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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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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

New information on authorised medicines

- Pegasys (*peginterferon alfa-2a*) - change in existing indication and new indication
  Treatment of hepatitis B and hepatitis C

Cancer

New medicines authorised

- Imatinib Teva (*imatinib*)
  Treatment of myeloid leukaemia

Withdrawal of applications for new medicines

- Loulla (*mercaptopurine*)
  Intended for the treatment of lymphoblastic leukaemia

Key to symbols used

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

Cardiovascular system

Positive CHMP opinions on new medicines

- Actelsar HCT (*telmisartan/hydrochlorothiazide*)
  Treatment of hypertension
- Tolucombi (*telmisartan/hydrochlorothiazide*)
  Treatment of hypertension

Withdrawal of applications for new medicines

- Ruvise (*imatinib mesilate*)
  Intended for the treatment of pulmonary arterial hypertension

Safety updates

- Tredaptive, Pelzont and Trevaclyn (*laropiprant / nicotinic acid*) - CHMP opinion
  Treatment of high blood fats

Diabetes

New information on authorised medicines

- Komboglyze (*saxagliptin / metformin hydrochloride*) - new indication
  Treatment of type 2 diabetes
- Onglyza (*saxagliptin*) - new indication
  Treatment of type 2 diabetes

HIV

Withdrawal of authorised medicines

- Viracept (*nelfinavir*)
  Treatment of HIV infection

Nervous system

Positive CHMP opinions on new medicines

- Maruxa (*memantine hydrochloride*)
  Treatment of Alzheimer's disease

Withdrawal of applications for new medicines

- Memantine FGK (*memantine*)
  Treatment of Alzheimer's disease

Ophthalmology

Positive CHMP opinions on new medicines

- Jetrea (*ocriplasmin*)
  Treatment of vitreomacular traction

Negative CHMP opinions on new medicines

- Raxone (*idebenone*) O
  Intended for the treatment of Leber's hereditary optic neuropathy (LHON)

Respiratory system

Arbitration procedures (non-safety related)

- Kantos Master (*beclomethasone diipropionate / formoterol fumarate*)
  Treatment of asthma

Rheumatology

New information on authorised medicines

- Ilaris (*canakinumab*) - new indication
  Treatment of gouty arthritis
- Humira (*adalimumab*) - change in indication
  Treatment of polyarticular juvenile idiopathic arthritis

Safety updates

- Review of tetrazepam-containing medicines (*tetrazepam*) - started
  Treatment of muscle spasms

Urology

New medicines authorised

- Betmiga (*mirabegron*)
  Treatment of overactive bladder syndrome

Vaccines

New medicines authorised

- Bexsero (*meningococcal group-B vaccine*)
  Prevention of meningitis B

Other medicines

New medicines authorised

- NexoBrid (*concentrate of proteolytic enzymes enriched in bromelain*)
  Treatment of dead skin tissue caused by burns
- Amyvid (*florbetapir (^{18}F)*)
  Used for brain scans in patients with memory problems

Safety updates

- European Medicines Agency to review third- and fourth-generation combined oral contraceptives
- Diane 35 (*cyproterone acetate / ethinylestradiol*) and generics
  Treatment of acne

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on pharmaceutical development of medicines for paediatric use
  Deadline for comments: 31/03/2013
- Concept paper on the need for a paediatric addendum to the guideline on clinical investigation of medicinal products for the treatment of acute heart failure
  Deadline for comments: 15/04/2013
- Draft guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities
  Deadline for comments: 30/06/2013
- Draft guideline on non-clinical and clinical development of similar biological medicinal products containing low-molecular-weight heparins
  Deadline for comments: 31/07/2013

Adopted guidelines

- Guideline on the evaluation of anticancer medicinal products in man
- Guideline on good pharmacovigilance practices: Module XV – Safety communication
- Guideline on good pharmacovigilance practices: Annex II - Templates: Direct healthcare-professional communication

Scientific committee activities

- CHMP January 2013 meeting highlights
- COMP February 2013 agenda and December 2012 meeting minutes
- PRAC January 2013 meeting highlights and PRAC November 2012 meeting minutes

Key to symbols used

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- PDCO January 2013 agenda and PDCO December 2012 meeting Minutes
- CAT January 2013 monthly report

Other publications

- EMA publishes guidance on preparing and reviewing summaries of product characteristics
- Advisory groups on publication of clinical-trial data
- EMA Budget for 2013
- Points to consider on good-clinical-practice inspection findings and the benefit-risk balance
- Presentations from the EMA training session on the new pharmaceutical legislation
- Framework for a close collaboration with Israel in place
- European Medicines Agency information day: The new individual-case-safety-report (ICSR) international standard and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E2B/M2 information day, 5 Feb 2013, EMA, London, UK
- Workshop on paediatric investigation plans in type-2 diabetes mellitus, 25 Feb 2013, EMA, London, UK
- Council of Europe's European Directorate for the Quality of Medicines & HealthCare (EDQM) and the EMA joint meeting on raw materials used for the production of cell based and gene therapy products, 3 Apr 2013, EDQM, Strasbourg, France
- Expert workshop on process validation for the manufacture of biotechnology-derived active substances, 9 Apr 2013, EMA, London, UK
- First meeting of the Modelling and Simulation Working Group
- Work plan for the Central Nervous System Working Party 2013
- Work plan for the Pharmacogenomics Working Party 2013
- Work plan for the Oncology Working Party 2013
- Work plan for the Radiopharmaceuticals Drafting Group 2013
- Work plan for the Joint CHMP / CVMP Quality Working Party 2013

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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