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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.

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Information on medicines

Antivirals/anti-infectives

Safety communication update

- EMA recommends avoidance of certain hepatitis C medicines and amiodarone together

Cancer

Positive CHMP opinions on new medicines

- Opdivo (*nivolumab*)
  Treatment of melanoma

New medicines authorised

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

Key to symbols used

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

Negative CHMP opinions on new medicines

- Lympreva (*dasiprotimut-t)*
  Intended for the treatment of follicular non-Hodgkin's lymphoma (cancer of the lymphatic system)

Supply shortages

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

Cardiovascular system

Positive CHMP opinions on new medicines

- Lixiana *(edoxaban*)
  Prevention of stroke and systemic embolism; treatment and prevention of deep vein thrombosis (DVT) and pulmonary embolism

Safety communication update

- Review of ibuprofen and dexibuprofen-containing medicines - PRAC recommendation (small increased cardiovascular risk with daily doses at or above 2,400 mg)
  Treatment of pain and inflammation
- EMA recommends avoidance of certain hepatitis C medicines and amiodarone together

Diabetes

Positive CHMP opinions on new medicines

- Duloxetine Mylan (*duloxetine*)
  Treatment of major depressive disorder, diabetic nerve pain and generalised anxiety disorder

New information on authorised medicines

- Levemir (*insulin detemir*) - change in use of the medicine
  Treatment of diabetes mellitus

Gastro-intestinal system

New information on authorised medicines

- Relistor (*methylnaltrexone bromide*) - change in indication
  Treatment of opioid-induced constipation
- Resolor (*prucalopride*) - change in indication
  Treatment of chronic constipation in adults

Gynaecology & Obstetrics

New information on authorised medicines

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

HIV

New medicines authorised

- Dutrebis (*lamivudine / raltegravir potassium*)
  Treatment of HIV-1 infection

Haematology

New medicines authorised

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

Metabolic system

New medicines authorised

- Mysimba (*naltrexone / bupropion*)
  Weight management in obese or overweight patients
- Saxenda *(liraglutide)*
  Weight management in obese or overweight patients

Nephrology

New medicines authorised

- Tasermity (*sevelamer hydrochloride)*
  Used to reduce phosphate levels in patients receiving haemodialysis or peritoneal dialysis

Nervous system

Positive CHMP opinions on new medicines

- Aripiprazole Pharmathen (*aripiprazole*)
  Treatment of schizophrenia and prevention of manic episodes in bipolar I disorder
- Aripiprazole Zentiva (*aripiprazole*)
  Treatment of schizophrenia and prevention of manic episodes in bipolar I disorder
- Duloxetine Mylan (*duloxetine*)
  Treatment of major depressive disorder, diabetic nerve pain and generalised anxiety disorder
- Hetlioz (*tasimelteon*)
  Treatment of non-24-hour sleep-wake disorder in blind adults
- Pregabalin Mylan Pharma *(pregabalin*)
  Treatment of epilepsy, neuropathic pain and generalised anxiety disorder
- Pregabalin Sandoz (*pregabalin*)
  Treatment of epilepsy, neuropathic pain and generalised anxiety disorder

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New information on authorised medicines

- Invega (*paliperidone*) - change in indication
  Treatment of schizoaffective disorder in adults

Arbitration procedures

- Merisone and Myoson (*tolperisone*) - outcome
  Treatment of post-stroke spasticity (muscle spam after stroke)

Supply shortages

- Buccolam (*midazolam*) - resolved
  Treatment of convulsive seizures

Respiratory system

Safety communication update

- Review of codeine-containing medicinal products - CMDh Position (not to be used in children below 12 years for cough and cold)

Other medicines

Positive CHMP opinions on new medicines

- Lumark (*lutetium (^{177}Lu) chloride*)
  Radiopharmaceutical precursor

Safety communication update

- Review of ibuprofen and dexibuprofen-containing medicines - PRAC recommendation (small increased cardiovascular risk with daily doses at or above 2,400 mg)
  Treatment of pain and inflammation

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on clinical investigation of medicinal products for the treatment of axial spondyloarthritis
  Deadline for comments: 30 June 2015
- Guideline on good pharmacovigilance practices (GVP) - Module XVI addendum I – Educational materials
  Deadline for comments: 30 June 2015

- Concept paper on the development of a guideline on quality and equivalence of topical products
  Deadline for comments: 22 July 2015
- Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of new active substance status of chemical substances
  Deadline for comments: 24 July 2015
- Draft concept paper on the need to revise the "Guideline on the evaluation of anticancer medicinal products in man" in order to provide guidance on the reporting of safety data from clinical trials
  Deadline for comments: 31 July 2015
- Draft guideline on clinical investigation of medicinal products for the treatment of venous thromboembolic disease
  Deadline for comments: 30 September 2015
- Draft guideline on the chemistry of active substances
  Deadline for comments: 24 October 2015

Adopted guidelines

- Compilation of individual product-specific guidance on demonstration of bioequivalence (Rev.1)

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - February 2015
- Medicinal products for human use: monthly figures - March 2015
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: April 2015
- CAT - agendas, minutes and reports
- CAT work plan 2015-2016
- 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 of the CHMP Blood Products Working Party

Other publications

- EMA 2014 annual report
- World Health Day 2015
- Preventing medication errors in the European Union - good practice guide consultation open
- News bulletin for small and medium-sized enterprises - Issue 31
- PCWP and HCPWP joint meeting - March 2015 - meeting documents

Key to symbols used

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- Industry stakeholder platform on the operation of the centralised procedure - April 2015 - meeting documents
- 20th anniversary scientific conference highlights - March 2015
- Joint workshop on chordoma as a model for very rare cancers - April 2015
- EMA/EGA joint workshop on the impact of the revised EMA guideline on the pharmacokinetic and clinical evaluation of modified-release dosage forms - April 2015
- Workshop: Promoting high quality scientific research in paediatric medicines - May 2015
- Joint DIA/EMA Information Day on Post-Authorisation Studies (PAS) - June 2015
- Workshop on haemophilia registries - July 2015
- Innovation and Biomarkers in Cancer Drug Development, Belgium - December 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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