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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.

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Information on medicines

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Zinforo (*ceftaroline fosamil*)
  Treatment of complicated skin and soft-tissue infections and community-acquired pneumonia

Safety communication update

- EMA advises doctors treating patients with nosocomial pneumonia with Doribax
  Treatment of nosocomial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections

Cancer

Positive CHMP opinions on new medicines

- Zoledronic acid Mylan (*zoledronic acid*)
  Prevention of skeletal related events in patients with cancer involving bone, and treatment of tumour-induced hypercalcaemia (TIH)

Key to symbols used

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

New medicines authorised

- Docetaxel Accord (*docetaxel*)
  Treatment of breast cancer, non-small lung cell cancer, prostrate cancer, gastric cancer and head and neck cancer
- Docetaxel Kabi *docetaxel*)
  Treatment of breast cancer, non-small lung cell cancer, prostrate cancer, gastric cancer and head and neck cancer

Withdrawal of applications for extension of indication

- Revlimid (*lenalidomide*)
  Intended to include maintenance treatment of newly diagnosed multiple-myeloma patients

Arbitration procedures

- Femara (*letrozole*)
  Treatment of breast cancer

Cardiovascular system

New information on authorised medicines

- Volibris (*ambrisentan*) - new contraindication
  Treatment of pulmonary arterial hypertension to improve exercise capacity

Safety communication update

- European Medicines Agency recommends restricting use of trimetazidine-containing medicines
  Treatment of angina pectoris

Dermatology

Positive CHMP opinions on new medicines

- Zyclara (*imiquimod*)
  Treatment of actinic keratoses

Endocrinology

New medicines authorised

- Signifor (*pasireotide*)
  Treatment of Cushing's disease when surgery has failed or is not an option

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Revestive (*teduglutide*)
  Treatment of short bowel syndrome

HIV

Withdrawal of applications for new medicines

- Egrifta (*tesamorelin*)
  Intended for the treatment of excess visceral adipose tissue in HIV-infected patients

Immune system

Arbitration procedures

- Loraxin (*loratadine*)
  Treatment of allergic rhinitis and long-term idiopathic urticaria

Metabolic system

Negative CHMP opinions on new medicines

- Elelyso (*taliglucerase alfa*)
  Intended for the treatment of type I Gaucher disease

Nervous system

Safety communication update

- EMA recommends restricting use of tolperisone medicines

Respiratory system

Positive CHMP opinions on new medicines

- Enurev Breezhaler, Seebri Breezhaler and Tovanor Breezhaler (*glycopyrronium bromide*)
  Maintenance treatment to relieve symptoms of chronic obstructive pulmonary disease

Rheumatology

New information on authorised medicines

- Humira (adulimumab)
  Treatment of severe axial spondyloarthritis
- Enbrel (*etanercept*) - new indication
  Treatment of arthritis, spondylitis and psoriasis

Vaccines

Other information

- Hexaxim - for use outside the EU
  Vaccination against diphtheria, tetanus, pertussis (whooping cough), hepatitis B, polio and invasive disease caused by the bacterium *Haemophilus influenzae* type B, including meningitis

Other medicines

Positive CHMP opinions on new medicines

- Cuprymina (copper (^{64}*Cu) chloride*)
  A radiopharmaceutical precursor - not intended for direct use in patients

Arbitration procedures

- Mifepristone Linepharma (*mifepristone*)
  Termination of pregnancy

Other information

Guidelines

Guidelines open for consultation

- Position paper on potential medication errors in the context of benefit-risk balance and risk minimisation measures
  Deadline for comments: 30 November 2012
- Concept paper on the need for revision of the note for guidance on the evaluation of the pharmacokinetics of medicinal products in patients with impaired renal function
  Deadline for comments: 31 July 2012
- Concept paper on the revision of the CHMP points to consider on the evaluation of medicinal products for the treatment of irritable bowel syndrome
  Deadline for comments: 31 August 2012
- Concept paper on the need of the guideline on clinical investigation of medicinal products for the treatment of gout
  Deadline for comments: 30 September 2012
- Concept paper on extrapolation of efficacy and safety in medicine development
  Deadline for comments: 30 September 2012
- Draft Guideline on core SmPC for human albumin solution
  Deadline for comments: 31 August 2012

Adopted guidelines

- Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus

- Guideline on similar biological medicinal products containing monoclonal antibodies – non-clinical and clinical issues
- Guideline on immunogenicity assessment of monoclonal antibodies intended for in-vivo clinical use
- Guideline on core summary of product characteristics for human plasma derived and recombinant coagulation factor VIII products
- Guideline on core summary of product characteristics for human plasma-derived and recombinant coagulation factor IX products
- CHMP guideline on detection and management of duplicate individual cases and individual case safety reports (ICSRs)

Scientific committee activities

- CHMP June meeting highlights
- COMP June meeting highlights
- PDCO June monthly report
- PhVWP June monthly report

Other publications

- Annual report 2011
- Analysis and assessment of the 2011 annual activity report of the Executive Director
- Minutes of the 75th meeting of the Management Board
- Agenda for the 76th meeting of the Management Board
- Management Board completes framework for conflicts of interests
- EMA breach-of-trust procedure on conflicts of interest for Management Board members
- EMA welcomes 1000th orphan designation
- EMA website on suspected side effect reports now in all 23 EU official languages
- EMA finalises first set of guidelines on good pharmacovigilance practices
- Two modules of guideline on good pharmacovigilance practices released for public consultation
- EMA reminds marketing-authorisation holders about requirement for paediatric annual reports
- EMA acts on deficiencies in Roche medicines-safety reporting
- Workshop on biosimilar monoclonal antibodies and immunogenicity of monoclonal antibodies, EMA, London, 24 October 2011
- EMA workshop on multiplicity issues in clinical trials, EMA, London, 16 November 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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