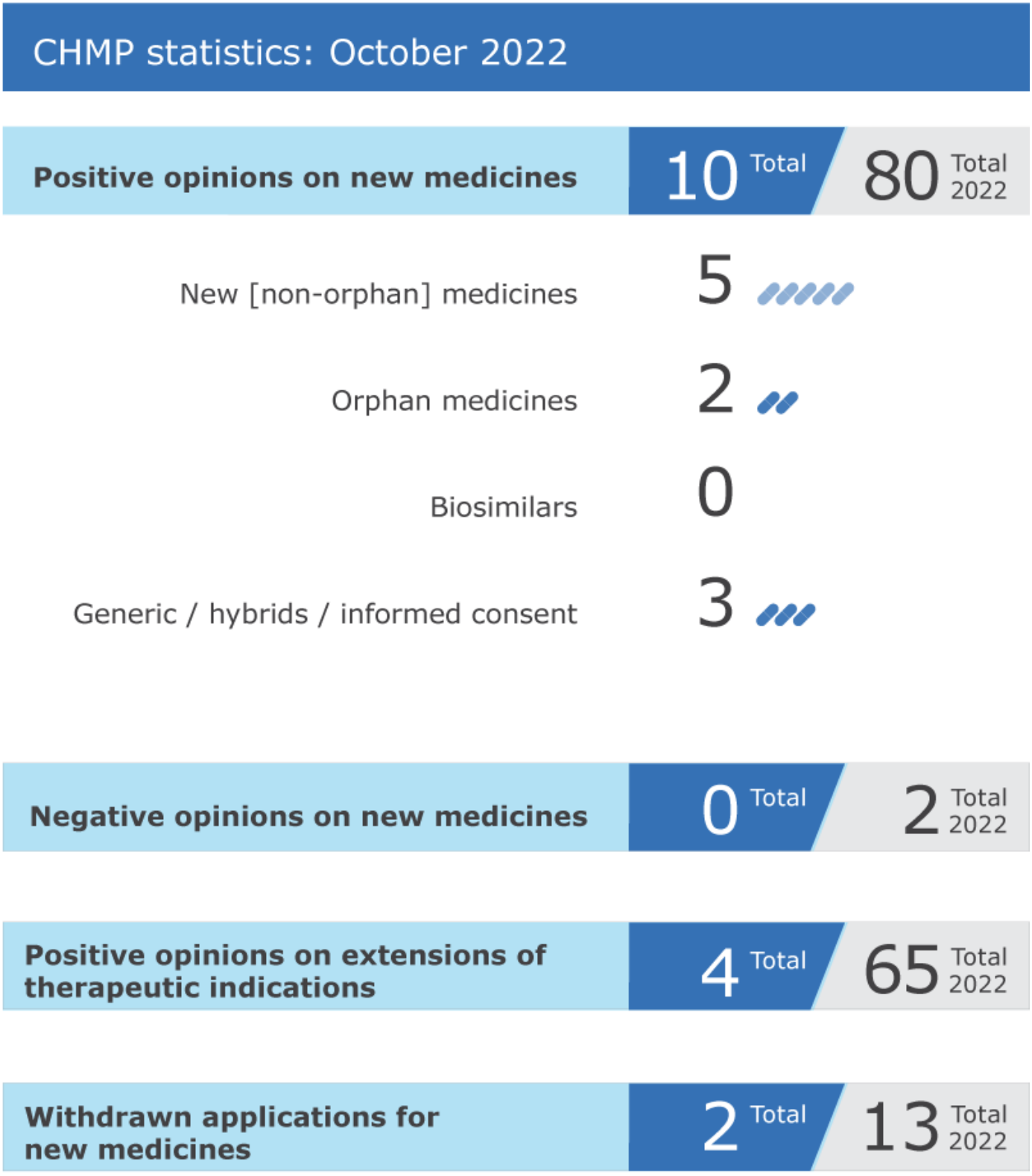
The committee recommended converting the conditional marketing authorisation of the COVID-19 vaccine **Vaxzevria** to a standard marketing authorisation.

Agenda and minutes

The agenda of the October 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 October 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

Ebvallo

International non-proprietary name (INN)

tabelecleucel

Marketing-authorisation applicant

Atara Biotherapeutics Ireland Limited

Therapeutic indication

Treatment of Epstein-Barr virus positive post-transplant lymphoproliferative disease

More information

Ebvallo: Pending EC decision

News announcement: First therapy to treat transplant patients with post-transplant lymphoproliferative disease

Name of medicine

Eladynos

INN

abaloparatide

Marketing-authorisation applicant

Radius Health Ireland Ltd

Therapeutic indication

Treatment of osteoporosis in postmenopausal women at increased risk of fracture

More information

Eladynos: Pending EC decision

Name of medicine

Livmarli

INN

maralixibat chloride

Marketing-authorisation applicant

Mirum Pharmaceuticals International B.V.

