59 Issue 59
January 2014

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

- Rocephin (*ceftriaxone*)
  Treatment of bacterial infections including pneumonia and meningitis

Cancer

Withdrawal of authorised medicines

- Docetaxel Teva Pharma (*docetaxel*)
  Used for the treatment of breast cancer, non-small cell lung cancer and prostate cancer

Negative CHMP opinions on new medicines

- Masiviera (*masitinib*)
  Intended for the treatment of pancreatic cancer

Key to symbols used

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

Cardiovascular system

Positive CHMP opinions on new medicines

- Adempas (*riociguat*)
  Treatment of pulmonary hypertension

Negative CHMP opinions on new medicines

- Reasanz (*serelaxin*)
  Intended for the treatment of acute heart failure

Safety communication update

- Review of Protelos/Osseor *(strontium ranelate)* - PRAC recommendation to suspend use due to risk of heart problems
  Treatment of osteoporosis

Diabetes

Positive CHMP opinions on new medicines

- Eperzan *(albiglutide*)
  Treatment of type 2 diabetes

Gynaecology & Obstetrics

Positive CHMP opinions on new medicines

- Hemoprostol (*misoprostol*)
  Treatment of post-labour bleeding
- Bemfola (*follitropin alfa*)
  Treatment of fertility disorders

Safety communication update

- Review of emergency contraceptives (*levonorgestrel, ulipristal*) - review started due to possible effect of body weight on the efficacy of these medicines

Haematology

New information on authorised medicines

- NovoThirteen (*catridecacog*) - extension of indication (extended paediatric use)
  Prevention of bleeding

Immune system

New information on authorised medicines

- Xolair (*omalizumab*) - new indication (chronic spontaneous urticaria)
  Treatment of allergic asthma

Metabolic system

Positive CHMP opinions on new medicines

- Cholic Acid FGK (*cholic acid*)
  Treatment of inborn errors of primary bile acid synthesis

Musculoskeletal system

Negative CHMP opinions on new medicines

- Translarna (*ataluren*)
  Intended for treatment of Duchenne muscular dystrophy

Nephrology

Withdrawal of applications for new medicines

- Winfuran (*nalfurafine*)
  Intended for the treatment of severe uraemic pruritus (itching due to kidney malfunction)

Nervous system

Positive CHMP opinions on new medicines

- Rivastigmine 3M Health Care Ltd (*rivastigmine*)
  Treatment of Alzheimer's disease
- Latuda (*lurasidone*)
  Treatment of schizophrenia

New medicines authorised

- Levetiracetam Hospira (*levetiracetam*)
  Treatment of epilepsy
- Brintellix (*vortioxetine*)
  Treatment of major depression

Negative CHMP opinions on new medicines

- Nerventra (*laquinimod*)
  Intended for treatment of multiple sclerosis

Rheumatology

Positive CHMP opinions on new medicines

- Zoledronic acid Teva Generics *(zoledronic acid)*
  Treatment of osteoporosis and Paget's disease

Safety communication update

- Review of Protelos/Osseor *(strontium ranelate)* - PRAC recommendation to suspend use due to risk of heart problems
  Treatment of osteoporosis

Vaccines

Withdrawal of authorised medicines

- Tritanrix HepB *(diphtheria, tetanus, pertussis (whole cell) and hepatitis-B (rDNA) vaccine (adsorbed))*
  Used for immunisation against diphtheria, tetanus, pertussis and hepatitis-B

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on core SmPC and package leaflet for (99Mo/99mTc) generator
  Deadline for comments: 15 April 2014
- Draft guideline on key aspects for the use of pharmacogenomic methodologies in the pharmacovigilance evaluation of medicinal products
  Deadline for comments: 30 July 2014

Adopted guidelines

- Guideline on clinical investigation of medicinal products in the treatment of lipid disorders
- Concept paper on the need for a reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development
- Joint Ministry of Health, Labour and Welfare / EMA reflection paper on the development of block copolymer micelle medicinal products
- Qualification of novel methodologies for drug development: guidance to applicants
- Guidelines on good pharmacovigilance practices: Introductory cover note, last updated with final definition annex revision 2 and Annex I - Definitions (Rev 2)
- Guideline for the conduct of efficacy studies for non-steroidal anti-inflammatory drugs
- ICH guideline S10 on photosafety evaluation of pharmaceuticals - Step 4
- ICH guideline Q4B annex 6 to note for evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on uniformity of dosage units – general chapter - Step 4

Scientific committee and working party activities

- EMA publishes minutes of CHMP, CVMP and CAT meetings for the first time
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines under evaluation - January meeting
- COMP - agendas, minutes and meetings reports
- PDCO - agendas, minutes and meeting reports
- PRAC - agendas, minutes and highlights
- PRAC signal recommendations requesting an update of the product information – Sep 2012 to Jul 2013
- Work plan for the CHMP Biologics Working Party 2014
- Work programme for the Working Party on Community Monographs and Community List 2014

Other publications

- Agenda of the 82nd meeting of the Management Board
- Training manual - Review of EMA documents addressed to the general public by patients and consumers
- EMA recommends 81 medicines for marketing authorisation in 2013
- Annual report from the SME office 2013
- News bulletin for small and medium-sized enterprises - Issue 26
- European Network of Paediatric Research at the European Medicines Agency newsletter: December 2013
- EMA releases guidance on the use of pharmacogenomics to improve safety monitoring of medicines
- EMA announces next steps for the maintenance of information on authorised medicines by MAHs
- Questions and answers: Article 31 pharmacovigilance referral
- EMA Implementation Working Group meeting with European Union pharmaceutical industry associations on the implementation of Article 57(2) of Regulation (EC) No. 726/2004 - March 2014 and May 2014
- European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe
- European Medicines Agency/International Federation for Animal Health Europe info day 2014
- Joint EMA / EDQM workshop on characterisation of new clotting factor concentrates (factor VIII and factor IX) with respect to potency assays used for labelling and testing of post-infusion samples
- Joint meeting of Good-clinical-practice compliance Inspectors Working Group and eClinical Forum representatives on electronic data capture systems and investigator site eSource readiness
- Dates of forthcoming SEED early dialogue meetings and deadlines for briefing book submissions in 2014
- Who are the originators of innovative medicines in the EU?
- Business hours and holidays
- Application process for the 2014 traineeship intake is now opened

Key to symbols used

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

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