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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.

To receive each new issue of the newsletter, please click here RSS feeds, choose 'Human medicines highlights newsletter' and then click on 'Subscribe to this feed'. Please note, in order to be able to view RSS feeds you need one of the following: a modern web browser; a web-based news reader or a desktop news reader. For a list of RSS readers please refer to our RSS guide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

Information on medicines

Antivirals/anti-infectives

New medicines authorised

- Posaconazole Accord (*posaconazole*)
  Treatment of various fungal diseases
- Posaconazole AHCL (*posaconazole*)
  Treatment of various fungal diseases

Other information

- Daklinza (*daclatasvir*) - Expiry of the marketing authorisation
  Treatment of chronic hepatitis C virus (HCV)

Cancer

Negative CHMP opinions on new medicines

- Doxolipad (*doxorubicin*)
  Intented to treat breast and ovarian cancer

Key to symbols used

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

Safety update

- Review of methotrexate containing medicinal products (*methotrexate*) - CHMP Opinion (measures to avoid dosing errors)
  Treatment of various cancers and inflammatory conditions
- Review of cyproterone containing medicinal products (*cyproterone*) - review started (risk of meningioma)
  Treatment of a range of conditions, including excessive hair growth, prostate cancer and acne, as well as in hormone replacement therapy

Gastro-intestinal system

Safety update

- Review of Xeljanz (*tofacitinib*) - PRAC recommendation (risk of blood clots in the lungs)
  Treatment of rheumatoid arthritis, psoriatic arthritis and severe ulcerative colitis

Gynaecology & Obstetrics

Negative CHMP opinions on new medicines

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  Intended to treat breast and ovarian cancer

Hormone system

Safety update

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Immune system

Safety update

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Nervous system

New medicines authorised

- Striascan (*ioflupane (123i)*)
  Diagnosis of movement disorders and dementia

Rheumatology

Safety update

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Other information

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - July 2019
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- 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

Other publications

- News bulletin for small and medium-sized enterprises - Issue 47
- Presentations of the European Medicines Agency and European Union payer community meeting, Zorginstituut Nederland, Diemen, The Netherlands, from 18/06/2019 to 18/06/2019
- EMA/FDA analysis shows high degree of alignment in marketing application decisions between EU and US
- Medicine for use outside EU: Tritanrix HB: Public statement on the withdrawal of the scientific opinion under Article 58

Events

- Global public meeting on draft ICH guideline on clinical trials

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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Further information about the European Medicines Agency and the work it does is available on our website:

http://www.ema.europa.eu

In particular, you may be interested in these links:

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