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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.

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Information on medicines

Cancer

New medicines authorised

- Carmustine Obvius (*carmustine*) generic of Carmubris
  Treatment of brain tumours, Hodgkin's lymphoma and non-Hodgkin's lymphomas

Cardiovascular system

Safety communication update

- Review of valsartan containing medicinal products - updates provided
  Treatment of high blood pressure, recent heart attack and heart failure
  - 2 August 2018 Preliminary assessment of possible risk to patients
  - 10 August 2018 EMA reviewing valsartan produced by another company Zhejiang Tianyu
  - 20 August 2018 Update on medicines containing valsartan from Zhejiang Tianyu

Key to symbols used

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

Dermatology

New medicines authorised

- Hyrimoz / Halimatoz / Hefiya (*adalimumab*) biosimilars of Humira
  Treatment of various inflammatory and autoimmune disorders

Diabetes

Communication on prevention of medication errors

- Amglidia (*glibenclamide)*
  Treatment of neonatal diabetes

Gastro-intestinal system

New medicines authorised

- Hyrimoz / Halimatoz / Hefiya (*adalimumab*) biosimilars of Humira
  Treatment of various inflammatory and autoimmune disorders

Gynaecology & Obstetrics

Safety communication update

- Review of Esmya (*ulipristal acetate*) - EC decision (new measures to minimise risk of rare but serious liver injury)
  Treatment of uterine fibroids (non-cancerous tumours of the womb)

Haematology

New medicines authorised

- Carmustine Obvius (*carmustine*) generic of Carmubris
  Treatment of brain tumours, Hodgkin's lymphoma and non-Hodgkin's lymphomas

Immune system

New medicines authorised

- Hyrimoz / Halimatoz / Hefiya (*adalimumab*) biosimilars of Humira
  Treatment of various inflammatory and autoimmune disorders

Supply shortages

- Cinryze (*C1 inhibitor (human)*) - shortage ongoing
  Treatment of hereditary angioedema (swelling beneath the skin)

Metabolic disorders

New medicines authorised

- Duzallo (*allopurinol / lesinurad*)
  Treatment of gout (build-up of uric acid in the joints, causing pain and swelling)
- Mepsevii (*vestronidase alfa*) O
  Treatment of mucopolysaccharidosis type VII (lysosomal storage disease)
- Myalepta (metreleptin) O
  Treatment of lipodystrophy (loss of fatty tissue under the skin and accumulation in liver and muscles)
- Nityr (*nitisinone*)
  Treatment of hereditary tyrosinamia type 1 (inability to breakdown an amino acid)
- Tegsedi (*inotersen*) O
  Treatment of hereditary transthyretin amyloidosis (abnormal build-up of proteins, particularly around nerves)

Communication on prevention of medication errors

- Myalepta (*metreleptin*) O
  Treatment of lipodystrophy (loss of fatty tissue under the skin and accumulation in liver and muscles)

Nervous system

New medicines authorised

- Aimovig (*erenumab*)
  Prevention of migraine
- Tegsedi (*inotersen*) O
  Treatment of transthyretin amyloidosis (abnormal build up of proteins, particularly around nerves)

Ophthalmology

New medicines authorised

- Hyrimoz / Halimatoz / Hefiya (*adalimumab*) biosimilars of Humira
  Treatment of various inflammatory and autoimmune disorders

Rheumatology

New medicines authorised

- Duzallo (*allopurinol / lesinurad*)
  Treatment of gout (build-up of uric acid in the joints, causing pain and swelling)
- Hyrimoz / Halimatoz / Hefiya (*adalimumab*) biosimilars of Humira
  Treatment of various inflammatory and autoimmune disorders

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on the use of minimal residual disease as a clinical endpoint in multiple myeloma studies
  Deadline for comments: 31 October 2018
- Draft guideline on biosimilar medicinal products containing recombinant granulocyte-colony stimulating factor (Annex to guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues)
  Deadline for comments: 15 February 2019
- Draft guideline on similar biological medicinal products containing recombinant granulocyte-colony stimulating factor (rG-CSF)
  Deadline for comments: 15 February 2019
- Draft guideline on clinical investigation of medicinal products in the treatment of epileptic disorders
  Deadline for comments: 17 February 2019

Adopted guidelines

- Agomelatine tablet 25 mg product-specific bioequivalence guidance
- Cholic acid product-specific bioequivalence guidance
- Guideline on clinical investigation of recombinant and human plasma-derived factor VIII products
- Guideline on core summary for product characteristics for human albumin solution
- Guideline on core summary of product characteristics for human plasma-derived and recombinant coagulation factor VIII products
- Ledipasvir/sofosbuvir product-specific bioequivalence guidance
- Posaconazole gastro-resistant tablet 100 mg product-specific bioequivalence guidance
- Vismodegib product-specific bioequivalence guidance

Other scientific recommendations

Classification of advanced therapy medicinal products (ATMPs)

- Autologous CD34+ cells transduced with a lentiviral vector containing the FANCA gene
- Cultured human olfactory ensheathing cells and olfactory nerve fibroblasts

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - July 2018
- CHMP - agendas, minutes and highlights

- CHMP - applications for new human medicines: August 2018
- 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
- Annual report of the Good Manufacturing and Distribution Practice Inspectors Working Group 2017

Other publications

- 100th meeting of the Management Board - minutes
- EU regulatory network reflection paper on the availability of authorised medicinal products for human and veterinary use
- Work programme of the HMA/EMA task force on availability of authorised medicines for human and veterinary use
- Brexit preparedness: EMA to further temporarily scale back and suspend activities
- Updated EMA tracking tool: relocation to Amsterdam - Main milestones
- EMA: working for every patient in Europe - video
- How are new medicines approved by EMA? - video
- Keeping medicines safe - video
- Fostering medicines for children - factsheet
- Development of medicines for rare diseases - factsheet
- EMA's interaction with industry stakeholders annual report 2017
- Scientific publication - Indications for Systemic Fluoroquinolone Therapy in Europe and Prevalence of Primary-Care Prescribing in France, Germany and the UK: Descriptive Population-Based Study
- Scientific publication - Latest clinical recommendations on valproate use for migraine prophylaxis in women of childbearing age: overview from European Medicines Agency and European Headache Federation

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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