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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

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Arpraziquantel (*Arpraziquantel*)
  Treatment of schistosomiasis (tropical disease caused by blood flukes). It is intended for use outside the EU.
- Fexinidazole Winthrop (*fexinidazole*)
  Treatment of sleeping sickness (African trypanosomiasis) caused by a parasite known as *Trypanosoma brucei gambiense*. It is intended for use outside the EU.

New information on authorised medicines

- Zinplava (*bezlotoxumab*) - extension of indication
  Prevention of recurrence of *Clostridioides difficile* infection (which can cause diarrhea and inflammation of the intestines)

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Mevlyq (*eribulin*) generic of Halaven
  Treatment of breast cancer and liposarcoma (cancer that starts in fatty tissue)
- Pomalidomide Viatris (*pomalidomide*) generic of Imnovid
  Treatment of multiple myeloma (cancer of the bone marrow)

New medicines authorised

- Finlee (*dabrafenib*)
  Treatment of glioma (a type of brain tumour)

Negative CHMP opinions on renewal of authorised medicine

- Blenrep (*belantamab mafodotin*)
  Intended for treatment of multiple myeloma (cancer of the bone marrow)

Cardiovascular system

Positive CHMP opinions on new medicines

- Dabigatran Etexilate Leon Farma (*dabigatran etexilate*) generic of Pradaxa
  Prevention and treatment of venous thromboembolic events (blood clots)
- Ibuprofen Gen.Orph (*ibuprofen*) generic of Pedea
  Treatment of patent ductus arteriosus (a heart defect) in preterm babies

New information on authorised medicines

- Metalyse (*tenecteplase*) - new pharmaceutical form
  Treatment of myocardial infarction (heart attacks)

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Velsipity (*Etrasimod arginine*)
  Treatment of ulcerative colitis (inflammatory condition of the intestines)

New information on authorised medicines

- Zinplava (*bezlotoxumab*) - extension of indication
  Prevention of recurrence of *Clostridioides difficile* infection (which can cause diarrhea and inflammation of the intestines)

Gynaecology & Obstetrics (pregnancy and female reproductive)

New medicines authorised

- Veoza (*fezolinetant*)
  Treatment of vasomotor symptoms (also referred to as hot flushes or night sweats) associated with menopause

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Casgevy (*exagamglogene autotemcel*) C O
  Treatment of transfusion dependent β-thalassemia and sickle cell disease (disorders of red blood cells)
- Pomalidomide Viatris (*pomalidomide*) generic of Imnovid
  Treatment of multiple myeloma (cancer of the bone marrow)

New information on authorised medicines

- VeraSeal (*human fibrinogen / human thrombin*) - extension of indication
  Treatment for stopping bleeding during surgeries

Negative CHMP opinions on renewal of authorised medicine

- Blenrep (*belantamab mafodotin*)
  Intended for treatment of multiple myeloma (cancer of the bone marrow)

Immune system

Positive CHMP opinions on new medicines

- Velsipity (*Etrasimod arginine*)
  Treatment of ulcerative colitis (inflammatory condition of the intestines)

New information on authorised medicines

- HyQvia (*human normal immunoglobulin*) - new indication
  Treatment of immunodeficiency syndromes

Nervous system

Positive CHMP opinions on new medicines

- Skyclarys (*Omaveloxolone*) O
  Treatment of Friedreich's ataxia (a genetic condition that affects movement and speech)

Supply shortages

- ADHD medicines (atomoxetine, methylphenidate, lisdexamfetamine) supply shortage

Vaccines

- Comirnaty: Periodic safety update report assessment 19 June 2022 to 18 December 2022
- Vaxzevria: Periodic safety update report assessment 29 December 2021 to 28 June 2022
- SPIKEVAX: Periodic safety update report assessment 19th June 2022 to 17th December 2022

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Key to symbols used

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Other information

Guidelines

Guidelines open for consultation

- Guideline on specific adverse reaction follow-up questionnaires (Specific AR FUQ)
  Deadline for comments: 9 February 2024
- Assessment of SmPC section 5.1: A Guide for Assessors of Centralised Applications - Scientific guideline
  Deadline for comments: 4 March 2024
- Development and manufacture of human medicinal products specifically designed for phage therapy - Scientific guideline
  Deadline for comments: 31 March 2024

Adopted guidelines

- Regulatory requirements for the development of medicinal products for Acute Kidney Injury (AKI) - Scientific guideline

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - November 2023
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: December 2023
- COMP - agendas, minutes and meetings reports
- HMPC - agendas, minutes and meetings reports
- PDCO - agendas, minutes and meeting reports
- PRAC - agendas, minutes and highlights
- PRAC statistics: December 2023
- PRAC recommendations on safety signals

Other publications

- First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU
- Global regulators strengthen efforts to ensure continuous availability of safe and high-quality medicines
- EU medicines agencies reflect on lessons learned from COVID-19
- Follow-up reply to Members of the European Parliament regarding mRNA COVID-19 vaccines
- Letter of support for a Composite endpoint method for acceptability evaluation of oral drug formulations in the paediatric population

- Synapse Labs Pvt. Ltd: EMA recommends suspension of medicines over flawed studies

Events

- EMA Management Board: highlights of December 2023 meeting
- EMA and European Organisation for Research and Treatment of Cancer (EORTC) workshop: How can patient-reported outcomes (PRO) and health-related quality of life (HRQoL) data inform regulatory decisions? - 29 February 2024
- Eleventh industry stakeholder platform on research and development support - 4 December 2023
- Second biannual Big Data Steering Group and industry stakeholders meeting - 27 November - Report

Explanation of terms used

Orphan medicine

A medicine intended for the treatment of a rare, serious disease. These medicines are granted orphan status during their development; at time of approval, orphan designations are reviewed to determine whether the information available to date allows maintaining the medicine's orphan status.

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 to generate complete data on the medicine.

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. These medicines are subject to specific post-authorisation obligations and monitoring.

Medicines assessed under Article 58

Article 58 of Regulation (EC) No 726/2004 allows the CHMP to give opinions, in co-operation with the World Health Organization, on medicinal products that are intended exclusively for markets outside of the European Union.

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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