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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 an e-mail alert when each new issue of the newsletter is published, send a request to: HMHnewsletter@ema.europa.eu

Information on medicines

Antivirals/anti-infectives

New medicines authorised

- Sovaldi (*sofosbuvir*)
  Treatment of chronic hepatitis C

Other information

- Ledipasvir/sofosbuvir (combination therapy) - compassionate use
  Treatment of chronic hepatitis C

Cancer

New medicines authorised

- Zoledronic Acid Accord (*zoledronic acid*)
  Prevention of bone complications and treatment of hypercalcaemia caused by tumours

Key to symbols used

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

Negative CHMP opinions on new medicines

- Masiviera (*masitinib*)
  Intended for the treatment of pancreatic cancer

Cardiovascular system

New medicines authorised

- Opsumit (*macitentan*)
  Treatment of pulmonary arterial hypertension

Negative CHMP opinions on new medicines

- Reasanz (*serelaxin*)
  Intended for the treatment of acute heart failure

Safety communication update

- Review of Protelos/Osseor (*strontium ranelate*) - CHMP Opinion (further restrictions in use due to risk of heart problems)
  Treatment of osteoporosis

Diabetes

Positive CHMP opinions on new medicines

- Vokanamet (*canagliflozin/metformin*)
  Treatment of diabetes mellitus

HIV

New medicines authorised

- Tivicay (*dolutegravir*)
  Treatment of human immunodeficiency virus (HIV-1)

Immune system

Withdrawal of applications for extension of indication

- Firazyr (*icatibant*)
  Intended for the treatment of angioedema (swelling under the skin)

Supply shortages

- Enbrel (*etanercept*) - risk of supply disruptions
  Treatment of arthritis and psoriasis

Metabolic system

Positive CHMP opinions on new medicines

- Vimizim (*elosulfase alfa*)
  Treatment of mucopolysaccharidosis (lysosomal storage disease)

Musculoskeletal system

New medicines authorised

- Zoledronic Acid Accord (*zoledronic acid*)
  Prevention of bone complications and treatment of hypercalcaemia caused by tumours

Nervous system

Positive CHMP opinions on new medicines

- Pregabalin Pfizer (*pregabalin*)
  Treatment of epilepsy, neuropathic pain and generalised anxiety disorder

New medicines authorised

- Tecfidera (*dimethyl fumarate*)
  Treatment of multiple sclerosis

Safety communication update

- Review of methysergide-containing medicines - CHMP opinion (restrictions in use due to concerns they could cause fibrosis)
  Prevention of migraines and cluster headaches

Respiratory system

Positive CHMP opinions on new medicines

- DuoResp Spiromax and BiResp Spiromax (*budesonide / formoterol*)
  Treatment of asthma and chronic obstructive pulmonary disease
- Incruse (*umeclidinium bromide)*
  Treatment of chronic obstructive pulmonary disease
- Anoro and Laventair (*umeclidinium bromide / vilanterol*)
  Treatment of chronic obstructive pulmonary disease
- Ulunar Breezhaler (*indacaterol / glycopyrronium bromide*)
  Treatment of chronic obstructive pulmonary disease

Rheumatology

Safety communication update

- Review of Protelos/Osseor (*strontium ranelate*) - CHMP Opinion (further restrictions in use due to risk of heart problems)
  Treatment of osteoporosis

Vaccines

Withdrawal of applications for new medicines

- Heplisav (*hepatitis b surface antigen)*
  Intended for the prevention of hepatitis B infection

Other medicines

Positive CHMP opinions on new medicines

- Hemangiol (*propranolol*)
  Treatment of infantile haemangioma (strawberry mark)

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Lessons learned from the review of the labelling of centrally authorised pandemic vaccines
  Deadline for comments: 20 May 2014
- Questions and answers on benzoic acid and benzoates in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'
  Deadline for comments: 31 May 2014
- Questions and answers on benzyl alcohol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'
  Deadline for comments: 31 May 2014
- Questions and answers on ethanol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'
  Deadline for comments: 31 May 2014

- Draft concept paper on revision of the points to consider on pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products and conversion to a CHMP guideline
  Deadline for comments: 31 May 2014
- Concept paper on review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products
  Deadline for comments: 31 May 2014
- Draft reflection paper on microbiological aspects of herbal medicinal products and traditional herbal medicinal products
  Deadline for comments: 15 June 2014
- Draft guideline on the investigation of subgroups in confirmatory clinical trials
  Deadline for comments: 31 July 2014
- Concept paper on the need for a single note for guidance on the chemistry of active substances
  Deadline for comments: 10 August 2014
- Draft guideline on the evaluation of medicinal products for the treatment of chronic constipation
  Deadline for comments: 31 August 2014
- Draft guideline on the evaluation of the pharmacokinetics of medicinal products in patients with decreased renal function
  Deadline for comments: 31 August 2014

Adopted guidelines

- Guideline on good pharmacovigilance practices: Module XVI– Risk minimisation measures - Selection of tools and effectiveness indicators
- Guideline on process validation for finished products - information and data to be provided in regulatory submissions
- Guideline on the use of porcine trypsin used in the manufacture of human biological medicinal products

Scientific committee and working party activities

- Medicinal products for human use: Monthly figures - January 2014
- CHMP - agendas, minutes and highlights
- CHMP - Applications for new human medicines: February 2014
- CAT - agendas, minutes and reports
- CAT – election of new chair, overview of 2013 and looking ahead
- CAT - Advanced therapy medicinal products - Key figures in 2013
- COMP - agendas, minutes and meetings reports
- COMP – overview of 2013 and looking ahead
- HMPC - agendas, minutes and meetings reports
- PDCO - agendas, minutes and meeting reports
- PRAC - agendas, minutes and highlights

- PRAC recommendations on signals adopted at the PRAC meeting of 3-6 February 2014
- Work plan for the Good Manufacturing Practice / Good Distribution Practice Inspectors Working Group 2014
- Work plan for the Pharmacokinetics Working Party 2014
- Work plan for the Good Clinical Practice Inspectors Working Group 2014
- Work plan for the Pharmacogenomics Working Party 2014
- Work plan for the Rheumatology-Immunology Working Party 2014
- Work plan for the Gastroenterology Drafting Group 2014
- Work plan for the Joint CHMP / CVMP Quality Working Party 2014
- Work plan for the EMA Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) 2014
- Work plan for the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) 2014
- PCWP meeting with all eligible organisations

Other publications

- EMA and FDA strengthen collaboration in pharmacovigilance area
- EMA updates guidance for annual strain change of seasonal influenza vaccines
- Rare Disease Day 2014 – twelve new orphan medicines available to patients over the past year
- Joint EMA/Parenteral Drug Association quality-by-design workshop
- Training session for patients and consumers involved in EMA activities
- Minutes of the EMA and EUnetHTA meeting
- Joint EMA, FDA, MHLW and PMDA orphan medicinal product workshop - March 2014
- SME workshop: Focus on quality for medicines containing chemical entities - April 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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http://www.ema.europa.eu

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