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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

HIV

New medicines authorised

- Evotaz (*atazanavir / cobicistat*)
  Treatment of HIV-1 infection

Nervous system

New medicines authorised

- Duloxetine Zentiva (*duloxetine*)
  Treatment of major depressive disorder, diabetic nerve pain and generalised anxiety disorder

Key to symbols used

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

Other information

Guidelines

Guidelines open for consultation

- Guideline on good pharmacovigilance practices (GVP) - Module VIII Addendum I – Requirements for transmission of information on non-interventional post-authorisation safety studies (Rev. 2)
  Deadline for comments: 09 October 2015
- Guideline on good pharmacovigilance practices (GVP) - Module VIII – Post-authorisation safety studies (Rev. 2)
  Deadline for comments: 09 October 2015
- Draft questions and answers on boric acid 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: 03 November 2015
- Draft questions and answers on sodium laurilsulfate 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: 03 November 2015
- Q3C (R6): Impurities: guideline for residual solvents - Step 2b
  Deadline for comments: 03 November 2015
- Application of the principles of the ICH M7 guideline to calculation of compound-specific acceptable intakes - Step 2b
  Deadline for comments: 03 February 2016
- Guideline for good clinical practice E6 (R2) 4 - Step 2b
  Deadline for comments: 03 February 2016

Adopted guidelines:

- Guidelines on good pharmacovigilance practices (GVP) - Introductory cover note, last updated with revision 1 of module IV on audits and launch of public consultation of module VIII and its addendum I on post-authorisation safety studies
- Guideline on good pharmacovigilance practices (GVP) - Module IV – Pharmacovigilance audits (Rev. 1)

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - July 2015
- 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 2014

Other publications

- Work programme of the European Medicines Agency 2015
- Public-friendly information on herbal medicines now available
- Making IT services for medicine regulation in Europe more efficient
- Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting: workshop on risk minimisation measures - September 2015
- Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting - September 2015
- The role of pharmacokinetic and pharmacodynamic measurements in the use of direct oral anticoagulants (DOACs) - November 2015
- Workshop on haemophilia registries - meeting documents
- Patients' and Consumers' Organisations (PCWP) June 2015 meeting - meeting documents
- Healthcare Professionals' Organisations (HCPWP) June 2015 meeting - meeting documents
- Patients' and Consumers' Organisations (PCWP) / Healthcare Professionals' Organisations (HCPWP) June 2015 joint meeting - meeting documents

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

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http://www.ema.europa.eu

In particular, you may be interested in these links:

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