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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 Teva (*imatinib mesilate*)
  Treatment of chronic myeloid leukaemia (CML)

New medicines authorised

- Dacogen (*decitabine*)
  Treatment of acute myeloid leukaemia (AML)
- Jakavi (*ruxolitinib*)
  Treatment of myelofibrosis

Withdrawal of applications for extension of indication

- Erbitux (*cetuximab*)
  Intended to include treatment of non-small lung cancer

Key to symbols used

Orphan medicine | Generic medicine | Biosimilar medicine | Conditional approval | Exceptional circumstances

New information on authorised medicines

- Thyrogen (*thyrotropin alfa*) - change in indication
  Treatment of thyroid cancer

Other information

- Caelyx (*doxorubicin hydrochloride*)
  Treatment of metastatic breast cancer, advanced cancer of the ovary, Kaposi's sarcoma, and multiple myeloma

Cardiovascular system

New information on authorised medicines

- Xarelto (*rivaroxaban*) - new indication and new contraindication
  Treatment of deep-vein thrombosis (DVT) and pulmonary embolism (PE)

Arbitration procedures

- Furosemide Vitabalans (*furosemide*)
  Intended to treat oedema, cirrhosis of the liver, and mild to moderation hypertension

Safety communication update

- Review of non-selective non-steroidal anti-inflammatory drugs (NSAIDs) and cardiovascular risk
- Review of diclofenac-containing medicine started

Diabetes

Positive CHMP opinions on new medicines

- Ryzodeg (*insulin degludec/insulin aspart*)
  Treatment of diabetes mellitus
- Tresiba (*insulin degludec*)
  Treatment of diabetes mellitus

Gastro-intestinal system

New information on authorised medicines

- Humira (*adalimumab*) - new indication
  Treatment of Crohn's disease

HIV

New information on authorised medicines

- Isentress (*raltegravir*) - change in indication
  Treatment of human immunodeficiency virus (HIV-1)

Metabolic system

Positive CHMP opinions on new medicines

- Bindren (*colestilan*)
  Treatment of hyperphosphataemia

Negative CHMP opinions on new medicines

- Qsiva (*phentermine/topiramate*)
  Intended to treat obesity

Nervous system

Positive CHMP opinions on new medicines

- Amyvid (*florbetapir*)
  Diagnosis of Alzheimer's

Negative CHMP opinions on new medicines

- Balaxur (*memantine hydrochloride/donepezil hydrochloride*)
  Intended to treat moderate to moderately severe Alzheimer's disease
- Acrescent (*memantine hydrochloride/donepezil hydrochloride*)
  Intended to treat moderate to moderately severe Alzheimer's disease

Respiratory system

New medicines authorised

- Tovanor Breezhaler (*glycopyrronium bromide*)
  Treatment for symptoms of chronic obstructive pulmonary disease (COPD)
- Enurev Breezhaler (*glycopyrronium bromide*)
  Treatment for symptoms of chronic obstructive pulmonary disease (COPD)
- Seebri Breezhaler (*glycopyrronium bromide*)
  Treatment for symptoms of chronic obstructive pulmonary disease (COPD)

Rheumatology

Positive CHMP opinions on new medicines

- Krystexxa (*pegloticase*)
  Treatment of severe chronic tophaceous gout

Safety communication update

- Review of non-selective non-steroidal anti-inflammatory drugs (NSAIDs) and cardiovascular risk
- Review of diclofenac-containing medicine started

Urology

Positive CHMP opinions on new medicines

- Betmiga (*mirabegron*)
  Treatment of urgency, increased micturition frequency and/or urgency incontinence

Vaccines

Safety communication update

- EMA reviews hypothesis on Pandemrix and development of narcolepsy

Other information

- Update on seasonal influenza vaccines produced by Novartis vaccines

Other medicines

Other information

- Review of Codeine-containing medicines
  Treatment of pain relief

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the need for revision of the guideline of medical products used in weight control
  Deadline for comments: 31/12/2012
- Draft guideline on the use of bovine serum in the manufacture of human biological medicinal products
  Deadline for comments: 31/12/2012
- Concept paper on the need for revision of the guideline on the evaluation of medicinal products in the treatment of primary osteoporosis
  Deadline for comments: 31/01/2013
- Guideline on clinical investigation of medicinal products for the treatment of multiple sclerosis (rev. 2)
  Deadline for comments: 09/04/2013
- Draft Guideline on clinical investigation of medicinal products for the treatment of acute heart failure
  Deadline for comments: 15/04/2013

Adopted guidelines

- Guideline on clinical investigation of medicinal products, including depot preparations, in the treatment of schizophrenia
- Additional guidance on documents relating to an active substance master file

- Paediatric addendum to CHMP guideline on clinical investigation of medicinal products in the treatment of lipid disorders

Scientific committee activities

- CHMP October meeting highlights
- COMP September meeting minutes and COMP meeting report on the review of applications for orphan designation: October 2012
- PDCO Minutes of the 5-7 September 2012 meeting and PDCO October monthly report
- CAT Monthly report
- PRAC – first experience and acronyms and abbreviations used in PRAC minutes
- PRAC meeting highlights from 1-3 October and from 29-31 October 2012

Other publications

- EMA starts infringement procedure to investigate Roche's alleged non-compliance with pharmacovigilance obligations
- EMA's conflicts-of-interests handling recognised in European Court of Auditors report
- European Network of Paediatric Research at the European Medicines Agency– Background information
- Report on Ethical considerations for paediatric trials
- Fifth report on the interaction with patients' and consumers' organisations (2011)
- EMA mid-year report 2012 from the Executive Director (January–June 2012)
- The annual EMA review of the year and outlook for 2013
- EMA workshop on multiplicity issues in clinical trials, London, 22 November 2012
- European SME Week 2012: 15-21 October
- European Medicines Agency publishes active substance list with lead Member State responsible for safety monitoring
- European Commission invites feedback on experience with the Paediatric Regulation
- European Union regulatory workshop on medication errors
- European Medicines Agency publishes list of EU reference dates and frequency of PSUR submission
- Changes to variation rules start to apply from 2 November 2012

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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