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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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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

Positive CHMP opinions on new medicines

- Voriconazole Accord (*voriconazole*)
  Treatment of fungal infections

New information on authorised medicines

- Viread (*tenofovir disoproxil fumarate*) - change in indication
  Treatment of hepatitis B

Cancer

Positive CHMP opinions on new medicines

- Iclusig (*ponatinib*)
  Treatment of leukaemia

Key to symbols used

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

New medicines authorised

- Zaltrap (*aflibercept*)
  Treatment of colorectal cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- Stayveer (*bosentan monohydrate*)
  Treatment of pulmonary arterial hypertension

New medicines authorised

- Actelsar HCT (*telmisartan/hydrochlorothiazide*)
  Treatment of high blood pressure

New information on authorised medicines

- Xarelto (*rivaroxaban*) - new indication
  Prevention of clotting events such as heart attacks and strokes

Safety update

- Review of cilostazol-containing medicines - CHMP opinion
  Treatment of intermittent claudication (poor blood supply in the legs)
- Review of nicotinic acid and related substances (*nicotinic acid, acipimox, xanitol nicotinate*) - started
  Treatment of lipid (fat) disorders

Diabetes

New medicines authorised

- Lyxumia (*lixisenatide*)
  Treatment of type 2 diabetes

Safety update

- Pancreatic risks with GLP-1-based therapies for treatment of type 2 diabetes

Gastro-intestinal system

Safety update

- Review of domperidone-containing medicines (*domperidone*) - started
  Treatment of nausea and vomiting, abdominal discomfort and heartburn

HIV

Positive CHMP opinions on new medicines

- Stribild (*elvitegravir / cobicistat / emtricitabine / tenofovir disproxil*)
  Treatment of HIV infection

Haematology

Positive CHMP opinions on new medicines

- Iclusig (*ponatinib*)
  Treatment of leukaemia

New information on authorised medicines

- Soliris (*eculizmab*) - change in indication
  Treatment of diseases involving the destruction of red blood cells

Safety update

- Review of Kogenate Bayer / Helixate NexGen (*octocog alfa*) - started
  Treatment of bleeding

Immune system

Positive CHMP opinions on new medicines

- HyQvia (*human normal immunoglobulin*)
  Treatment of patients with low levels of antibodies

Metabolic system

Safety update

- Review of nicotinic acid and related substances (*nicotinic acid, acipimox, xanitol nicotinate*) - started
  Treatment of lipid (fat) disorders

Nervous system

Positive CHMP opinions on new medicines

- Tecfidera (*dimethyl fumarate*)
  Treatment of multiple sclerosis
- Aubagio (*teriflunomide*)
  Treatment of multiple sclerosis
- Memantine ratiopharm (*memantine hydrochloride*)
  Treatment of Alzheimer's disease

Withdrawal of applications for new medicines

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

Key to symbols used

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Respiratory system

Negative CHMP opinions on new medicines

- Labazenit (*budesonide / salmeterol*)
  Intended for the treatment of asthma

Rheumatology

New information on authorised medicines

- MabThera (*rituximab*) - new indication
  Treatment of granulomatosis with polyangiitis and microscopic polyangiitis

Other medicines

New medicines authorised

- Selincro (*nalemefene*)
  Treatment of alcohol dependence

Negative CHMP opinions on new medicines

- Defitelio (*defibrotide*)
  Intended for the treatment and prevention of veno-occlusive disease (VOD) of the liver

Safety update

- Review of flupirtine-containing medicines (*flupirtine*) - started
  Treatment of pain

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the need for revision of the note for guidance on the clinical investigation of medicinal products for the treatment of cardiac failure
  Deadline for comments: 31/05/2013
- Concept paper on the need to revise the guideline on the clinical development of fixed-dose combinations of medicinal products regarding dossier content requirements
  Deadline for comments: 31/05/2013
- Draft guideline on the declaration of the quantitative composition / labelling of biological medicinal products that contain modified proteins as active substance
  Deadline for comments: 01/10/2013

- Draft guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia
  Deadline for comments: 31/08/2013
- Draft guideline on the pharmacokinetic and clinical evaluation of modified-release dosage forms
  Deadline for comments: 15/09/2013
- Draft guideline on influenza vaccines – quality module
  Deadline for comments: 08/08/2013
- Draft guideline on clinical investigation of medicinal products for the treatment of systemic lupus erythematosus, cutaneous lupus and lupus nephritis
  Deadline for comments: 04/09/2013
- Draft guideline on the use of porcine trypsin used in the manufacture of human biological medicinal products
  Deadline for comments: 31/08/2013
- Draft guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy
  Deadline for comments: 31/08/2013

Adopted guidelines

- Reflection paper on Immune Tolerance Induction in haemophilia A patients with inhibitors
- Reflection paper on the data requirements for intravenous liposomal products developed with reference to an innovator liposomal product
- Reflection paper on Immune Tolerance Induction in haemophilia A patients with inhibitors
- Guideline on the risk-based approach according to annex I, part IV of Directive 2001/83/EC applied to advanced-therapy medicinal products
- Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human follicle-stimulating hormone (r-hFSH)
- Guideline on similar biological medicinal products containing interferon beta

Scientific committee activities

- CHMP meeting highlights - March 2013
- PDCO meeting minutes - February 2013
- PDCO monthly report - March 2013
- CAT monthly report - March 2013
- PRAC meeting minutes - February 2013
- PRAC meeting highlights - March 2013

Other publications

- European Medicines Agency updates procedural guidance in line with new pharmacovigilance legislation
- European Medicines Agency issues recommendations for 2013/2014 seasonal flu vaccine composition

Key to symbols used

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- CellSeed Europe Ltd. withdraws its marketing-authorisation application for OraNera (autologous oral mucosal epithelial cells)
- EU agencies to advise on risks from phenylbutazone in horsemeat
- 14 March 2013: World Kidney Day: 'Acute kidney injury: stop kidney attack!'
- Annual workshop on the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)
- European Medicines Agency focuses on new legislation, increased efficiency and transparency in 2013 work programme
- Tackling medication errors: European Medicines Agency workshop calls for coordinated EU approach

New and updated EMA brochures

- Better analysis and understanding of data and information as part of the European Union's new pharmacovigilance legislation
- Collection of key information on medicines as part of the European Union's new pharmacovigilance legislation
- Better vigilance for public health protection - Overview of the new European Union pharmacovigilance legislation
- Working with healthcare professionals
- Environmental risk-assessment of medicines
- Better medicines for children
- Working with patients and consumers
- Biosimilar medicinal products

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

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