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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
Published monthly by the European Medicines Agency

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

- Vemlidy (*tenofovir alafenamide*)
  Treatment of chronic hepatitis B
- Zinplava (*bezlotoxumab*)
  Prevention of infection with *Clostridium difficile* bacteria

Cancer

New medicines authorised

- Ibrance (*palbociclib*)
  Treatment of breast cancer
- Lartruvo (*olaratumab*) O C
  Treatment of adults with advanced soft tissue sarcoma

Key to symbols used

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

- Kisplyx (*lenvatinib*)
  Treatment of renal cell carcinoma (kidney cancer)

New information on authorised medicines

- Arzerra (*ofatumumab*) - change in indication
  Treatment of lymphocytic leukaemia (blood cancer)
- Caprelsa (*vandetanib*) - change in indication
  Treatment of medullary thyroid cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- Tadalafil Generics (*tadalafil*)
  Treatment of pulmonary arterial hypertension

Dermatology

New information on authorised medicines

- Humira (*adalimumab*) - change in indication
  Treatment of hidradenitis suppurativa (acne inversa)

Diabetes

Positive CHMP opinions on new medicines

- Fiasp (*insulin aspart*)
  Treatment of diabetes mellitus
- Lusduna (*insulin glargine*)
  Treatment of diabetes mellitus
- Suliqua (*insulin glargine / lixisenatide*)
  Treatment of diabetes mellitus

New medicines authorised

- Glyxambi (*empagliflozin / linagliptin*)
  Treatment of diabetes mellitus

Supply shortages

- Insuman Basal and Comb 25 (*insulin human*) - shortage resolved
  Treatment of diabetes mellitus

Haematology

Positive CHMP opinions on new medicines

- Afstyla (*lonoctocog alfa*)
  Prevention and treatment of bleeding in patients with haemophilia A

New information on authorised medicines

- Arzerra (*ofatumumab*) - change in indication
  Treatment of lymphocytic leukaemia (blood cancer)

HIV

Positive CHMP opinions on new medicines

- Darunavir Mylan (*darunavir*)
  Treatment of HIV infection

New medicines authorised

- Emtricitabine/Tenofovir disoproxil Zentiva (*emtricitabine / tenofovir disoproxil*)
  Treatment of HIV infection

Hormone system

New medicines authorised

- Parsabiv (*etelcalcetide*)
  Treatment of hyperparathyroidism in patients with chronic kidney disease on haemodialysis therapy

Immune system

New information on authorised medicines

- Ruconest (*conestat alfa*) - new pharmaceutical form
  Treatment of hereditary angioedema (swelling beneath the skin)

Nephrology

New medicines authorised

- Kisplyx (*lenvatinib*)
  Treatment of renal cell carcinoma (kidney cancer)
- Parsabiv (*etelcalcetide*)
  Treatment of hyperparathyroidism in patients with chronic kidney disease on haemodialysis therapy

Nervous system

New information on authorised medicines

- Vimpat (*lacosamide*) - change in indication
  Treatment of partial-onset seizures in patients with epilepsy

Rheumatology

Positive CHMP opinions on new medicines

- Movymia (*teriparatide*)
  Treatment of osteoporosis
- Terrosa (*teriparatide*)
  Treatment of osteoporosis

Vaccines

New information on authorised medicines

- Nimenrix (*meningococcal group A, C, W 135 and Y conjugate vaccine*) - change in indication
  Active immunisation against invasive meningococcal diseases caused by Neisseria meningitidis group A, C, W-135, and Y

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products
  Deadline for comments: 28 February 2017
- Concept paper on the need for revision of the guideline on clinical investigation of medicinal products in the treatment of depression
  Deadline for comments: 28 February 2017
- Draft reflection paper providing an overview of the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs
  Deadline for comments: 31 May 2017

Adopted guidelines

- Guideline on clinical investigation of medicinal products for prevention of venous thromboembolism (VTE) in non-surgical patients
- Guideline on non-clinical and clinical development of similar biological medicinal products containing low-molecular-weight-heparins
- Guideline on the chemistry of active substances
- Paediatric addendum on the CHMP guideline on clinical investigation of medicinal products for the treatment of acute heart failure

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - October 2016
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines under evaluation: November 2016
- 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
- 10 years of the Patients' and Consumers' Working Party
- PCWP and HCPWP joint meeting: Workshop on social media - 19 Sep 2016 - meeting documents

Other publications

- European Commission launches a public consultation on the Paediatric Regulation
- Minutes of the 93rd meeting of the Management Board
- How to facilitate development of cancer treatment based on genetically modified T-cells
- Modelling and simulation in the development of medicines
- Clinical data for two more medicines now available online
- Development challenges for medicines for central nervous system disorders
- How big data can be used for the development and regulation of medicines
- Active pharmaceutical ingredients: Japan joins international collaboration on GMP inspections
- Marisa Delbò elected as new chair of herbal medicines committee

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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