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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

Safety communication update

- Review of polymyxin-containing medicines (*colistin / colistimethate sodium*) - CHMP Opinion (updated recommendations for the treatment of antibiotic-resistant infections)
  Treatment of bacterial infections

Cancer

Positive CHMP opinions on new medicines

- Lynparza (*olaparib*) O
  Treatment of ovarian, fallopian tube and primary peritoneal cancers

New medicines authorised

- Zydelig (*idelalisib*)
  Treatment of chronic lymphocytic leukaemia and follicular lymphoma (blood cancers)

Key to symbols used

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

New information on authorised medicines

- Xtandi (*enzalutamide*) - new indication
  Treatment of prostate cancer

Supply shortages

- Xofigo (*radium-223 dichloride*)
  Treatment of prostate cancer

Safety communication update

- Review of Iclusig (*ponatinib*) O - CHMP opinion (measures to minimise risk of blood clots and narrowing of blood vessels)
  Treatment of leukaemia

Cardiovascular system

Arbitration procedure

- Plendil and associated names (*felodipine*) - outcome
  Treatment of hypertension and angina (chest pain)

Safety communication update

- Review of Iclusig (*ponatinib*) O - CHMP opinion (measures to minimise risk of blood clots and narrowing of blood vessels)
  Treatment of leukaemia
- Review of testosterone-containing medicines - PRAC recommendation (review did not find increase in heart problems)
  Treatment of hypogonadism (reduced testosterone production in men)

Diabetes

New medicines authorised

- Abasria (*insulin glargine*)
  Treatment of diabetes mellitus

Gynaecology & Obstetrics

Positive CHMP opinions on new medicines

- Duavive (*estrogens conjugated / bazedoxifene*)
  Treatment of symptoms of menopause
- Lynparza (*olaparib*) O
  Treatment of ovarian, fallopian tube and primary peritoneal cancers

Safety communication update

- Review of valproate and related substances - PRAC recommendation (strengthening of restrictions on use in women and girls)
  Treatment of epilepsy and bipolar disorder and prevention of migraine

HIV

New medicines authorised

- Triumeq (*abacavir sulfate / dolutegravir sodium / lamivudine*)
  Treatment of HIV infection

Haematology

Positive CHMP opinions on new medicines

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

New medicines authorised

- Accofil (*filgrastim*)
  Treatment of neutropenia (low level of white blood cells)
- Zydelig (*idelalisib*)
  Treatment of chronic lymphocytic leukaemia and follicular lymphoma (blood cancers)

Safety communication update

- Review of Iclusig (*ponatinib*) - CHMP opinion (measures to minimise risk of blood clots and narrowing of blood vessels)
  Treatment of leukaemia

Hormone system

Safety communication update

- Review of testosterone-containing medicines - PRAC recommendation (review did not find increase in heart problems)
  Treatment of hypogonadism (reduced testosterone production in men)

Metabolic system

Supply shortages

- Fabrazyme (*agalsidase beta*)
  Treatment of Fabry disease

Nephrology

New medicines authorised

- Velphoro (*mixture of polynuclear iron(III)-oxyhydroxide, sucrose and starches*)
  Used to reduce phosphate levels in patients with kidney disease

Nervous system

Positive CHMP opinions on new medicines

- Duloxetine Lilly (*duloxetine*)
  Treatment of depression, anxiety and diabetic nerve pain
- Paliperidone Janssen (*paliperidone*)
  Treatment of schizophrenia

Arbitration procedure

- Oxynal, Targin and associated names (*oxycodone hydrochloride / naloxone hydrochloride)* - outcome
  Treatment of severe pain and restless legs syndrome

Safety communication update

- Review of valproate and related substances - PRAC recommendation (strengthening of restrictions on use in women and girls)
  Treatment of epilepsy and bipolar disorder and prevention of migraine

Other medicines

Positive CHMP opinions on new medicines

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

New medicines authorised

- Busulfan Fresenius Kabi (*busulfan*)
  Conditioning treatment prior to blood-stem cell transplantation

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the need for revision of the points to consider on the clinical investigation of new medicinal products for the treatment of acute coronary syndrome
  Deadline for comments: 15 January 2015
- Draft guideline on influenza vaccines – submission and procedural requirements
  Deadline for comments: 30 January 2015

Key to symbols used

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Adopted guidelines

- Reflection paper on the requirements for selection and justification of starting materials for the manufacture of chemical active substances
- Guideline on similar biological medicinal products

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - September 2014
- CHMP - agendas, minutes and highlights
- CHMP applications for new human medicines: October 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 Biostatistics Working Party 2014

Other publications

- EMA mid-year report 2014 from the Executive Director
- Information on suspected side effects of nationally authorised medicines now available through a single website
- Pilot phase to involve patients in benefit/risk discussions at CHMP meetings
- Incorporating patients' views during evaluation of benefit-risk by the EMA scientific committees
- Annual report on EMA's interaction with patients, consumers, healthcare professionals and their organisations (2013)
- EMA advises on development plan for GSK Ebola vaccine
- EMA ready to start assessment of Ebola vaccines and treatments as soon as data are made available
- Facilitating global development of biosimilars
- Revised framework for development of influenza vaccines
- Discussion paper on the clinical investigation of medicines for the treatment of Alzheimer's disease and other dementias
- News bulletin for small and medium-sized enterprises - Issue 29
- The annual EMA review of the year and outlook for 2015 - November 2014
- EU clinical trials portal and Union database meeting with stakeholders - November 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.

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