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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

Positive CHMP opinions on new medicines

- Xydalba (*dalbavancin*)
  Treatment of acute bacterial skin and skin structure infections

New medicines authorised

- Harvoni (*sofosbuvir / ledipasvir*)
  Treatment of hepatitis C

Cancer

New information on authorised medicines

- Revlimid (*lenalidomide*) O - new indication
  For the continuous treatment of patients with previously untreated multiple myeloma who are not eligible for transplant

Key to symbols used

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

- Velcade (*bortezomib*) - new indication
  Treatment of patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation

Cardiovascular system

Positive CHMP opinions on new medicines

- Clopidogrel ratiopharm (*clopidogrel*)
  Prevention of problems caused by blood clots, such as heart attack

Withdrawal of authorised medicines

- Ipreziv (*azilsartan medoxomil*)
  Treatment of hypertension

Dermatology

Positive CHMP opinions on new medicines

- Xydalba (*dalbavancin*)
  Treatment of acute bacterial skin and skin structure infections

Diabetes

New medicines authorised

- Trulicity (*dulaglutide*)
  Treatment of type-2 diabetes mellitus

New information on authorised medicines

- Tresiba (*insulin degludec*) - change in indication
  Treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year

Gastro-intestinal system

New medicines authorised

- Moventig (*naloxegol*)
  Prevention of constipation

HIV

New medicines authorised

- Rezolsta (*darunavir / cobicistat*)
  Treatment of HIV-1 infection

Haematology

New medicines authorised

- Nuwiq (*simoctocog alfa (rFVIII)*)
  Treatment and prevention of bleeding in patients with haemophilia A

Nephrology

Positive CHMP opinions on new medicines

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

Nervous system

Positive CHMP opinions on new medicines

- Xadago (*safinamide*)
  Treatment of Parkinson's disease

Ophthalmology

Positive CHMP opinions on new medicines

- Holoclar (*ex vivo autologous corneal epithelial cells including stem cells*) O C
  Treatment of patients with limbal stem-cell deficiency due to ocular burns (burns to the eye)

Respiratory system

Positive CHMP opinions on new medicines

- Quinsair (*levofloxacin*) O
  Management of chronic pulmonary infections in patients with cystic fibrosis

New medicines authorised

- Brimica Genuair / Duaklir Genuair (*aclidinium bromide / formoterol fumarate dihydrate*)
  Treatment of chronic obstructive pulmonary disease
- Budesonide/Formoterol Teva / Vylaer Spiromax *(budesonide / formoterol)*
  Treatment of asthma and chronic obstructive pulmonary disease
- Budesonide/Formoterol Teva Pharma B.V. (*budesonide / formoterol fumarate dihydrate*)
  Treatment of asthma

Vaccines

Safety communication update

- Review of Fluad vaccine - PRAC finds no evidence that vaccine caused deaths in Italy
  Immunisation against seasonal influenza

Other medicines

Positive CHMP opinions on new medicines

- Mysimba (*naltrexone / bupropion*)
  Management of weight of overweight or obese adults

New medicines authorised

- Tadalafil Mylan (*tadalafil*)
  Treatment of erectile dysfunction

New information on authorised medicines

- Xiapex (*collagenase Clostridium histolyticum*) - new indication
  Treatment of men with Peyronie's disease (changes in the shape of the penis)

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft questions and answers on cyclodextrins in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'
  Deadline for comments: 28 February 2015
- Draft questions and answers on propylene glycol and esters in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'
  Deadline for comments: 28 February 2015
- Guideline on the use of minimal residue disease as an endpoint in chronic lymphocytic leukaemia studies
  Deadline for comments: 30 June 2014

Adopted guidelines

- Reflection paper on clinical aspects related to tissue engineered products
- Guideline on the use of phthalates as excipients in human medicinal products
- Guideline on quality of transdermal patches
- Compilation of individual product-specific guidance on demonstration of bioequivalence
- Guideline on core Summary of Product Characteristics (SmPC) for human plasma derived and recombinant coagulation factor IX products

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - November 2014
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines CHMP - December 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
- Revised framework for the interaction of the Agency with patients' and consumers' organisations
- Revised framework for interaction between the EMA and patients and consumers and their organisations: Annex I - EMA activities where patients and consumers are involved
- Revised framework for interaction between the EMA and patients and consumers and their organisations: Annex II – Action plan

Other publications

- EMA Management Board: highlights of December 2014 meeting
- Status of the adaptive pathways pilot project
- Experimental Ebola treatments still at early stage of development
- GVK Biosciences review: some Member States suspend marketing authorisations for concerned medicines
- News bulletin for pharmacovigilance programme update - Issue 2
- Mitigating risks due to the use of antibiotics in animals
- European Medicines Agency workshop on the clinical investigation of medicines for the treatment of Alzheimer's disease - November 2014 - meeting documents
- Innovative Medicines Initiative WEB-RADR workshop - December 2014
- Expert meeting on the clinical investigation of medicines for the treatment of paediatric hepatitis C - December 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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http://www.ema.europa.eu

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