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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

Withdrawal of applications for new medicines

- Ertapenem Hospira *(ertapenem)*
  Intended for the treatment of bacterial infections

Cancer

Positive CHMP opinions on new medicines

- Venclyxto (*venetoclax*)
  Treatment of treatment of leukaemia

New medicines authorised

- Cabometyx (*cabozantinib*)
  Treatment of renal cell carcinoma (kidney cancer)
- Onivyde (*irinotecan hydrochloride trihydrate*)
  Treatment of cancer of the pancreas

Key to symbols used

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

New information on authorised medicines

- Opdivo (*nivolumab*) - new indication
  Treatment of Hodgkin lymphoma
- Trisenox (*arsenic trioxide*) - change in indication
  Treatment of leukaemia

Withdrawal of applications for new medicines

- Pemetrexed ditromethamine Hospira (*pemetrexed*)
  Intended of lung cancer
- Zemfirza (*cediranib*)
  Intended for the treatment of ovarian cancer

Cardiovascular system

New medicines authorised

- Thorinane (*enoxaparin sodium*)
  Treatment and prevention of various disorders related to blood clots

Diabetes

Arbitration procedures

- Review of metformin-containing medicines - outcome of procedure
  Treatment of type 2 diabetes

Gastro-intestinal system

Positive CHMP opinions on new medicines

- SomaKit-TOC (*edotreotide*)
  Used for the diagnosis of certain tumours originating in the gut or pancreas

Haematology

Positive CHMP opinions on new medicines

- Venclyxto (*venetoclax*)
  Treatment of leukaemia

New information on authorised medicines

- Opdivo (*nivolumab*) - new indication
  Treatment of Hodgkin lymphoma
- Trisenox (*arsenic trioxide*) - change in indication
  Treatment of leukaemia

Hepatology

Key to symbols used

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

Hepatology

Positive CHMP opinions on new medicines

- Ocaliva (*obeticholic acid*)
  Treatment of a liver disease known as primary biliary cholangitis

HIV

Positive CHMP opinions on new medicines

- Emtricitabine / Tenofovir disoproxil Mylan (*emtricitabine / tenofovir disoproxil*) / Tenofovir disoproxil Mylan (*tenofovir disoproxil*)
  Treatment of HIV infection
- Emtricitabine / Tenofovir disoproxil Krka (*emtricitabine / tenofovir disoproxil*)
  Treatment of HIV infection

Hormone system

Positive CHMP opinions on new medicines

- Rekovelle (*follitropin delta*)
  Used to stimulate ovaries in fertility treatments

Nephrology

New medicines authorised

- Cabometyx (*cabozantinib*)
  Treatment of renal cell carcinoma (kidney cancer)

Arbitration procedures

- Review of metformin-containing medicines - outcome of procedure
  Treatment of type 2 diabetes mellitus

Nervous system

New information on authorised medicines

- Zebinix (*eslicarbazepine acetate*) - change in indication
  Treatment of partial-onset seizures

Communication on prevention of medication errors

- Keppra (*levetiracetam*)
  Treatment of epilepsy

Ophthalmology

Positive CHMP opinions on new medicines

- Cystadrops (*mercaptamine*)
  Treatment of cystine crystal deposits in the eye

New information on authorised medicines

- Lucentis (*ranibizumab*) - change in indication
  Treatment of visual impairment due to choroidal neovascularisation

Respiratory system

Withdrawal of applications for new medicines

- Pemetrexed ditromethamine Hospira (*pemetrexed*)
  Intended for the treatment of lung cancer

Other information

Guidelines

Guidelines open for consultation

- Concept paper on good manufacturing practice and marketing authorisation holders
  Deadline for comments: 31 Dec 2016
- ICH E11(R1) guideline on clinical investigation of medicinal products in the pediatric population: Step 2b
  Deadline for comments: 13 April 2017
- Concept paper on preparation of a guideline on the 4 evaluation of medicinal products indicated for the 5 treatment and prophylaxis of respiratory syncytial virus 6 (RSV) infection
  Deadline for comments: 31 Jan 2017

Adopted guidelines

- Guideline on the clinical investigation of medicinal products to prevent development/slow progression of chronic renal insufficiency

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - September 2016
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: October 2016
- CAT - agendas, minutes and reports

- 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
- PCWP meeting with all eligible organisations - Nov 2016
- Training session for patients and consumers interested in EMA activities - Nov 2016

Other publications

- EMA Management Board: highlights of October 2016 meeting
- Opening up clinical data on new medicines
- How to make better use of patient registries to collect high-quality data on medicines
- First comprehensive overview of global initiatives on medicine regulation published
- New search page for periodic safety update report single assessments (PSUSAs)
- 2nd annual scientific workshop at EMA: Applying regulatory science to neonates - meeting documents
- Tenth stakeholder forum on the pharmacovigilance legislation - meeting documents
- 2016 EU GCP Inspectors Working Group Workshop - Oct 2016
- EMA workshop on qualification and reporting of physiologically-based pharmacokinetic (PBPK) modelling and simulation - Nov 2016
- EMA / EBE fifth annual regulatory conference on optimising the development of advanced therapies to meet patient needs - Dec 2016

Explanation of terms used

Orphan medicine

A medicine intended for the treatment of a rare, serious disease.

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.

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.

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

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