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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 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

- Exviera (*dasabuvir*)
  Treatment of hepatitis C
- Viekirax (*ombitasvir / paritaprevir / ritonavir*)
  Treatment of hepatitis C

Cancer

New medicines authorised

- Imbruvica (*ibrutinib*) O
  Treatment of mantle cell lymphoma (a blood cancer)

Key to symbols used

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

Withdrawal of applications for new medicines

- Egranli (*balugrastim*)
  Intended for the treatment of chemotherapy-induced neutropenia (low level of white blood cells) and febrile neutropenia

Withdrawal of authorised medicines

- Topotecan Eagle (*topotecan*)
  Used for the treatment of small cell lung cancer and cancer of the cervix

Cardiovascular system

Positive CHMP opinions on new medicines

- Zontivity (*vorapaxar*)
  Prevention of problems caused by blood clots, such as heart attacks

Safety communication update

- Review of Corlentor/Procoralan (*ivabradine*) - CHMP Opinion (recommends measures to reduce risk of heart problems)
  Treatment of angina (chest pain) and heart failure
- Review of testosterone-containing medicines - CMDh Position (no consistent evidence of an increased risk of heart problems)
  Treatment of hypogonadism (reduced testosterone production in men)

Diabetes

New medicines authorised

- Xultophy (*insulin degludec / liraglutide*)
  Treatment of type 2 diabetes mellitus

Gynaecology & Obstetrics

Positive CHMP opinions on new medicines

- Senshio (*ospemifene*)
  Treatment of vulvar and vaginal atrophy

Other information

- ellaOne (*ulipristal acetate*) - availability without prescription
  Prevention of unintended pregnancy following unprotected sexual intercourse or contraceptive failure

Safety communication update

- Review of valproate and related substances - CMDh Position (strengthening of warnings on use in women and girls)
  Treatment of epilepsy and bipolar disorder and prevention of migraine

Haematology

Withdrawal of applications for new medicines

- Egranli (*balugrastim*)
  Intended for the treatment of chemotherapy-induced neutropenia (low level of white blood cells) and febrile neutropenia

Withdrawal of authorised medicines - extension of indication

- Ceprotin (*human protein C*)
  Intended for the treatment of acquired protein c deficiency

Hormone system

Safety communication update

- Review of testosterone-containing medicines - CMDh Position (no consistent evidence of an increased risk of heart problems)
  Treatment of hypogonadism (reduced testosterone production in men)

Immune system

Positive CHMP opinions on new medicines

- Cosentyx (*secukinumab*)
  Treatment of psoriasis
- Otezla (*apremilast*)
  Treatment of psoriasis and psoriatic arthritis

Arbitration procedures

- Nasonex (*mometasone furoate*) - outcome
  Treatment of rhinitis and nasal polyps

Metabolic system

Positive CHMP opinions on new medicines

- Cerdelga (*eliglustat*) O
  Treatment of Gaucher disease

Musculoskeletal system

New information on authorised medicines

- Inductos (*dibotermin alfa*) - change in indication
  Treatment of spine fusion

Nephrology

Positive CHMP opinions on new medicines

- Sevelamer carbonate Zentiva (*sevelamer*)
  Used to reduce phosphate levels in patients with kidney disease

Nervous system

Positive CHMP opinions on new medicines

- Rasagiline ratiopharm (*rasagiline*)
  Treatment of Parkinson's disease

Safety communication update

- Review of valproate and related substances - CMDh Position (strengthening of warnings on use in women and girls)
  Treatment of epilepsy and bipolar disorder and prevention of migraine

Ophthalmology

New information on authorised medicines

- Travatan (*travoprost*) - new indication
  Treatment of elevated intraocular pressure in children

Respiratory system

Positive CHMP opinions on new medicines

- Ofev (*nintedanib*)
  Treatment of pulmonary fibrosis (scarring of the lungs)
- Nasonex (*mometasone furoate*) - outcome
  Treatment of rhinitis and nasal polyps

Rheumatology

Positive CHMP opinions on new medicines

- Otezla (*apremilast*)
  Treatment of psoriasis and psoriatic arthritis

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on revision of the addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections to specifically address the clinical development of new agents to treat disease due to mycobacterium tuberculosis
  Deadline for comments: 28 February 2015

Adopted guidelines

- Questions and answers: Positions on specific questions addressed to the pharmacokinetics working party
- Guideline on the use of phthalates as excipients in human medicinal products
- Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities
- Guideline on the pharmacokinetic and clinical evaluation of modified-release dosage forms

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - October 2014
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines under evaluation by the CHMP: November 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

Other publications

- EMA policy on the handling of declarations of interests of scientific committees' members and experts
- EMA releases practical guidance on access-to-documents requests
- European Antibiotic Awareness Day 2014
- New antiretrovirals improve quality of life of HIV/AIDS patients
- Investigation into reports of serious adverse events following use of Fluad

- Training overview for patients and consumers involved in EMA activities
- EC-EMA-China Food and Drugs Administration bilateral and International Summit of Heads of Medicines Regulatory Agencies
- EMA workshop on the investigation of subgroups in confirmatory clinical trials - Nov 2014
- Training session for patients and consumers involved in EMA activities - Nov 2014
- PCWP meeting with all eligible organisations - Nov 2014
- Workshop on the 'guideline on pharmaceutical development of medicines for paediatric use' - Dec 2014
- EMA/EFPIA workshop on the importance of dose finding and dose selection for the successful development, licensing and lifecycle management of medicinal products - Dec 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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