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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 an e-mail alert when each new issue of the newsletter is published, send a request to: HMHnewsletter@ema.europa.eu

Information on medicines

Cancer

New medicines authorised

- Gazyvaro (*obinutuzumab*)
  Treatment of previously untreated chronic lymphocytic leukaemia

Cardiovascular system

Safety communication update

- Review of bromocriptine-containing medicines - CMDh Position (restriction of use due to risk of cardiovascular, neurological and psychiatric effects)
  Prevention and suppression of lactation

Withdrawal of applications for new medicines

- Imagify (*perflubutane*)
  Ultrasound imaging agent for the detection of coronary artery disease

Key to symbols used

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

Gynaecology & Obstetrics

- Review of bromocriptine-containing medicines - CMDh Position (restricted use for stopping milk production due to risk of side effects, particularly cardiovascular, neurological and psychiatric effects) Prevention and suppression of lactation

Haematology

New medicines authorised

- Gazyvaro (*obinutuzumab*)
  Treatment of chronic lymphocytic leukaemia

Nervous system

- Review of bromocriptine-containing medicines - CMDh Position (restricted use for stopping milk production due to risk of side effects, particularly cardiovascular, neurological and psychiatric effects) Prevention and suppression of lactation

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft revision of EudraVigilance access policy for medicines for human use
  Deadline for comments: 15 September 2014
- Questions and answers on wheat starch containing gluten in the context of the revision of the guideline on excipients in the label and package leaflet of medicinal products for human use
  Deadline for comments: 31 October 2014
- Draft concept paper on guideline on the clinical investigation of human normal immunoglobulin for intravenous administration and core summary of product characteristics
  Deadline for comments: 31 October 2014
- Concept paper on good genomics biomarker practices
  Deadline for comments: 04 November 2014
- Concept paper on revision of guideline on epidemiological data on blood-transmissible infections
  Deadline for comments: 31 December 2014

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - July 2014
- CHMP - agendas, minutes and highlights
- 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
- Annual report of the Pharmacovigilance Inspectors Working Group for 2013

Other publications

- Europe to boost cooperation with international partners on generics
- EMA consults on updates to its policy on access to EudraVigilance
- Antimicrobial resistance – EMA releases draft advice on the impact on public health and animal health of the use of antibiotics in animals
- Plasma Master File (PMF) Epidemiology workshop - November 2014
- News bulletin for pharmacovigilance programme update - Issue 1
- EMA publishes booklet on European regulatory system for medicines
- EMA report from workshop of pharmacovigilance in the paediatric population
- Healthcare professionals' organisations involved in the Agency's activities

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.

Visit our website

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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