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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

New marketing authorisations

- Eurartesim (*piperaquine tetraphosphate and dihydroartemisinin*)
  Treatment of malaria

Cancer

Positive CHMP opinions on new medicines

- Caprelsa (*vandetanib*)
  Treatment of thyroid cancer
- Docetaxel Mylan (*docetaxel*)
  Treatment of breast cancer

New information on authorised medicines

- Erbitux (*cetuximab*) - change in indication and new contraindication
  Refers to colorectal cancer

Key to symbols used

Orphan medicine | Generic medicine | Biosimilar medicine | Conditional approval | Exceptional circumstances

- Herceptin (*trastuzumab*) - new indication
  Treatment of early breast cancer

Other information

- Busilvex (busulfan) - precautionary recall
  Preparative treatment before transplantation of haematopoietic progenitor cells
- Caelyx (*doxorubicin hydrochloride*) - recommendations in the context of supply problems
  Treatment of breast cancer, cancer of the ovary, Kaposi's sarcoma, and multiple myeloma
- Velcade (*bortezomib*) - precautionary recall
  Treatment of multiple myeloma
- Vidaza (*azacitidine*) - precautionary recall
  Treatment of myelodysplastic syndromes and leukaemia

Cardiovascular system

Safety communication update

- Buflomedil (*buflomedil*) - suspension of marketing authorisation
  Treatment of peripheral arterial occlusive disease (PAOD)
- Pradaxa (*dabigatran etexilate*) - update on risk of bleeding
  Prevention of venous thromboembolic events, stroke and systemic embolism

Diabetes

Withdrawal of marketing authorisation applications

- Janacti (*sitagliptin and pioglitazone*)
  Intended for the treatment of type 2 diabetes

Immune diseases

Positive CHMP opinions on new medicines

- Desloratadine ratiopharm (*desloratadine*)
  Intended for the treatment of allergic rhinitis or urticaria
- Desloratadine Actavis (*desloratadine*)
  Intended for the treatment of allergic rhinitis or urticaria

Withdrawal of marketing authorisation applications

- Desloratadine Krka (*desloratadine*)
  Intended for the treatment of allergic rhinitis or urticaria
- Kalbitor (*ecallantide*)
  Intended for the treatment of hereditary angioedema

Nervous system

New information on authorised medicines

- Rebif (*interferon beta-1a*) - new indication
  Treatment of multiple sclerosis

Negative CHMP opinions

- Sumatriptan Galpharm (*sumatriptan*)
  Intended for the relief of migraine attacks

Negative CHMP opinions on extension of indication

- Ariclaim, Xeristar and Cymbalta (*duloxetine*)
  Intended for the treatment of somatic pain

Ophthalmology

New information on authorised medicines

- Nevanac (*nepafenac*) - new indication
  Reduction in the risk of postoperative macular oedema

Rheumatology

New marketing authorisations

- Vyndaqel (*tafamidis*) O E
  Treatment of transthyretin amyloidosis

Other medicines

Safety communication update

- Pholcodine (*pholcodine*)
  Treatment of non-productive cough

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the update of guidance on the clinical development of medicinal products for the treatment of HIV
  Deadline for comments: 31 January 2012
- Concept paper on the revision of the guideline on similar biological medicinal product
  Deadline for comments: 29 February 2012

Key to symbols used

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

- Draft guideline on the clinical investigation of medicinal products for the treatment of urinary incontinence
  Deadline for comments: 31 May 2012
- Draft guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human follicle stimulating hormone (r-hFSH)
  Deadline for comments: 31 May 2012

Scientific committee activities

- CHMP highlights from the November meeting
- COMP monthly report from the November meeting
- PDCO monthly report from the November meeting
- PhVWP monthly report from the November meeting

Other publications

- Guido Rasi begins as new head of European Medicines Agency
- Andreas Pott appointed Deputy Executive Director of European Medicines Agency
- European Medicines Agency welcomes new Head of Finance and Budget
- PCWP/HCP WG minutes from the June joint meeting
- PCWP minutes from the September meeting
- BMWP work plan for 2012
- SWP work plan for 2012
- Expressions of interest invited for workshop on medicines for older people
- Registration open for Committee for Advanced Therapies stakeholders workshop
- European and international experts discuss the way forward in developing ophthalmology medicines
- Creating electronic drug information for prescribing in the European Union
- European Medicines Agency hosts first workshop on subgroup analysis
- EMA-EFPIA modelling and simulation workshop
- Frequently asked questions: Translations
- Quality Review of Documents human product-information annotated template (English) version 8
- European Antibiotic Awareness Day: 18 November 2011
- World AIDS Day: 1 December 2011

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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