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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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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 an e-mail alert when each new issue of the newsletter is published, send a request to: HMHnewsletter@ema.europa.eu

Information on medicines

Cancer

Positive CHMP opinions on new medicines

- Imatinib Actavis (*imatinib*)
  Treatment of Philadelphia-chromosome positive chronic myeloid leukaemia

Cardiovascular system

Withdrawal of applications for new medicines

- Ruvise (*imatinib*)
  Expected to be used in the treatment of pulmonary arterial hypertension

Arbitration procedures (non-safety related)

- Furosemide Vitabalans (*furosemide*)
  Intended for the treatment of congestive heart failure, cirrhosis of the liver and hypertension

Key to symbols used

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

Diabetes

New medicines authorised

- Tresiba (*insulin degludec*)
  Treatment of type-1 and type-2 diabetes
- Ryzodeg (*insulin degludec and insulin aspart*)
  Treatment of type-1 and type-2 diabetes

HIV

Other information

- Vistide (*cidofovir*)
  Treatment of cytomegalovirus eye infections in patients with AIDS

Hormonal system

Safety communication update

- Diane 35 (cyproterone- and ethinylestradiol-containing medicines)
  Treatment of acne and other hormone-related conditions and contraception
- Combined hormonal contraceptives (*chlormadinone, desogestrel, dienogest, drospirenone, etonogestrel, gestodene, nomegestrol, norelgestromin or norgestimate*)
  Oral contraception

Immune system

New information on authorised medicines

- Privigen (*human normal immunoglobin*) - extension of indication
  Treatment of inflammatory demyelinating polyneuropathy

Metabolic system

Positive CHMP opinions on new medicines

- Pheburane (*sodium phenylbutyrate*) O
  Treatment of urea-cycle disorders

Musculoskeletal system

Withdrawal of applications for new medicines

- Hyalograft C autograft (*cultured autologous chondrocytes on hyaluronan based scaffold*)
  Intended for the surgical repair of cartilage defects of the knee

Nephrology

New medicines authorised

- BindRen (*colestilan*)
  Used to control hyperphosphataemia (high blood phosphate levels) in patients with kidney disease

Nervous system

Positive CHMP opinions on new medicines

- Nemdatine (*memantine*)
  Treatment of Alzheimer's disease
- Memantine Mylan (*memantine*)
  Treatment of Alzheimer's disease
- Memantine LEK (*memantine*)
  Treatment of Alzheimer's disease

Rheumatology

New medicines authorised

- Krystexxa (*pegloticase*)
  Treatment of tophaceous gout

Vaccines

Positive CHMP opinions on new medicines

- Hexyon (*diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus influenzae type b conjugate vaccine (adsorbed)*)
  Vaccination against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b
- Hexacima (*diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus influenzae type b conjugate vaccine (adsorbed)*)
  Vaccination against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b

New information on authorised medicines

- Cervarix (*human papillomavirus vaccine (recombinant, adjuvanted, adsorbed*)) - extension of indication
  Vaccination against premalignant genital (cervical, vulvar and vaginal) lesions causally related to certain oncogenic human-papillomavirus (HPV) types

Other medicines

Negative CHMP opinions on new medicines

- Osiva (*phentermine and topiramate*)
  Treatment of obesity

Other information

Guidelines

Guidelines open for consultation

- Reflection paper on the development of block-copolymer-micelle medicinal products
  Deadline for comments: 1 July 2013
- Reflection paper on good-clinical-practice compliance in relation to trial master files (paper and / or electronic) for management, audit and inspection of clinical trials
  Deadline for comments: 30 April 2013

Adopted guidelines

- Points to consider - Distant / virtual pharmacovigilance inspections of marketing-authorisation holders during a crisis situation

Scientific committee activities

- CHMP meeting highlights - February 2013
- COMP meeting report - February 2013
- COMP meeting minutes - January 2013
- COMP – strengthened interactions with patients and international partners
- PDCO monthly report - February 2013
- PDCO meeting minutes - January 2013
- PDCO - towards more and better information on the use of medicines for children
- CAT – focus on incentives for SMEs and strengthened interaction with stakeholders
- CAT monthly meeting report - February 2013
- PRAC meeting minutes - January 2013
- HMPC meeting report - January 2013

Other publications

- Work plan for the EMA Working Party with Patients' and Consumers' organisations (PCWP) 2013
- PCWP meeting with all eligible organisations, 30-Nov-2012 - Minutes & presentations
- Healthcare Professionals' Working Group (HCPWG), EMA, London, UK, 27-Feb-2013
- PCWP and HCPWG joint meeting, EMA, London, UK, 27 - 28-Feb-2013
- The PROTECT project on pharmacovigilance achieves key objectives
- World Cancer Day: 4 February 2013

- Outcome of the EMA survey on advanced-therapy-medicinal-product certification for small and medium-sized enterprises - Commission Regulations (EC) No. 1349/2007 and 668/2009
- EMA and EC renew confidentiality arrangement with Japan
- EMA excellence in pharmacovigilance: Clinical trials and post-marketing training course, EMA, London, UK, 18 - 20-Feb-2013
- Public consultation opens on standard paediatric investigation plans for two types of cancer in children
- SME office: outcomes of seven years of active support to small and medium-size businesses
- Medication-errors workshop - final programme, EMA, London, UK, 28-Feb - 1-Mar-2013
- EU 28: science, medicines, health - a regulatory system fit for the future, Dubrovnik, Croatia, 6 - 7-May 2013
- European Union enlargement
- EMA most frequently asked questions
- Adjusted fees for applications to European Medicines Agency from 1 April 2013
- Frequently asked questions - Trainees at the European Medicines Agency
- EMA revises three guidance documents to include orphan-related information

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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