Therapeutic indication

Treatment of cholestatic pruritus in patients with Alagille syndrome

More information

Livmarli: Pending EC decision

Name of medicine

Locametz

INN

gozetotide

Marketing-authorisation applicant

Novartis Europharm Limited

Therapeutic indication

Diagnosis of prostate cancer

More information

Locametz: Pending EC decision

Name of medicine

Qdenga

Common name

dengue tetravalent vaccine (live, attenuated)

Marketing-authorisation applicant

Takeda GmbH

Therapeutic indication

Prevention of dengue disease

More information

Qdenga: Pending EC decision

Name of medicine

Pluvicto

INN

lutetium (177Lu) vipivotide tetraxetan

Marketing-authorisation applicant

Novartis Europharm Limited

Therapeutic indication

Treatment of prostate cancer

More information

Pluvicto: Pending EC decision

Name of medicine

Spevigo

INN

spesolimab

Marketing-authorisation applicant

Boehringer Ingelheim International GmbH

Therapeutic indication

Treatment of flares in adult patients with generalised pustular psoriasis

More information

Spevigo: Pending EC decision

Positive recommendations on new generic medicines

Name of medicine

Dimethyl fumarate Teva

INN

dimethyl fumarate

Marketing-authorisation holder

TEVA GmbH

Therapeutic indication

Treatment of multiple sclerosis

More information

Dimethylfumarate Teva: Pending EC decision

Name of medicine

Pemetrexed Baxter

INN

pemetrexed

Marketing-authorisation applicant

Baxter Holding B.V.

Therapeutic indication

Treatment of malignant pleural mesothelioma and non-small cell lung cancer

More information

Pemetrexed Baxter: Pending EC decision

Name of medicine

Plerixafor Accord

INN

plerixafor

Marketing-authorisation applicant

Accord Healthcare S.L.U.

Therapeutic indication

Treatment of lymphoma and multiple myeloma

More information

To be published shortly

Positive recommendations on extensions of indications

Name of medicine

Brukinsa

INN

zanubrutinib

Marketing-authorisation holder

BeiGene Ireland Ltd

More information

Brukinsa: Pending EC decision

Name of medicine

Libtayo

INN

cemiplimab

Marketing-authorisation holder

Regeneron Ireland Designated Activity Company (DAC)

More information

Libtayo: Pending EC decision

Name of medicine

Lyumjev

INN

insulin lispro

Marketing-authorisation holder

Eli Lilly Nederland B.V.

More information

Lyumjev: Pending EC decision

Name of medicine

Xydalba

INN

dalbavancin

Marketing-authorisation holder

AbbVie Deutschland GmbH & Co. KG

More information

Xydalba: Pending EC decision

Withdrawals of initial marketing authorisation applications

Name of medicine

Hervelous

INN

trastuzumab

Marketing-authorisation applicant

Prestige Biopharma Belgium

More information

Hervelous: Withdrawn application

Name of medicine

Tuznue

INN

trastuzumab

Marketing-authorisation applicant

Prestige Biopharma Belgium

More information

Tuznue: Withdrawn application

Positive recommendations on medicines for use outside the European Union

Name of medicine

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda

Common name

dengue tetravalent vaccine (live, attenuated)

More information

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda

News announcement: New vaccine to protect people in the EU and worldwide against dengue

Other updates

Overview of (invented) names reviewed in September 2022 by the Name Review Group (NRG) adopted at the CHMP meeting of 10-13 October 2022 (PDF/142.16 KB) (new)

Adopted

First published: 14/10/2022
EMA/825713/2022

Scientific advice and protocol assistance adopted during the CHMP meeting 10-13 October 2022 (PDF/242.62 KB) (new)

Adopted

First published: 14/10/2022
EMA/CHMP/SAWP/827118/2022

Related content

- Brukinsa: EPAR
- Libtayo: EPAR
- Lyumjev (previously Liumjev): EPAR
- Vaxzevria (previously COVID-19 Vaccine AstraZeneca): EPAR
- Xydalba: EPAR
- Lyumjev (previously Liumjev): Pending EC decision
- Pluvicto: Pending EC decision
- Pemetrexed Baxter: Pending EC decision
- Livmarli: Pending EC decision
- Eladynos: Pending EC decision
- Tuznue: Withdrawn application
- Brukinsa: Pending EC decision
- Spevigo: Pending EC decision
- Libtayo: Pending EC decision
- Qdenga: Pending EC decision

- Xydalba: Pending EC decision
- Locametz: Pending EC decision
- Ebvallo: Pending EC decision
- Dimethyl fumarate Teva: Pending EC decision
- Hervelous: Withdrawn application
- Brukinsa: Pending EC decision
- Xydalba: Paediatric investigation plan
- Libtayo: Paediatric investigation plan
- Vaxzevria (previously COVID-19 Vaccine AstraZeneca): Paediatric investigation plan
- Livmarli: Orphan designation
- Ebvallo: Orphan designation

Related content

- First therapy to treat transplant patients with post-transplant lymphoproliferative disease (14/10/2022)
- New vaccine to protect people in the EU and worldwide against dengue (14/10/2022)
- Committee for Medicinal Products for Human Use (CHMP): 10-13 October 2022
- CHMP: Agendas, minutes and highlights

Please note that not all documents associated with this page are published at the same time. This page is updated with new documents as soon as they become available. Therefore, users are asked to check the page regularly.

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