EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 11-14 September 2023

News 15/09/2023

Nine new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended nine medicines for approval at its September 2023 meeting.

The CHMP recommended granting a marketing authorisation for **Ebglyss** (lebrikizumab), for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents.

A positive opinion was adopted for **Finlee*** (dabrafenib) for the treatment of glioma, a type of brain tumour that begins in glial cells, the cells that surround and support nerve cells.

The Committee gave a positive opinion for **Vanflyta*** (quizartinib), for the treatment of adult patients with diagnosed acute myeloid leukaemia, a cancer of the blood and bone marrow.

Yorvipath* (palopegteriparatide), a parathyroid hormone replacement therapy, received a positive opinion for the treatment of chronic hypoparathyroidism in adults. Hypoparathyroidism is a disorder in which the glands in the neck do not produce enough parathyroid hormone.

The committee granted a positive opinion for **Zilbrysq*** (zilucoplan) for the treatment of generalised myasthenia gravis in adults. This chronic autoimmune neuromuscular condition causes muscle weakness in different parts of the body.

The CHMP recommended granting a marketing authorisation for **Zoonotic Influenza Vaccine Seqirus** (surface antigen, inactivated, adjuvanted), for the active immunisation against H5N1 subtype of Influenza A virus. This is an informed consent application that makes use of data from the dossier of a previously authorised medicine, with the marketing authorisation holder of that medicine giving consent for the use of their data in the application.

The committee adopted a positive opinion for the biosimilar medicine **Herwenda** (trastuzumab) for the treatment of metastatic and early breast cancer and metastatic gastric cancer.

The CHMP recommended granting a paediatric-use marketing authorisation (PUMA) for **Aqumeldi** (enalapril maleate) for the treatment of heart failure, and a marketing authorisation for **Catiolanze** (latanoprost) for the reduction of elevated intraocular pressure. Both medicines were submitted in hybrid applications, which rely in part on the results of pre-clinical tests and clinical trials of an already authorised reference product and in part on new data.

Recommendations on extensions of therapeutic indication for 11 medicines

The committee recommended 11 extensions of indication for medicines that are already authorised in the European Union (EU): **Adcetris**, **Enhertu**, **Kaftrio**, **Kalydeco**, **Keytruda**, **Nordimet**, **Olumiant**, **Pepaxti**, **Ryeqo, Takhzyro** and **Voxzogo**.

Non-renewal of conditional marketing authorisations

The committee recommended not renewing the conditional marketing authorisation of two medicines: **Translarna** (ataluren), a medicine for treating patients with Duchenne muscular dystrophy (a genetic disorder characterised by the progressive loss of muscle), and **BlenRep** (belantamab mafodotin) a medicine used to treat multiple myeloma (a cancer of the bone marrow).

These CHMP opinions will now be forwarded to the European Commission (EC), which will issue a final legally binding decision applicable in all EU Member States.

Public health communications on Translarna and BlenRep are available in the grid below.

COVID-19 update

The CHMP has recommended authorising two adapted vaccines targeting the Omicron XBB.1.5 subvariant: an adapted **Comirnaty** vaccine that received a positive opinion on 30 August 2023 (for more information, see news announcement) and an adapted **Spikevax** vaccine recommended for approval during the present meeting of the CHMP (for more information, see news announcement).

Skycovion withdrew their application for the prevention of COVID-19 in individuals 18 years of age and older. A question-and-answer document is available in the grid below.

Withdrawals of applications

Three applications for marketing authorisation were withdrawn during their assessment: **Lutholaz**, for use in cancer patients to reduce the duration of neutropenia and prevent febrile neutropenia, **Vivjoa**, for the treatment and prevention of vulvovaginal candidiasis, and **Skycovion** (see above). Question-and-answer documents on these withdrawals are available in the grid below.

The marketing authorisation holder for **Iclusig** withdrew an application for the use of this medicine in the treatment of adults newly diagnosed with Philadelphia chromosome-positive

acute lymphoblastic leukaemia, a type of blood cancer. A question-and-answer document on this withdrawal is available in the grid below.

Start of referral

The CHMP started a review of all available information on the benefits and risks of **Mysimba** (naltrexone / bupropion), a medicine used along with diet and exercise to help manage weight in adults. The review is carried out under Article 20 of Regulation (EC) No 726/2004. For more information, see the public health communication in the grid below.

