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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

Arbitration procedures

- Zinnat (*cefuroxime axetil*)
  Treatment of certain bacterial infections
- Zinacef (*cefuroxime sodium*)
  Treatment of certain bacterial infections
- Tavanic (*levofloxacin*)
  Treatment of certain bacterial infections

Cancer

Positive CHMP opinions on new medicines

- Inlyta (*axitinib*) O
  Treatment of advanced renal cell carcinoma

Key to symbols used

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

New medicines authorised

- Capecitabine Accord (*capecitabine*)
  Treatment of colon cancer, metastatic colorectal cancer, advanced gastric cancer and locally advanced or metastatic breast cancer
- Capecitabine Krka (*capecitabine*)
  Treatment of colon cancer, metastatic colorectal cancer, advanced gastric cancer and locally advanced or metastatic breast cancer
- Capecitabine Teva (*capecitabine*)
  Treatment of colon cancer, metastatic colorectal cancer, advanced gastric cancer and locally advanced or metastatic breast cancer
- Zoledronic acid Actavis (*zoledronic acid*)
  Prevention of bone complications in adults with advanced cancer affecting the bone (fractures, spinal compression, bone disorders and hypercalcaemia)
- Zoledronic acid Medac *zoledronic acid*)
  Prevention of bone complications in adults with advanced cancer affecting the bone (fractures, spinal compression, bone disorders and hypercalcaemia)
- Sancuso (*granisetron*)
  Prevention of nausea and vomiting caused by chemotherapy
- Pixuvri (*pixantrone*)
  Treatment of non-Hodgkin's B cell lymphoma

New information on authorised medicines

- Votrient (*pazopanib*) - new indication
  Treatment of advanced soft tissue sarcoma (STS)

Safety communication update

- MabThera (*rituximab*)
  Treatment of non-Hodgkin's lymphoma and chronic lymphocytic leukaemia

Cardiovascular system

New information on authorised medicines

- Pradaxa (*dabigatran etexilate*) - change to a contraindication
  Prevention of venous thromboembolic events following hip or knee replacement surgery and prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation

Arbitration procedures

- Flolan (*epoprostenol*)
  Treatment of pulmonary arterial hypertension and prevention of venous thromboembolic events during haemodialysis

Safety communication update

- Pradaxa (*dabigatran etexilate*)
  Prevention of venous thromboembolic events in patients following hip or knee replacement surgery

Diabetes

Positive CHMP opinions on new medicines

- Jentadueto (*linagliptin and metformin hydrochloride*)
  Treatment of type 2 diabetes mellitus

Haematology

Positive CHMP opinions on new medicines

- NovoThirteen (*catridecacog*)
  Prophylactic treatment of bleeding in patients with congenital factor XIII A-subunit deficiency

Musculoskeletal system

New information on authorised medicines

- Protelos and Osseor (*strontium ranelate*) - new indication
  Treatment of osteoporosis in men at increased risk of fracture

Nervous system

Positive CHMP opinions on new medicines

- Fycompa (*perampanel*)
  Treatment of partial-onset seizures in patients with epilepsy

New medicines authorised

- Riluzole Zentiva (*riluzole*)
  Treatment of amyotrophic lateral sclerosis (ALS)

Respiratory system

Positive CHMP opinions on new medicines

- Eklira Genuair and Bretaris Genuair (*aclidinium bromide*)
  Treatment of chronic obstructive pulmonary disease (COPD)

Rheumatology

Safety communication update

- MabThera (*rituximab*)
  Treatment of rheumatoid arthritis

Vaccines

New medicines authorised

- Nimenrix (*Neisseria meningitidis*)
  Vaccination against invasive meningococcal disease

Other medicines

Positive CHMP opinions on new medicines

- Kalydeco (*ivacaftor*)
  Treatment of cystic fibrosis

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the need for a guideline on multiplicity issues in clinical trials
  Deadline for comments: 30 August 2012
- Draft guideline on clinical investigation of medicinal products for prevention of venous thromboembolism (VTE) in patients undergoing high VTE-risk surgery
  Deadline for comments: 30 November 2012
- Draft Guideline on quality of biological active substances produced by transgene expression in animals
  Deadline for comments: 30 November 2012
- Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision 1)
  Deadline for comments: 30 November 2012

Adopted guidelines

- Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells
- Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials

Scientific committee activities

- CHMP May meeting highlights and Medicines under evaluation by the CHMP
- COMP May meeting highlights
- PDCO May monthly report
- CAT May monthly report
- PhVWP May monthly report

Key to symbols used

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

Other publications

- European Medicines Agency website upgraded with new features
- Fifth stakeholder forum on the implementation of the new pharmacovigilance legislation, EMA, London, 25 May 2012
- Questions and answers on implementation of pharmacovigilance legislation
- Brochure - Communication with stakeholders
- Brochure - Better vigilance for public health protection
- Brochure - Regulatory action to safeguard public health
- Brochure - Collection of key information on medicines
- Brochure - Better analysis and understanding of data and information
- Brochure - European Network of Paediatric Research at the European Medicines Agency
- Brochure - Overview of the European Medicines Agency's role, activities and priorities for 2012
- European Medicines Agency boosts EU transparency with online publication of suspected side effect reports
- European Medicines Agency launches new e-learning course for Article 57(2) requirements on submission of information on medicines
- Specific privacy statement for public consultations
- Work plan for the Central Nervous System Working Party (CNSWP) 2012
- Orphan incentives
- Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Group (HCP WG) joint meeting, EMA, London, 28 February 2012
- European Medicines Agency workshop for micro, small and medium-sized enterprises (SMEs) – Focus on pharmacovigilance, EMA, London, 19 April 2012
- European Medicines Agency workshop on pharmacogenomics: from science to clinical care, EMA, London, 8-9 October 2012
- Vaccines Working Party closed workshop on correlates for the protection and serological assays for influenza vaccines, EMA, London, 30-31 May 2012
- EMA publishes supplementary information on funding for medicine safety studies through Seventh Framework Programme
- World Hypertension Day: 17 May 2012
- International Clinical Trials Day: 20 May 2012

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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