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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.

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

- Mekinist (*trametinib*)
  Treatment of melanoma

New information on authorised medicines

- Nexavar (*sorafenib*) O - extension of indication
  Treatment of thyroid cancer, in addition to liver and kidney cancer

Withdrawal of extension of indication

- Votrient (*pazopanib*)
  Intended for the treatment of ovarian, fallopian tube or primary peritoneal cancer

Safety communication update

- EMA alerts EU healthcare professionals after vials of falsified Herceptin identified - list of batches concerned

Key to symbols used

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

Cardiovascular system

New medicines authorised

- Adempas (*riociguat*)
  Treatment of pulmonary hypertension

New information on authorised medicines

- Pradaxa (*dabigatran etexilate*) - new indication
  Treatment/prevention of deep-vein thrombosis and pulmonary embolism, in addition to blood clots in veins after hip or knee surgery, stroke and systemic embolism

Safety communication update

- Review of renin-angiotensin-system (RAS)-acting agents - PRAC recommendation (combined use of these medicines is not recommended due to increased risk of side effects on the heart, circulation and kidneys, especially in patients with kidney impairment or diabetes)
  Treatment of high blood pressure and congestive heart failure
- Review of domperidone-containing medicines - CMDh Position (restrictions in use due to risk of effects on the heart; no longer authorised for the treatment of bloating or heartburn)
  Treatment of nausea and vomiting
- Review of testosterone-containing medicines - review started (concerns on potential side effects on the heart)
  Treatment of hypogonadism (reduced testosterone production in men)

Diabetes

Positive CHMP opinions on new medicines

- Jardiance (*empagliflozin*)
  Treatment of type 2 diabetes mellitus
- Vokanamet (*canagliflozin / metformin*)
  Treatment of type 2 diabetes mellitus

New medicines authorised

- Eperzan (*albiglutide*)
  Treatment of type 2 diabetes mellitus

Gastro-intestinal system

Safety communication update

- Review of domperidone-containing medicines - CMDh Position (restrictions in use due to risk of effects on the heart; no longer authorised for the treatment of bloating or heartburn)
  Treatment of nausea and vomiting

Gynaecology & Obstetrics

Arbitration procedures

- Tibolona Aristo and Tibocina and associated names (*tibolone*) - outcome
  Used to alleviate symptoms of menopause

Safety communication update

- Review of linoladiol N and linoladiol HN (*estradiol*) - CHMP outcome following re-examination (further changes in use to manage potential risk of side effects)
  Topical treatment of conditions of the genital area in women after menopause

Hormone system

Safety communication update

- Review of renin-angiotensin-system (RAS)-acting agents - PRAC recommendation (combined use of these medicines is not recommended due to increased risk of side effects on the heart, circulation and kidneys, especially in patients with kidney impairment or diabetes)
  Treatment of high blood pressure and congestive heart failure
- Review of testosterone-containing medicines - review started (concerns on potential side effects on the heart)
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Immune system

Safety communication update

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Metabolic system

New medicines authorised

- Cholic Acid FGK (cholic acid)
  Treatment of inborn errors in primary bile acid synthesis

Nervous system

New medicines authorised

- Latuda (*lurasidone*)
  Treatment of schizophrenia
- Rivastigmine 3M Health Care Ltd (*rivastigmine*)
  Treatment of Alzheimer's disease

New information on authorised medicines

- Invega (*paliperidone*) - new indication
  Treatment of schizophrenia in adolescents 15 years and older, in addition to schizophrenia in adults and psychotic or manic symptoms of schizoaffective disorder in adults

- Gilenya (*fingolimod*) - change in indication
  Treatment of multiple sclerosis

Supply shortages

- Buccolam (*midazolam*)
  Treatment of convulsive seizures

Safety communication update

- Review of zolpidem-containing medicines - CMDh Position (endorses new advice to minimise risk of accidents when driving due to reduced alertness)
  Treatment of insomnia