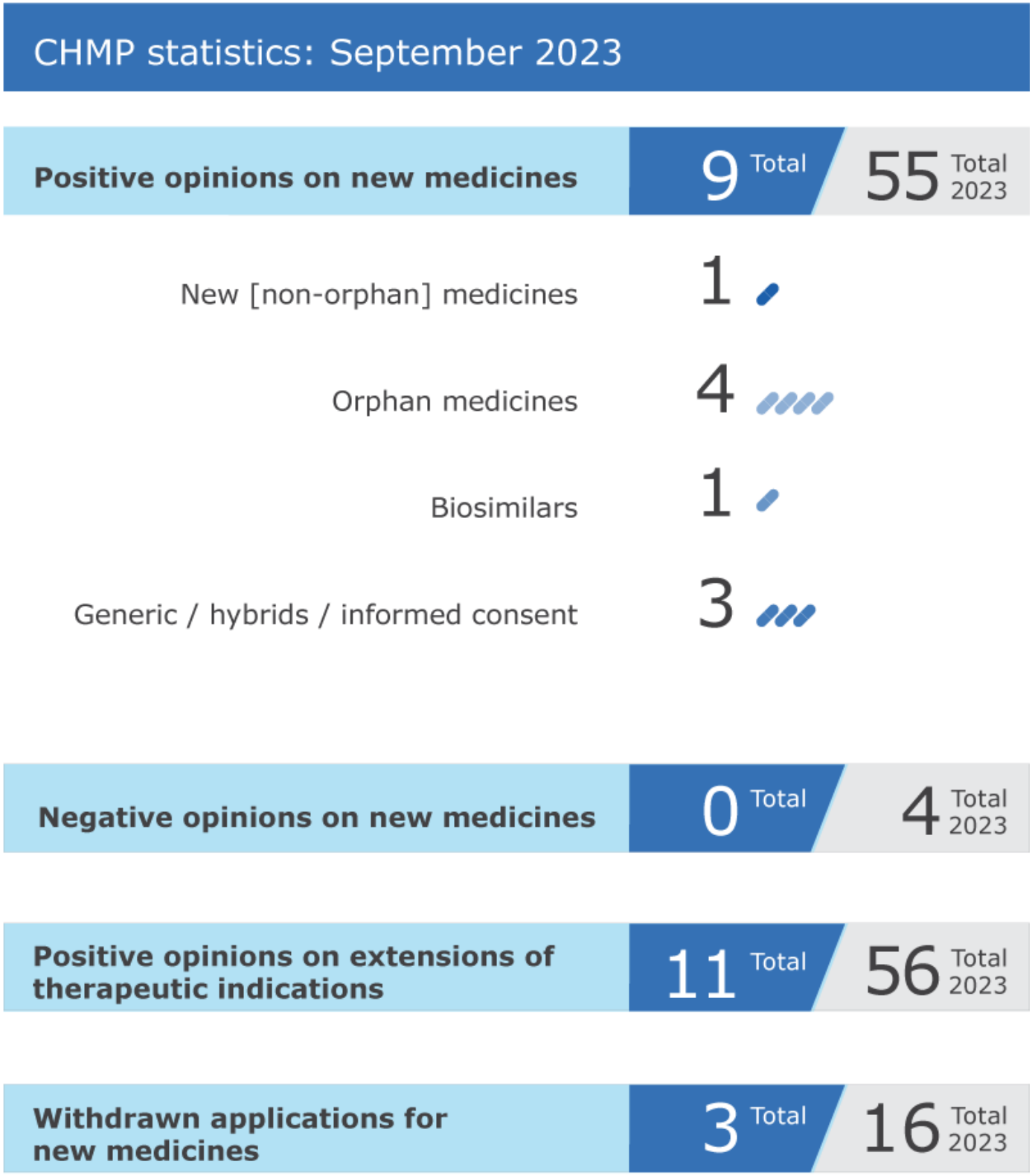
The committee also started a referral procedure for **Havrix** (inactivated, adsorbed), a vaccine protecting against infections caused by hepatitis A virus. The aim of this referral is to harmonise the prescribing information across the various countries where the product is approved after several inconsistencies have been identified. This review is carried out under Article 30 of Regulation (EC) No 726/2004. For more information, see the public health communication in the grid below.

