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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.

To receive each new issue of the newsletter, please click here RSS feeds, choose 'Human medicines highlights newsletter' and then click on 'Subscribe to this feed'. Please note, in order to be able to view RSS feeds you need one of the following: a modern web browser; a web-based news reader or a desktop news reader. For a list of RSS readers please refer to our RSS guide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

Information on medicines

Antivirals/anti-infectives

New medicines authorised

- Exviera (*dasabuvir*)
  Treatment of hepatitis C

Cancer

Positive CHMP opinions on new medicines

- Ristempa (*pegfilgrastim*)
  Treatment of neutropenia (low level of white blood cells) and chemotherapy-induced neutropenia
- Zykadia (*ceritinib*) C
  Treatment non-small cell lung cancer

Key to symbols used

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

New information on authorised medicines

- Adenuric (*febuxostat*) - new indication (for the 120 mg strength)
  Prevention and treatment of hyperuricaemia (high blood levels of uric acid) in patients undergoing chemotherapy
- Avastin (*bevacizumab*) - new indication
  Treatment of metastatic carcinoma of the cervix
- Vectibix (*panitumumab*) - change in indication
  Treatment of colorectal cancer

Cardiovascular system

Safety communication update

- Review of hydroxyzine-containing medicines - PRAC recommendation (new measures to minimise known heart risks)
  Various uses including relief of anxiety disorders, relief of pruritus (itching), premedication before surgery, and treatment of sleep disorders

Dermatology

Safety communication update

- Review of hydroxyzine-containing medicines - PRAC recommendation (new measures to minimise known heart risks)
  Various uses including relief of anxiety disorders, relief of pruritus (itching), premedication before surgery, and treatment of sleep disorders

Diabetes

Other information

- Toujeo (previously Optisulin) (*insulin glargine*) - addition of a new formulation
  Treatment of diabetes mellitus

Gastro-intestinal system

New information on authorised medicines

- Vectibix (*panitumumab*) - change in indication
  Treatment of colorectal cancer

Gynaecology & Obstetrics

New medicines authorised

- Senshio (*ospemifene*)
  Treatment of vulvar and vaginal atrophy

New information on authorised medicines

- Avastin (*bevacizumab*) - new indication
  Treatment of metastatic carcinoma of the cervix

HIV

New information on authorised medicines

- Sustiva (*efavirenz*) - change in indication
  Treatment of HIV-1 adults, adolescents and children

Haematology

Positive CHMP opinions on new medicines

- Ristempa (*pegfilgrastim*)
  Treatment of neutropenia (low level of white blood cells) and chemotherapy-induced neutropenia

New medicines authorised

- Rixubis (*nonacog gamma*)
  Treatment and prevention of bleeding in patients with haemophilia B

New information on authorised medicines

- Soliris (*eculizumab*) O - change in indication
  Treatment of paroxysmal nocturnal haemoglobinuria

Withdrawal of application for a new indication

- Rienso (*ferumoxytol*)
  Intended to extend treatment of anaemia (low red blood cells count) to patients with any underlying condition

Immune system

New medicines authorised

- Otezla (*apremilast*)
  Treatment of psoriasis and psoriatic arthritis

New information on authorised medicines

- Humira (*adalimumab*) - new indication
  Treatment of paediatric plaque psoriasis

Metabolic system

New medicines authorised

- Cerdelga (*eliglustat*) O
  Treatment of Gaucher disease

Nephrology

Positive CHMP opinions on new medicines

- Jinarc (*tolvaptan*) O
  Treatment of polycystic kidney disease

Nervous system

Safety communication update

- Review of hydroxyzine-containing medicines - PRAC recommendation (new measures to minimise known heart risks)
  Various uses including relief of anxiety disorders, relief of pruritus (itching), premedication before surgery, and treatment of sleep disorders

Respiratory system

New medicines authorised

- Ofev (*nintedanib*) O
  Treatment of pulmonary fibrosis (scarring of the lungs)

Safety communication update

- Review of ambroxol and bromhexine-containing medicines - CMDh Position (product information to be updated on the small risk of severe allergic reactions)
  Expectorants (to clear the airways), relief of sore throat and treatment of breathing disorders in premature and newborn babies

Rheumatology

New medicines authorised

- Otezla (*apremilast*)
  Treatment of psoriasis and psoriatic arthritis

Other medicines

New medicines authorised

- Scenesse (*afamelanotide*)
  Prevention of phototoxicity in erythropoietic protoporphyria (EPP) O E

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the revision of annex 1 of the guidelines on good manufacturing practice – manufacture of sterile medicinal products
  Deadline for comments: 31 March 2015

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - January 2015
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: February 2015
- 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 CHMP Biologics Working Party 2015
- Work plan for the Biosimilar Medicinal Products Working Party 2015
- Work plan for the Gastroenterology Drafting Group 2015
- Work plan for the Infectious Diseases Working Party 2015
- Work plan for the Pharmacogenomics Working Party 2015
- Work plan for the Pharmacokinetics Working Party 2015
- Work plan for the Radiopharmaceuticals Drafting Group 2015
- Work plan for the Oncology Working Party 2015
- Mandate of the Enpr-EMA working groups

Other publications

- EMA explains its redaction rules
- Major European research project on monitoring and evaluation of medicines concludes
- Identification of medicines: EU task force to implement new international standards

- Rare Disease Day 2015
- EMA - Ebola timeline and assessment report for Article-5(3) procedure: medicinal products under development for treatment of Ebola
- Safety signals: recommendations now available in all EU languages
- Annual report from the SME office 2014
- PROTECT symposium - February 2015
- PCWP and HCPWP joint meeting and Information session on biosimilars - March 2015
- Enpr-EMA coordinating group and working group meeting - January 2015

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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http://www.ema.europa.eu

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