Respiratory system

Safety communication update

- Review of codeine containing medicinal products - review started (risk of morphine toxicity)
  Treatment of cough and cold in children
- Review of ambroxol and bromhexine-containing medicines - review started (concerns related to number of allergic reactions)
  Expectorants (to clear the airways), relieve sore throat and treatment of breathing disorders in premature and newborn babies

Rheumatology

New medicines authorised

- Zoledronic acid Teva Generics (*zoledronic acid*)
  Treatment of osteoporosis and Paget's disease

New information on authorised medicines

- Prolia (*denosumab*) - change in indication
  Treatment of osteoporosis in postmenopausal women, **and in men** at increased risk of fractures

Withdrawal of applications for new medicines

- Ditelos and Issarlos (*strontium ranelate / colecalciferol*)
  Intended for the treatment of osteoporosis

Safety communication update

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Vaccines

New information on authorised medicines

- Gardasil (human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)) - new indication
  Prevention of oncogenic human-papillomavirus (HPV) types

- Silgard (human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)) - new indication
  Prevention of oncogenic human-papillomavirus (HPV) types

Other medicines

Safety communication update

- Review of oral methadone medicines containing providone - review started (reports of kidney failure which may be linked to the misuse of oral solutions)
  Used in rehabilitation programs in patients dependent on opioids
- Review of adrenaline (epinephrine) auto-injectors - review started (due to concerns over the delivery of adrenaline from auto-injectors/detailed instructions for appropriate use)
  Treatment of anaphylaxis (severe allergic reactions)
- Review of Caustinerf arsenical and Yranicid arsenical (*ephedrine hydrochloride, lidocaine and arsenous anhydride*) - CHMP Opinion (recommendation to revoke authorisations due to concerns over the risk of genotoxic effects (damage to the genetic material in cells) and cell death in tissues around the teeth)
  Used in dental pastes

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft European Union individual case safety report (ICSR) implementation guide
  Deadline for comments: 30 June 2014
- Draft concept paper on the establishment of a guideline on the selection of sterilisation processes for drug products
  Deadline for comments: 09 July 2014
- Reflection paper on anthelmintic resistance
  Deadline for comments: 31 July 2014
- Guideline on the role of the pathological Complete Response as an endpoint in neoadjuvant breast cancer studies
  Deadline for comments: 31 July 2014
- Draft guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues
  Deadline for comments: 31 July 2014
- Draft guideline on non-clinical local tolerance testing of medicinal products
  Deadline for comments: 31 July 2014

- Draft guideline on process validation for the manufacture of biotechnology-derived active substances and data to be provided in the regulatory submission
  Deadline for comments: 31 October 2014

Adopted guidelines

- Guideline on stability testing for applications for variations to a marketing authorisation
- Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU

Scientific committee and working party activities

- Medicinal products for human use: monthly figures: March 2014
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: April 2014
- CAT - agendas, minutes and meeting reports
- COMP - agendas, minutes and meeting reports
- HMPC - agendas, minutes and meeting reports
- PDCO - agendas, minutes and meeting reports
- PRAC - agendas, minutes and highlights
- PRAC recommendations on safety signals
- CHMP Blood Products Working Party work programme 2014
- PCWP/HCPWP joint meeting: meeting documents and Workshop on regulatory and methodological standards to improve benefit/risk evaluation of medicines: meeting documents

Other publications

- EMA publishes 2013 annual report
- EMA announces final steps for its clinical-trial data policy
- EMA and EU national competent authorities agree on action plan to address medication errors
- EMA introduces new fee incentives for SMEs for post-authorisation activities
- EMA and Australian regulator strengthen collaboration in the area of orphan medicines
- Specifications for additional efficacy studies for medicines published in the Official Journal of the EU
- World Health Day 2014: focus on diseases transmitted by vectors
- Second periodic safety update report information day
- Pharmacovigilance in the paediatric population workshop
- EMA workshop on the clinical investigation of medicines for the treatment of Alzheimer's disease - November 2014
- 2013 annual report on EudraVigilance: over 1 million adverse reaction reports received and processed

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.

Visit our website

Further information about the European Medicines Agency and the work it does is available on our website:

http://www.ema.europa.eu

In particular, you may be interested in these links:

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