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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

- Sofosbuvir - compassionate use
  Treatment of hepatitis C virus infection

Cancer

New medicines authorised

- Provenge (*autologous peripheral blood mononuclear cells activated with PAP-GM-CSF*)
  Treatment of prostate cancer
- Giotrif (*afatinib*)
  Treatment of non-small-cell lung cancer

Negative CHMP opinions on extension of use

- Xgeva (*denosumab*)
  Prevention of bone complications in adults with a solid tumour that has spread to the bone

Key to symbols used

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

Cardiovascular system

Positive CHMP opinions on new medicines

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

Arbitration procedures

- Intravenous nicardipine medicines
  Treatment of high blood pressure

Diabetes

New medicines authorised

- Incresync (*alogliptin and pioglitazone*)
  Treatment of type 2 diabetes
- Vipdomet (*alogliptin and metformin*)
  Treatment of type 2 diabetes

Safety communication update

- NovoMix 30 FlexPen and Penfill (*insulin aspart*) - batches to be recalled
  Treatment of diabetes

Gynaecology & Obstetrics

New medicines authorised

- Ovaleap (*follitropin alfa*)
  Treatment of infertility

Safety communication update

- Review of short-acting beta-agonists in obstetric indications - CMDh
  Risk of cardiovascular side effects
- Review of combined hormonal contraceptives (*desogestrel, gestodene, norgestimate, etonogestrel, drospirenone, dienogest, chlormadinone, nomegestrol, norelgestromin)* - PRAC recommendation
  Risk of venous thromboembolism (VTE or blood clots in veins)

HIV

New medicines authorised

- Tybost (*cobicistat*)
  Treatment of HIV-1 infection

New information on authorised medicines

- Eviplera (*Emtricitabine / rilpivirine / tenofovir disoproxil*) - change in indication
  Treatment of HIV-1 infection

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Haematology

New medicines authorised

- Voncento (*coagulation factor VIII and human von Willebrand factor*)
  Treatment and prevention of bleeding
- Evarrest (*fibrinogen and thrombin*)
  Prevention of bleeding during surgery

Immune system

New medicines authorised

- Remsima (*infliximab*)
  Treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis

Metabolic system

New medicines authorised

- Orphacol (*cholic acid*)
  Treatment of defects in bile acid production
- Procysbi (*mercaptamine*)
  Treatment of nephropathic (kidney) cystinosis

Nervous system

Positive CHMP opinions on new medicines

- Brintellix (*vortioxetine*)
  Treatment of major depressive episodes
- Levetiracetam Hospira (*levetiracetam*)
  Treatment of epilepsy

Safety communication update

- Review of valproate and related substances - review started
  Risk of birth defects and developmental problems

Respiratory system

New medicines authorised

- Ultibro Breezhaler and Xoterna Breezhaler (*indacaterol and glycopyrronium bromide*)
  Treatment of symptoms of chronic obstructive pulmonary disease (COPD)

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Rheumatology

New information on authorised medicines

- Cimzia (*certolizumab pegol*) - new indication
  Treatment of active psoriatic arthritis

Vaccines

New information on authorised medicines

- Vepacel- new indication to include children and adolescents from 6 months onwards
  Active immunisation against H5N1 subtype of influenza A virus
- Pandemic Influenza Vaccine H5N1 Baxter - new indication to include children and adolescents from 6 months onwards
  Prevention of influenza in an officially declared pandemic situation
- Synflorix- new indication to include children and adolescents 6 weeks up to 5 years of age
  Immunisation against invasive disease, pneumonia and acute otitis media

Other medicines

Safety communication update

- Review of hydroxyethyl-starch solutions - PRAC recommendation and CMDh endorsement
  Increased risk of kidney injury and mortality

Medicines under additional monitoring

- Updated list of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft reflection paper on the data requirements for intravenous iron-based nanocolloidal products developed with reference to an innovator medicine
  Deadline for comments: 28 February 2014
- Concept paper on the development of a guideline on the demonstration of therapeutic equivalence for locally applied and locally acting products in the gastrointestinal tract
  Deadline for comments: 31 December 2013
- Concept paper on the revision of a guideline on the format and content of applications for paediatric investigation plans
  Deadline for comments: 3 January 2014

- Draft concept paper on need for revision of the guideline on medicinal products for the treatment of Alzheimer's disease and other dementias
  Deadline for comments: 31 January 2014
- Draft guideline on the clinical development of medicinal products for the treatment of HIV-1 infection (revision 3)
  Deadline for comments: 31 March 2014

Adopted guidelines

Scientific committee and working party activities

- CAT monthly report - October meeting
- CHMP meeting highlights - October meeting
- CHMP - start of community reviews - October meeting
- CHMP - applications for new medicines under evaluation - October meeting
- Scientific advice and protocol assistance adopted during the CHMP - October meeting
- COMP minutes - July meeting
- COMP meeting report - October meeting
- COMP agenda - November meeting
- PDCO monthly report - October meeting
- PDCO minutes - September meeting
- PRAC recommendations on signals adopted at the September meeting
- PRAC highlights - October meeting
- PRAC minutes - September meeting
- HMPC report - September meeting
- Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) joint meeting - Workshop on the patient's voice in the evaluation of medicines
- CHMP/Biologics Working Party report on pancreatin-containing products

Other publications

- Agenda of the 81st meeting of the Management Board
- EMA's Management Board supports plan to publish agendas and minutes of all committees
- Publication and access to clinical-trial data: an inclusive development process
- EMA publishes a video explaining the concept of medicines under additional monitoring
- EMA publishes report on conflicts of interests workshop
- EMA explores ways to further involve patients in the benefit-risk assessment of medicines
- EMA begins to publish recommendations based on safety signals

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- News bulletin for small and medium-sized enterprises - Issue 25
- Seventh stakeholders' forum on the implementation of the new pharmacovigilance legislation
- EU and Japan improve information-sharing in the area of good manufacturing practice using EudraGMDP database
- Workshop on clinical investigation of new medicines for the treatment of multiple sclerosis
- Agenda - EMA / health-technology-assessment-body workshop on parallel scientific advice in drug development
- EMA launches a new version of EudraCT
- EMA and social media
- Medicines for older people
- How access to full clinical-trial data sets will benefit medicines developers
- Workshop on methods for efficacy studies in everyday medical practice

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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7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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