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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.

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Information on medicines

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Voriconazole Hospira (*voriconazole*)
  Treatment of fungal infections

New medicines authorised

- Sivextro (*tedizolid phosphate*)
  Treatment of acute bacterial skin infections
- Vantobra (*tobramycin*)
  Treatment of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients with cystic fibrosis
- Viekirax (*ombitasvir / paritaprevir / ritonavir*)
  Treatment of hepatitis C
- Xydalba (*dalbavancin*)
  Treatment of acute bacterial skin infections

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Akynzeo *(netupitant / palonosetron)*
  Prevention of nausea and vomiting associated with chemotherapy
- Lenvima (*lenvatinib*)
  Treatment of thyroid carcinoma

Cardiovascular system

New medicines authorised

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

Arbitration procedures

- Ikorel and Dancor (*nicorandil*) - outcome
  Treatment of angina (chest pain)

Safety communication update

- Review of hydroxyzine-containing medicines - CMDh Position (new measures to minimise known heart risks)
  Various uses including relief of anxiety disorders, relief of pruritus (itching), premedication before surgery, and treatment of sleep disorders

Dermatology

New medicines authorised

- Sivextro (*tedizolid phosphate*)
  Treatment of acute bacterial skin infections
- Xydalba (*dalbavancin*)
  Treatment of acute bacterial skin infections

Safety communication update

- Review of hydroxyzine-containing medicines - CMDh Position (new measures to minimise known heart risks)
  Various uses including relief of anxiety disorders, relief of pruritus (itching), premedication before surgery, and treatment of sleep disorders

Diabetes

Positive CHMP opinions on new medicines

- Synjardy (*empagliflozin / metformin)*
  Treatment of type 2 diabetes mellitus

Supply shortages

- Insuman Rapid, Basal and Comb *(insulin human)*
  Treatment of diabetes type 1 and 2

Hormone system

Withdrawal of applications for new medicines

- Ketoconazole AID-SCFM (*ketoconazole*)
  Intended for the treatment of Cushing's syndrome

Immune system

New medicines authorised

- Cosentyx (*secukinumab*)
  Treatment of psoriasis

Nephrology

New medicines authorised

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

Nervous system

New medicines authorised

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

Safety communication update

- Review of hydroxyzine-containing medicines - CMDh Position (new measures to minimise known heart risks)
  Various uses including relief of anxiety disorders, relief of pruritus (itching), premedication before surgery, and treatment of sleep disorders

Ophthalmology

New medicines authorised

- Holoclar (*ex vivo expanded autologous human corneal epithelial cells containing stem cells*)
  Replacement of damaged cells caused by burns to the eye

Respiratory system

New medicines authorised

- Vantobra (*tobramycin*)
  Treatment of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients with cystic fibrosis

Safety communication update

- Review of codeine-containing medicines - PRAC recommendation (restrictions on its use because of the risk of serious side effects)
  Treatment of cough and cold in children

Rheumatology

Safety communication update

- Periodic review of aclasta (*zoledronic acid*) - CHMP Opinion (further measures to minimise risk of osteonecrosis of the jaw)
  Treatment of osteoporosis and Paget's disease

Vaccines

Positive CHMP opinions on new medicines

- Gardasil 9 (*human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed)*)
  Prevention of human papillomavirus (HPV) diseases

New information on authorised medicines

- Tamiflu (*oseltamivir*) - change in indication
  Treatment and prevention of influenza
- **Other information**
  EU recommendations for 2015/2016 seasonal flu vaccine composition

Other medicines

Arbitration procedures

- Iogol and associated names (*diclofenac epolamine*) - start
  Treatment of pain and inflammation

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Key to symbols used

Orphan medicine | Generic medicine | Biosimilar medicine | Conditional approval | Exceptional circumstances

Other information

Guidelines

Guidelines open for consultation

- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) on electronic common technical document v4.0 draft ICH implementation guide v2.0 - Step 2
  Deadline for comments: 22 May 2015
- Draft guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances
  Deadline for comments: 31 May 2015
- Draft concept paper on the need for revision of the guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials
  Deadline for comments: 30 June 2015
- Questions and answers on 'Guideline on the environmental risk assessment of medicinal products for human use'
  Deadline for comments: 30 June 2015

Adopted guidelines

- Guideline on core SmPC and package leaflet for (99Mo/99mTc) generator
- Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues
- Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration
- Paediatric addendum to the note for guidance on the clinical investigation on medicinal products in the treatment of hypertension
- Guideline on clinical investigation of medicinal products for the treatment of systemic lupus erythematosus and lupus nephritis
- Questions and answers: Positions on specific questions addressed to the Pharmacokinetics Working Party
- Final reflection paper on the data requirements for intravenous iron-based nano-colloidal products developed with reference to an innovator medicinal product
- Final guideline on adjustment for baseline covariates in clinical trials
- Guideline on clinical investigation of medicinal products for the treatment of multiple sclerosis

Scientific committee and working party activities

- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: March 2015

- 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
- Work plan for the GMP/GDP Inspectors Working Group 2015
- Work plan for GCP Inspectors Working Group 2015
- Work plan for the Vaccine Working Party 2015
- Work plan for Biostatistics Working Party 2015

Other publications

- European Commissioner for Health and Food Safety visits EMA
- EMA Management Board: highlights of March 2015 meeting
- European Union Medicines Agencies Network Strategy to 2020 - Consultation open
- Work programme of the EMA 2015
- Celebrating 20 years: EMA launches anniversary book
- Overview of patient involvement along the medicines lifecycle at EMA
- Key milestones of EMA interactions with patients and consumers
- Training and support for patients and consumers
- Involvement of patient representatives in scientific advisory groups at the EMA
- Standard operating procedure for evaluation procedure for eligibility of patients', consumers' and healthcare professionals' organisations
- Standard operating procedure for re-evaluation and financial re-assessment procedures for eligible patients', consumers' and healthcare professionals' organisations
- EnprEMA newsletter: February 2015
- News bulletin for pharmacovigilance programme update - Issue 3
- Minutes of the EnprEMA coordinating group teleconference - January 2015
- Minutes of the EnprEMA working group chairs teleconference - January 2015
- Science, Medicines, Health: Patients at the heart of future innovation conference - video recording
- SME workshop: Focus on chemistry, manufacturing and controls (CMC) regulatory compliance for biopharmaceuticals and advanced therapies - Apr 2015
- Third industry stakeholder platform: operation of EU pharmacovigilance legislation - Mar 2015
- Collaboration on neonatal issues between researchers and the EMA - Mar 2015
- EMA/EGA joint workshop on the impact of the revised EMA guideline on the pharmacokinetic and clinical evaluation of modified-release dosage forms - Apr 2015

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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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30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
E-mail info@ema.europa.eu **Website** www.ema.europa.eu