Agenda and minutes

The agenda of the September 2023 CHMP meeting is published on EMA's website. Minutes of the July 2023 CHMP meeting will be published in the coming weeks.

CHMP statistics

Key figures from the September 2023 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	Ebglyss

International non-proprietary name (INN)	lebrikizumab
Marketing-authorisation applicant	Almirall, S.A.
Therapeutic indication	Treatment of moderate-to-severe atopic dermatitis in adults and adolescents
More information	Ebglyss: Pending EC decision

Name of medicine	Finlee
INN	dabrafenib
Marketing-authorisation applicant	Novartis Europharm Limited
Therapeutic indication	Treatment of glioma
More information	Finlee: Pending EC decision

Name of medicine	Vanflyta
INN	quizartinib
Marketing-authorisation applicant	Daiichi Sankyo Europe GmbH
Therapeutic indication	Treatment of adult patients with diagnosed acute myeloid leukaemia (AML)
More information	Vanflyta: Pending EC decision

Name of medicine	Yorvipath
INN	palopegteriparatide
Marketing-authorisation applicant	Ascendis Pharma Bone Diseases A/S
Therapeutic indication	Parathyroid hormone replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism
More information	Yorvipath: Pending EC decision

Name of medicine	Zilbrysq
INN	zilucoplan
Marketing-authorisation applicant	UCB Pharma S.A.
Therapeutic indication	Treatment of generalised myasthenia gravis in adults
More information	Zilbrysq : Pending EC decision

Name of medicine	Zoonotic Influenza Vaccine Seqirus
Common name	zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)
Marketing-authorisation applicant	Seqirus S.r.l.
Therapeutic indication	Active immunisation against H5 subtype of Influenza A virus
More information	Zoonotic Influenza Vaccine Seqirus : Pending EC decision

Positive recommendation on new biosimilar medicine

Name of medicine	Herwenda
INN	trastuzumab
Marketing-authorisation applicant	Sandoz GmbH
Therapeutic indication	Treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC)
More information	Herwenda: Pending EC decision

Positive recommendation on new hybrid medicine

Name of medicine	Aqumeldi
INN	enalapril maleate

Marketing-authorisation applicant	Proveca Pharma Limited
Therapeutic indication	Treatment of heart failure
More information	Aqumeldi: Pending EC decision

Name of medicine	Catiolanze
INN	latanoprost
Marketing-authorisation applicant	Santen Oy
Therapeutic indication	Reduction of elevated intraocular pressure (IOP)
More information	Catiolanze: Pending EC decision

Positive recommendations on extensions of indications

Name of medicine	Adcetris
INN	brentuximab vedotin
Marketing-authorisation holder	Takeda Pharma A/C
More information	Adcetris: 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	Kaftrio
INN	ivacaftor / tezacaftor / elexacaftor

Marketing-authorisation holder	Vertex Pharmaceuticals (Ireland) Limited
More information	Kaftrio: Pending EC decision

Name of medicine	Kalydeco
INN	ivacaftor
Marketing-authorisation holder	Vertex Pharmaceuticals (Ireland) Limited
More information	Kalydeco: Pending EC decision

Name of medicine	Keytruda
INN	pembrolizumab
Marketing-authorisation holder	Merck Sharp & Dohme B.V.
More information	Keytruda: Pending EC decision

Name of medicine	Nordimet
INN	methotrexate
Marketing-authorisation holder	Nordic Group B.V.
More information	Nordimet: Pending EC decision

Name of medicine	Olumiant
INN	baricitinib
Marketing-authorisation applicant	Eli Lilly Nederland B.V.
More information	Olumiant: Pending EC decision

Name of medicine	Pepaxti
INN	melphalan flufenamide
Marketing-authorisation applicant	Oncopeptides AB
More information	Pepaxti: Pending EC decision

Name of medicine	Ryeqo
INN	relugolix / estradiol / norethisterone acetate
Marketing-authorisation applicant	Gedeon Richer Plc.
More information	Ryeqo: Pending EC decision

Name of medicine	Takhzyro
INN	lanadelumab
Marketing-authorisation applicant	Takeda Pharmaceuticals International AG Ireland Branch
More information	Takhzyro: Pending EC decision

Name of medicine	Voxzogo
INN	vosoritide
Marketing-authorisation applicant	BioMarin International Limited
More information	Voxzogo: Pending EC decision

