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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
Published monthly by the European Medicines Agency

An agency of the European Union

IN THIS ISSUE

This newsletter is addressed primarily to organisations representing patients, consumers and healthcare professionals. It provides a summary of key information relating to medicines for human use published during the previous month by the European Medicines Agency.

Information is selected based on recommendations from consulted patients, consumers and healthcare professionals, and does not necessarily cover all relevant information published by the Agency.

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Information on medicines

Antivirals/anti-infectives

New medicines authorised

- Hepcludex (*bulevirtide*) O
  Treatment of chronic hepatitis delta virus infection in patients with compensated liver disease
- Pretomanid FGK (*pretomanid*) O C
  Treatment of tuberculosis
- Xenleta (*lefamulin*)
  Treatment of community-acquired pneumonia

Key to symbols used

O Orphan medicine | Generic medicine | Biosimilar medicine | C Conditional approval | E Exceptional circumstances

Cardiovascular system

New medicines authorised

- Apixaban Accord (*apixaban*)
  Treatment and prevention of blood clots and prevention of stroke

Immune system

New medicines authorised

- Idefirix (*imlifidase*)
  Prevention of organ rejection for patients undergoing kidney transplantation

Nephrology (kidney conditions)

New medicines authorised

- Idefirix (*imlifidase*)
  Prevention of organ rejection for patients undergoing kidney transplantation

Respiratory system

New medicines authorised

- Kaftrio (*elexacaftor / tezacaftor / ivacaftor*)
  Treatment of cystic fibrosis

Other medicines

New medicines authorised

- Gencebok (*caffeine citrate*)
  Treatment of primary apnoea (cessation of breathing) in premature newborns
- Methylthioninium chloride Cosmo (*methylthioninium chloride*)
  Diagnostic agent to help visualise lesions in the colon and rectum

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Scientific committee and working party activities

- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: August 2020
- COMP - agendas, minutes and meetings reports
- HMPC - agendas, minutes and meetings reports
- PDCO - agendas, minutes and meeting reports
- PRAC - agendas, minutes and highlights
- PRAC recommendations on safety signals

COVID-19

- COVID-19 What's new

Other publications

- Communication@EMA – how are we doing?
- Report: Meeting summary - PCWP/HCPWP joint meeting on 2 June 2020
- Report: Meeting summary - PCWP/HCPWP joint meeting on 24 June 2020
- Questions and answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products

Events

- EMA Clinical Trial Information System (CTIS) webinar: dynamic demo of sponsor workspace , Virtual meeting, 21 September 2020

Explanation of terms used

Orphan medicine

A medicine intended for the treatment of a rare, serious disease. These medicines are granted orphan status during their development; at time of approval, orphan designations are reviewed to determine whether the information available to date allows maintaining the medicine's orphan status.

Generic medicine

A medicine that is essentially the same as one that has already been authorised for use.
(The latter is known as the 'reference medicine')

Biosimilar medicine

A biological medicine that is similar to another biological medicine which has already been authorised for use.
(Biosimilar medicines are also known as 'similar biological' medicines)

Conditional approval

A medicine that fulfils an unmet medical need may, if its immediate availability is in the interest of public health, be granted a conditional marketing authorisation on the basis of less complete clinical data than are normally required, subject to specific obligations being imposed on the authorisation holder to generate complete data on the medicine.

Exceptional circumstances

A medicine may be approved in some cases where the applicant cannot provide comprehensive data on the safety or efficacy of the medicine under normal conditions of use, due to exceptional circumstances such as ethical issues or the rarity of the disease concerned. These medicines are subject to specific post-authorisation obligations and monitoring.

Medicines assessed under Article 58

Article 58 of Regulation (EC) No 726/2004 allows the CHMP to give opinions, in co-operation with the World Health Organization, on medicinal products that are intended exclusively for markets outside of the European Union.

Note on the centralised authorisation procedure

To obtain a single marketing authorisation (licence) for a medicine that is valid in all Member States of the European Union (EU) – via a process known as the 'centralised procedure' – the company or person developing the medicine must submit an application to the European Medicines Agency.

The Agency's Committee for Medicinal Products for Human Use (CHMP) carries out a scientific evaluation of the information contained in the application and prepares an opinion (scientific recommendation). The Agency transmits this (positive or negative) opinion to the European Commission, which then issues a Decision granting or refusing the marketing authorisation.

When the CHMP adopts a positive opinion on a medicine, the Agency publishes on its website a 'summary of opinion', in the first instance, followed by more detailed information in a 'European public assessment report (EPAR)' after the marketing authorisation has been granted.

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http://www.ema.europa.eu

In particular, you may be interested in these links:

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If you have a question relating to the content of this Newsletter, please send it via www.ema.europa.eu/contact

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