38 Issue 38
March 2012

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**


Antivirals/anti-infectives 1
Cancer 1
Cardiovascular system 2
Musculoskeletal 2
Nervous system 3
Vaccines 3
Other medicines 4
Guidelines 4
Scientific committee activities 5
Other publications 5
Explanation of terms used 6


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

- Colobreathe (*colistimethate sodium*)
  Treatment of lung infection caused by the bacteria *Pseudomonas aeruginosa*

### New information on authorised medicines

- Vfend (*voriconazole*) - supply shortage
  Treatment of fungal infections

## Cancer

### Positive CHMP opinions on new medicines

- Docetaxel Accord (*docetaxel*)
  **Treatment of breast cancer,** non-small cell lung cancer, prostate cancer, gastric **adenocarcinoma and head a**nd neck cancer

**Key to symbols used**

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

- Docetaxel Kabi (*docetaxel*)
  Treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer
- Zoledronic Acid Teva (*zoledronic acid*)
  Prevention of skeletal related events in treatment of tumour-induced hypercalcaemia

### New marketing authorisations

- Mercaptopurine Nova Laboratories (*mercaptopurine*)
  Treatment of acute lymphoblastic leukaemia (ALL)
- Zelboraf *(vemurafenib)*
  Treatment of melanoma

### New information on authorised medicines

- Tyverb (*lapatinib*) - withdrawal of application for an extension of indication
  Treatment of breast cancer

### Arbitration procedures

- Femara (*letrozole*)
  Treatment for breast cancer

### Other information

- Caelyx (*doxorubicin hydrochloride*) - recommendation to transfer manufacturing site
  Treatment of metastatic breast cancer, advanced ovarian cancer, Kaposi's sarcoma and multiple myeloma
- Ceplene (*histamine dihydrochloride*) - recommendation to transfer manufacturing site
  Treatment of acute myeloid leukaemia (AML)

## Cardiovascular system

### New information on authorised medicines

- Ventavis (*iloprost*) - CHMP positive opinion on the removal of a contraindication
  Treatment of hypertension

### Arbitration procedures

- Norvasc (*amlodipine*)
  Treatment of cardiovascular problems such as hypertension and angina

## Musculoskeletal

### Positive CHMP opinions on new medicines

- Zoledronic Acid Teva (*zoledronic acid*)
  Prevention of skeletal related events in treatment of tumour-induced hypercalcaemia
- Zoledronic Acid Teva Pharma (*zoledronic acid*)
  Treatment of osteoporosis

### Safety communication update

- Protelos and Osseor (*strontium ranelate*)
  Treatment of osteoporosis

# Nervous system

### Withdrawal of applications for extension of indication

- Exelon and Prometax (*rivastigmine*)
  Treatment of Alzheimer's dementia

### New information on authorised medicines

- Qutenza (*capsaicin*) - withdrawal of application for an extension of indication
  Treatment of peripheral neuropathic pain

# Vaccines

### New marketing authorisations

- Vepacel (A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated))
  Protection against flu caused by the H5N1 influenza A virus

### Withdrawal of marketing authorisation

- Prepandemic Influenza Vaccine (H5N1) GlaxoSmithKline Biologicals (split virion, inactivated, adjuvanted)
  Intended to be given before or during the next influenza pandemic to prevent flu caused by the H5N1 type of the virus

### New information on authorised medicines

- Menveo (*meningococcal group A, C, W-135 and Y conjugate vaccine*) - new indication
  Active immunisation of children (from 2 years of age), adolescents and adults against invasive disease caused by four groups of the bacterium *N. meningitidis* (A, C, W135, and Y)
- ProQuad (*measles, mumps, rubella and varicella vaccine (live)*) - change to indication
  Can be administered to individuals from 9 months of age under special circumstances
- Ixiaro (*inactivated Japanese encephalitis viruses*)
  Protection against Japanese encephalitis

### Arbitration procedures

- Priorix (*measles, mumps and rubella vaccine (live)*)
  Protection against measles, mumps and rubella (German measles)

### Other information

- EMA issues recommendations for 2012/2013 seasonal flu vaccine composition

# Other medicines

### New marketing authorisations

- Esmya (*ulipristal*)
  Treatment of symptoms of uterine fibroids

### Withdrawal of marketing authorisation applications

- Megestrol Alkermes (*megestrol*)
  Intended for the treatment of anorexia, cachexia or an unexplained significant weight loss

### New information on authorised medicines

- Kogenate Bayer and Helixate Nexgen (*octocog alfa*)
  Treatment and prevention of bleeding in patients with haemophilia A

### Arbitration procedures

- Priligy (*dapoxetine*)
  Treatment of premature ejaculation

### Safety communication update

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

# Other information

# Guidelines

### Guidelines open for consultation

- Concept paper on the need for revision of the guideline on excipients in the label and package leaflet of medicinal products for human use (CPMP/463/00)
  Deadline for comments: 31 May 2012
- Concept paper on guidance for DNA vaccines
  Deadline for comments: 30 June 2012
- Concept paper on the need for revision of the points to consider on clinical investigation of medicinal products for the treatment of Amyotrophic Lateral Sclerosis
  Deadline for comments: 30 June 2012
- Reflection paper on the non-clinical and clinical development for oral and topical HIV pre-exposure prophylaxis (PrEP)
  Deadline for comments: 30 June 2012

### Adopted guidelines

- Concept paper on no need for revision of the guideline on medicinal products for the treatment of Alzheimer's disease and other dementias
- Reflection paper on the pharmaceutical development of intravenous medicinal products containing active substances solubilised in micellar systems

# Scientific committee activities

- CHMP highlights from the 12-15 March 2012 meeting
- CAT monthly report from the March 2012 meeting
- CAT re-elects Christian Schneider as chair
- PDCO monthly report from the March 2012 meeting
- Positions on specific questions addressed to the Pharmacokinetics Working Party

# Other publications

- EMA Management Board strengthens conflicts of interest policies and transparency
- European medicines regulators agree a common, Europe-wide approach for the identification of commercially confidential information and personal data
- EU Clinical Trials Register information now available through WHO's International Clinical Trials Registry Platform
- Quality of medicines questions and answers: Part 1
- Quality of medicines questions and answers: Part 2
- Increased fees coming into effect on 1 April 2012
- EMA holds workshop on vaccines development against Schmallenberg virus, London, UK, 10 April 2012
- Paper calls for continued support for development of advanced therapies
- Statement of revenue and expenditure of the European Medicines Agency 2012
- European Medicines Agency launches electronic application form pilot
- Report on the expert workshop on setting specifications for biotech products
- International collaboration on good manufacturing practice inspections expanded
- Summary meeting report on the EMA workshop with EU pharmaceutical industry associations on the implementation of Article 57(2), second subparagraph of Regulation (EC) No. 726/2004
- EMA publishes updated set of mandatory Article 57(2) requirements for marketing authorisation holders

# 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:

About us

Patients and carers

Healthcare professionals

European public assessment reports

**European Medicines Agency**

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union