61 Issue 61
March 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

Antivirals/anti-infectives 1
Cancer 2
Cardiovascular system 2
Dermatology 2
Diabetes 2
Gastro-intestinal system 3
Gynaecology & Obstetrics 3
Immune system 3
Nervous system 3
Ophthalmology 4
Respiratory system 4
Rheumatology 4
Other medicines 4
Medicines under additional monitoring 4
Guidelines 4
Scientific committee and working party activities 5
Other publications 6
Explanation of terms used 7

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

- Ebilfumin (*oseltamivir*)
  Treatment and prevention of influenza
- Olysio (*simeprevir*)
  Treatment of chronic hepatitis C

New medicines authorised

- Sirturo (*bedaquiline*) O C
  Treatment of multi-drug resistant tuberculosis

New information on authorised medicines

- Pegasys (*peginterferon alfa-2a*) - change in the indication for chronic hepatitis C
  Treatment of chronic hepatitis B and C

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Folcepri (*etarfolatide*) C O
  Diagnostic medicine for ovarian cancer
- Neocepri (*folic acid)* C O
  Diagnostic medicine for ovarian cancer
- Vynfinit (*vintafolide*) C O
  Treatment of ovarian cancer

New medicines authorised

- Cometriq (*cabozantinib*) O
  Treatment of medullary thyroid carcinoma

Negative CHMP opinions on new medicines (outcome of re-examination)

- Masican (*masitinib*) O
  Intended for the treatment of gastrointestinal stromal tumour (a cancer of the stomach and bowel)

Cardiovascular system

Safety communication update

- Review of domperidone-containing medicines - PRAC recommendation (restrictions in use due to risk of effects on the heart; no longer authorised for the treatment of bloating or heartburn)
  Treatment of nausea and vomiting

Dermatology

New medicines authorised

- Mirvaso (*brimonidine*)
  Treatment of facial erythema of rosacea (a long-term skin condition)

Diabetes

Positive CHMP opinions on new medicines

- Jardiance (*empagliflozin*)
  Treatment of type 2 diabetes mellitus

New information on authorised medicines

- Tresiba (*insulin degludec)* - new indication (to be used in combination with GLP-1 receptor agonists)
  Treatment of type 2 diabetes mellitus
- Victoza (*liraglutide*) - new indication (to be used in combination with basal insulin)
  Treatment of type 2 diabetes mellitus

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Entyvio (*vedolizumab*)
  Treatment of ulcerative colitis and Crohn's disease

Negative CHMP opinions on new medicines (outcome of re-examination)

- Masican (*masitinib*) O
  Intended for the treatment of gastrointestinal stromal tumour (a cancer of the stomach and bowel)

Safety communication update

- Review of domperidone-containing medicines - PRAC recommendation (restrictions in use due to risk of effects on the heart; no longer authorised for the treatment of bloating or heartburn)
  Treatment of nausea and vomiting

Gynaecology & Obstetrics

Positive CHMP opinions on new medicines

- Folcepri (*etarfolatide*) C O
  Diagnostic medicine for ovarian cancer
- Neocepri (*folic acid*) C O
  Diagnostic medicine for ovarian cancer
- Vynfinit (*vintafolide*) C O
  Treatment of ovarian cancer

Immune system

Positive CHMP opinions on new medicines

- Entyvio (*vedolizumab*)
  Treatment of ulcerative colitis and Crohn's disease

Withdrawal of authorised medicines

- Leflunomide Teva (*leflunomide*)
  Intended for the treatment of rheumatoid arthritis

Nervous system

New medicines authorised

- Neuraceq (*florbetaben (^{18}F)*)
  Diagnostic agent for Alzheimer's disease and other cognitive impairments

Safety communication update

- Zolpidem-containing medicines - PRAC recommendation (advice to minimise the risk of accidents due to reduced alertness)
  Treatment of insomnia

Key to symbols used

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

Ophthalmology

New medicines authorised

- Izba (*travoprost*)
  Treatment of elevated intraocular pressure in ocular hypertension or open-angle glaucoma

Respiratory system

Positive CHMP opinions on new medicines

- Revinty Ellipta (*fluticasone furoate / vilanterol trifenatate)*
  Treatment of asthma and chronic obstructive pulmonary disease

Rheumatology

Withdrawal of authorised medicines

- Leflunomide Teva (*leflunomide*)
  Intended for the treatment of rheumatoid arthritis

Safety communication update

- Review of diacerein-containing medicines for oral administration - PRAC recommendation and CMDh position following re-examination (restricted use to manage risk of severe diarrhoea and effects on liver)
  Treatment of osteoarthritis

Other medicines

Positive CHMP opinions on new medicines

- Sylvant (*siltuximab*)
  Treatment of multicentric Castleman's disease (a disease of the lymph nodes)

Medicines under additional monitoring

- Updated list of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU
  Deadline for comments: 28 March 2014

Key to symbols used

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

- Draft reflection paper on the wording of indication for medicinal products for treatment of type 2 diabetes
  Deadline for comments: 03 June 2014
- Question and answer on expression/declaration of potency in quantitative and qualitative composition for Vancomycin products
  Deadline for comments: 04 June 2014
- Draft guideline on core SmPC for human fibrinogen products
  Deadline for comments: 04 June 2014
- Draft concept paper for a guideline on user safety of topically administered products
  Deadline for comments: 30 June 2014
- Concept paper on the revision of the guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins
  Deadline for comments: 30 June 2014

Adopted guidelines

- Guideline on the declaration of the quantitative composition / potency labelling of biological medicinal products that contain modified proteins as active substance
- Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - February 2014
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: March 2014
- CAT - agendas, minutes and reports
- COMP - agendas, minutes and meetings reports
- HMPC - agendas, minutes and meetings reports
- PDCO - agendas, minutes and meeting reports
- PRAC - agendas, minutes and highlights
- PRAC - recommendations on safety signals
- Work plan for the Biosimilar Medicinal Products Working Party 2014
- Work plan for Biostatistics Working Party 2014
- Work plan for the Central Nervous System Working Party 2014
- Work plan for the joint CVMP/ CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (JEG 3Rs)
- Work plan for the Infectious Diseases Working Party 2014
- Work plan for the Vaccine Working Party 2014

Other publications

- EMA Management Board endorses revised policy on handling of declarations of interests
- EMA Management Board - minutes of the 82nd meeting
- EMA Management Board - 83rd meeting
- EMA work programme for 2014
- EMA publishes first summary of a risk-management plan for a medicine
- EMA launches adaptive licensing pilot project
- EMA issues recommendations for 2014/2015 seasonal flu vaccine composition
- World TB Day – three new medicines recommended in last six months for patients with multidrug-resistant tuberculosis
- EMA and FDA extend pilot programme for parallel assessment of quality-by-design applications
- Propylene glycol in medicinal products for children
- News bulletin for small and medium-sized enterprises - Issue 27
- Joint EMA/FDA/MHLW-PMDA orphan medicinal product workshop
- 6th ICH E2B (R3) Individual Case Safety Report (ICSR) information day - May 2014
- Sixth annual workshop on the European Network of Paediatric Research - June 2014

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

© European Medicines Agency, 2014. Reproduction is authorised provided the source is acknowledged.