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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

Antivirals/anti-infectives

Safety updates

- Medicines studied at Cetero Research Facility (Ribavirin Teva, Ribavirin Teva Pharma B.V.,Tygacil)

Cancer

Positive CHMP opinions on new medicines

- Perjeta (*pertuzumab*)
  Treatment of breast cancer

New medicines authorised

- Ibandronic acid Accord (*ibandronic acid*)
  Prevention of skeletal events in patients with breast cancer and bone metastases and treatment of hypercalcaemia caused by tumours

Key to symbols used

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

Withdrawal of applications for new medicines

- Jenzyl (*ridaforolimus*)
  Intended for the treatment of soft-tissue sarcoma or bone sarcoma

Safety updates

- Medicines studied at Cetero Research Facility (Temodal)

Cardiovascular system

New information on authorised medicines

- Pradaxa (*dabigatran etexilate*) - new contraindication
  Prevention of venous thromboembolic events, stroke and systematic embolism

Negative CHMP opinions on new medicines

- Kynamro (*mipomersen sodium*)
  Intended for the treatment of familial hypercholesterolaemia

Safety updates

- Tredaptive, Pelzont and Trevaclyn (*laropiprant and nicotinic acid*) - started
  Treatment of dyslipidaemia

Diabetes

New medicines authorised

- Forxiga (*dapaglifozin propanediol monohydrate*)
  Treatment of type-2 diabetes

Withdrawal of applications for new medicines

- Solumarv, Combimarv, Isomarv medium (*insulin human*)
  Intended for the treatment of diabetes

Haematology

Safety updates

- Protamine containing medicinal products
  Treatment of bleeding caused by heparin during surgery
- Fibrinogen-containing solutions for sealant (*fibrin*) - CHMP opinion
  Used as sealant during surgery to help reduce bleeding

Immune system

New information on authorised medicines

- Ilaris (*canakinuab*) - new indication
  Treatment of cryopyrin-associated periodic sydromes

Key to symbols used

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Nervous system

New medicines authorised

- Memantine Merz (*memantine hydrochloride*)
  Treatment of Alzheimer's disease

Positive CHMP opinions on new medicines

- Adasuve (*loxapine*)
  Treatment of bipolar disorder and schizophrenia

New information on authorised medicines

- Abilify (*aripiprazole*) - new indication
  Treatment of Bipolar disorder and schizophrenia

Negative CHMP opinions on new medicines

- Fanaptum (*iloperidone*)
  Intended for the treatment of schizophrenia

Ophthalmology

New medicines authorised

- Eylea (*aflibercept*)
  Treatment of age-related macular degeneration

Other information

- Use of phosphates in eye drops

Vaccines

Positive CHMP opinions on new medicines

- Hexaxim (*diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)*)
  Prevention of diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenza* type b

New information on authorised medicines

- Ixiaro (*Japanese encephalitis vaccine*) - new indication
  Treatment of Japanese encephalitis

Safety updates

- Monovalent and multivalent measles, mumps, rubella and/or varicella vaccines
  Treatment of measles, mumps, rubella and/or varicella

Other medicines

Positive CHMP opinions on new medicines

- Selincro (*nalmefene*)
  Treatment of alcohol dependence

Safety updates

- Fibrinogen-containing solutions for sealant (*fibrin*) - CHMP opinion
  Used as sealant during surgery to help reduce bleeding

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on clinical investigation of medicinal products in the treatment of lipid disorders
  Deadline for comments: 15/03/2012

Adopted guidelines

- Guideline on core summary of product characteristics for human normal immunoglobulin for intravenous administration (IVIg) revision 4
- Reflection paper on classification of advanced-therapy medicinal products

Scientific committee activities

- CHMP December meeting highlights and CHMP December meeting: Start of Community reviews and CHMP December applications review
- COMP January Agenda and COMP November meeting minutes
- PDCO December report and PDCO November meeting minutes
- Report from CAT interested parties focus group on incentives for academia, hospitals and charities
- CAT December monthly report
- PRAC October meeting minutes

Other publications

- Advisory groups on publication of clinical-trial data
- List of European Union reference dates and frequency of submission of periodic safety update reports
- Brochure - Overview of the European Medicines Agency's role, activities and priorities for 2013

- Only For Children Pharmaceuticals withdraws its marketing authorisation application for Loulla (mercaptopurine)
- European Medicines Agency reviews its operations and prepares for reorganisation in 2013
- Questions and answers: Urgent Union procedure (Article 107i)
- European Medicines Agency's Management Board endorses work programme 2013
- News bulletin for small and medium-sized enterprises - Issue 22
- CAT-Translational Centre for Regenerative Medicine Leipzig collaborative workshop - advanced-therapy medicinal products: from bench to bedside. Regulatory path for translation of research to commercial medicinal products, Leipzig, Germany
- Sixth stakeholder forum on the implementation of the new pharmacovigilance legislation
- Good pharmacovigilance practices
- Questions and answers on generic medicines
- Report - Workshop on health-related quality of life in oncology
- Medicinal products for human use: Monthly figures - November 2012
- Work plan for the Safety Working Party 2013
- Work plan for the Vaccine Working Party 2013
- Work plan for the CHMP Biologics Working Party 2013
- Work plan for the Infectious Diseases Working Party 2013
- Work plan for the Cardiovascular Working Party 2013
- Work plan for the Biosimilar Medicinal Products Working Party 2013
- Work plan for the European Medicines Agency / CHMP Working Group with Healthcare Professionals' Organisations 2013
- Work plan for the Gastroenterology Drafting Group 2013
- Work plan for the Rheumatology-Immunology Working Party 2013
- Work plan for the Respiratory Drafting Group 2013
- Work plan for the Urology Drafting Group 2013

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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