Non-renewal of Conditional Marketing Authorisation

Name of medicine	BlenRep

INN	belantamab mafodotin
Marketing-authorisation holder	GlaxoSmithKline (Ireland) Limited
More information	EMA recommends non-renewal of authorisation of multiple myeloma medicine Blenrep

Name of medicine	Translarna
INN	ataluren
Marketing-authorisation holder	PTC Therapeutics International Limited
More information	EMA recommends non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna

Withdrawals of initial marketing authorisation applications

Name of medicine	Lutholaz
INN	pegfilgrastim
Marketing-authorisation applicant	YES Pharmaceutical Development Services GmbH
More information	Lutholaz: Withdrawn application

Name of medicine	Vivjoa
INN	oteseconazole
Marketing-authorisation applicant	Gedeon Richter Plc.
More information	Vivjoa: Withdrawn application

Name of medicine	Skycovion
INN	GBP510

Marketing-authorisation applicant	SK Chemicals GmbH
More information	Skycovion: Withdrawn application

Withdrawal of application to change the marketing authorisation

Name of medicine	Iclusig
INN	ponatinib
Marketing-authorisation holder	Incyte Biosciences Distribution B.V.
More information	Iclusig: Withdrawn application

Start of referral

Name of medicine	Mysimba
INN	naltrexone hydrochloride / bupropion hydrochloride
Marketing-authorisation holder	Orexigen Therapeutics Ireland Limited
More information	Mysimba: Article 20 referral

Name of medicine	Havrix
Common name	hepatitis A virus (inactivated, adsorbed)
Marketing-authorisation holder	GlaxoSmithKline Biologicals
More information	Havrix: Article 30 referral

Other updates

Scientific advice and protocol assistance adopted during the CHMP meeting 11-14 September 2023 (PDF/244.62 KB) (new)

Adopted

First published: 15/09/2023
EMA/CHMP/SAWP/416080/2023

Start of Union reviews adopted during the CHMP meeting of 11-14 September 2023 (PDF/125.33 KB) (new)

First published: 15/09/2023
EMA/351480/2023

Related content

- Adcetris: EPAR
- Blenrep: EPAR
- Enhertu: EPAR
- Iclusig: EPAR
- Kaftrio: EPAR
- Kalydeco: EPAR
- Keytruda: EPAR
- Mysimba: EPAR
- Nordimet: EPAR
- Olumiant: EPAR
- Pepaxti: EPAR
- Ryeqo: EPAR
- Spikevax (previously COVID-19 Vaccine Moderna): EPAR
- Takhzyro: EPAR
- Translarna: EPAR
- Voxzogo: EPAR
- Skycovion: Withdrawn application
- Nordimet: Pending EC decision
- Voxzogo: Pending EC decision
- Adcetris: Pending EC decision
- ZILBRYSQ: Pending EC decision
- Keytruda: Pending EC decision
- Yorvipath: Pending EC decision
- Keytruda: Withdrawn application
- Vivjoa: Withdrawn application
- Olumiant: Pending EC decision
- Finlee: Pending EC decision
- Translarna: Withdrawn application
- Ebglyss: Pending EC decision
- Lutholaz: Withdrawn application

- Pepaxti: Pending EC decision
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- Iclusig: Withdrawn application
- Zoonotic Influenza Vaccine Seqirus: Pending EC decision
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- Enhertu: Pending EC decision
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- Herwenda: Pending EC decision
- Olumiant: Withdrawn application
- Takhzyro: Pending EC decision
- Catiolanze: Pending EC decision
- Translarna: Paediatric investigation plan
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- Adcetris: Paediatric investigation plan
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- Spikevax (previously COVID-19 Vaccine Moderna): Paediatric investigation plan
- Enhertu: Paediatric investigation plan
- Translarna: Orphan designation
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- Takhzyro: Orphan designation

- Blenrep: Orphan designation
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- Yorvipath: Orphan designation
- Finlee: Orphan designation
- ZILBRYSQ: Orphan designation
- Iclusig: Article 20 procedures
- Janus kinase inhibitors (JAKi): Article 20 procedures
- Methotrexate containing medicinal products: Article 31 referrals
- Mysimba: Article 20 procedures

Related content

- Committee for Medicinal Products for Human Use (CHMP): 11-14 September 2023
- CHMP: Agendas, minutes and highlights

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