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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

Positive CHMP opinions on new medicines

- Degarelix Accord (*degarelix acetate*)
  Treatment of prostate cancer
- Enrylaze (*crisantaspase*)
  Treatment of acute lymphoblastic leukaemia (a type of blood cancer)
- Inaqovi (*cedazuridine / decitabine*) O
  Treatment of myeloid leukaemia (a type of blood cancer)
- Orserdu (*elacestrant*)
  Treatment of breast cancer
- Talvey (*talquetamab*) C O
  Treatment of multiple myeloma, a type of white blood cell cancer

Key to symbols used

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

- Tepkinly (*epcoritamab*)
  Treatment of large B-cell lymphoma (a type of blood cancer)
- Tevimbra (*tislelizumab*)
  Treatment of oesophageal cancer (cancer of the gullet)

New medicines authorised

- Columvi (*glofitamab*)
  Treatment of blood cancer called diffuse large B-cell lymphoma (a type of blood cancer)
- Lytgobi (*futibatinib*)
  Treatment of biliary tract cancer (a cancer of the bile ducts, the tubes that carry bile from the liver and gallbladder to the gut)
- Pylclari (*piflufolastat (18F)*)
  Diagnostic medicine used in adults with prostate cancer to detect prostate cancer cells

New information on authorised medicines

- Keytruda (*pembrolizumab*) - new indication
  Treatment of oesophageal cancer (cancer of the gullet)
- Opdivo (*nivolumab*) - extension of indication
  Treatment of Stage IIB and IIC melanoma (skin cancer that has not spread beyond the skin to lymph nodes or other tissues)

Withdrawal of applications for extension of indication

- Gazyvaro (*obinutuzumab*)
  Intended to prevent a serious side effect (cytokine release syndrome) that occurs with the blood cancer medicine Columvi

Negative CHMP opinions on new medicines

- Krazati (*adagrasib*)
  Intended for treatment of non-small cell lung cancer

Cardiovascular system

New medicines authorised

- Camzyos (*mavacamten*)
  Treatment of hypertrophic cardiomyopathy (a disease in which there is thickening of the heart muscle)

Diabetes

Supply shortages

- Insuman (*insulin human)*
  Treatment of diabetes type I and type II
- Rybelsus (*semaglutide*)
  A diabetes medicine used to control blood glucose (sugar) levels in adults whose type 2 diabetes is not controlled well enough

Haematology (blood conditions)

Withdrawal of applications for new medicines

- Jesduvroq (*daprodustat*)
  Treatment of symptomatic anaemia in patients with chronic kidney disease

Hepatology (liver conditions)

New information on authorised medicines

- Bylvay (*odevixibat*) - new indication
  Treatment of intense itching in patients with Alagille syndrome, a disease in which bile cannot drain properly from the liver

HIV

Positive CHMP opinions on new medicines

- Apretude (*cabotegravir*)
  Prevention of sexually acquired HIV-1 in combination with safer sex practices

Immune system

Positive CHMP opinions on new medicines

- Litfulo (*ritlecitinib*)
  Treatment of alopecia areata (a disease in which the immune system attacks hair follicles, causing inflammation)

Withdrawal of applications for new medicines

- Jesduvroq (*daprodustat*)
  Treatment of symptomatic anaemia in patients with chronic kidney disease

Nervous system

Positive CHMP opinions on new medicines

- Tyruko (*natalizumab*)
  Treatment of multiple sclerosis

New medicines authorised

- Briumvi (*ublituximab*)
  Treatment of multiple sclerosis
- Ztalmy (*ganaxolone*)
  Treatment of epileptic seizures in children from 2 to 17 years of age

Ophthalmology (eye conditions)

Positive CHMP opinions on new medicines

- Yesafili (*aflibercept*)
  Treatment of conditions caused by excess growth of blood vessels in the eye, including age-related macular degeneration (AMD)

Respiratory system

Positive CHMP opinions on new medicines

- Lyfnua (*gefapixant*)
  Treatment of chronic cough

New medicines authorised

- Abrysovo (*Respiratory syncytial virus vaccines*)
  Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)

Withdrawal of applications for new medicines

- Gefzuris (*gefapixant*)
  Intended for treatment of chronic cough

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- Tyenne (*tocilizumab*)
  Treatment of rheumatoid arthritis (a disease causing inflammation of the joints)

New information on authorised medicines

- Olumiant (*baricitinib*) - change of indication
  Treatment of active juvenile idiopathic arthritis (a disease causing inflammation of the joints in children)

Vaccines

New medicines authorised

- Abrysovo (*Respiratory syncytial virus vaccines*)
  Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)

New information on authorised medicines

- Spikevax (previously COVID-19 Vaccine Moderna) (*elasomeran / imelasomeran and elasomeran / davesomeran and elasomeran / COVID-19 mRNA vaccine (nucleoside-modified)*) - extension of indication
  Prevention of COVID-19 in children 6 months of age
- Ervebo (*Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)*) - extension of indication
  Prevention of Ebola virus disease

Other medicines

New medicines authorised

- Qaialdo (spironolactone)
  Treatment of several conditions that cause refractory oedema (swelling due to fluid build up that does not respond to standard treatment)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- ICH Reflection paper on proposed international harmonisation of real-world evidence terminology and convergence of general principles regarding planning and reporting of studies using real-world data, with a focus on effectiveness of medicines
  Deadline for comments: 30 September 2023
- Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle
  Deadline for comments: 31 December 2023

Adopted guidelines

- Qualification Opinion for Stride velocity 95th centile as primary endpoint in studies in ambulatory Duchenne Muscular Dystrophy studies

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - June 2023
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: July 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 recommendations on safety signals

Other publications

- Global regulators confirm good safety profile of COVID-19 vaccines
- Phasing out of extraordinary COVID-19 regulatory flexibilities
- EMA statement on ongoing review of GLP-1 receptor agonists
- EMA public stakeholder meeting on COVID-19: how safe and effective vaccines are developed and authorised in the EU
- Recommendations of the Executive Steering Group on Shortages and Safety of Medicinal Products on the availability of a subset of antibiotics
- European Health Union: EU steps up action to prevent shortages of antibiotics for next winter
- Reflection paper on the use of artificial intelligence in the lifecycle of medicines
- The use of Artificial Intelligence (AI) in the medicinal product lifecycle
- First RSV vaccine to protect infants up to 6 months of age and older adults
- Start of a review concerning the conduct of studies at Synapse Labs Pvt. Ltd, India
- Paving the way towards coordinated clinical trials in public health emergencies in the EU
- Nitrosamine impurities
- Medicines for older people

Events

- European Medicines Agency / Emergency Task Force and European Commission workshop on lessons learned on clinical trials in public health emergencies - 9 June 2023 - Agenda
- Meeting of the Executive Steering Group on Shortages of Medical Devices (MDSSG) - 19 June 2023 - Agenda
- Fifth Industry Standing Group (ISG) meeting - 26 June 2023 - Agenda
- ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 - Public Consultation - 13 July 2023 - Agenda
- Shaping a European innovation ecosystem: EU-Innovation network multi-stakeholder meeting - 26 September 2023 - Agenda
- EMA multi-stakeholder workshop on Acute Respiratory Distress Syndrome - 21 November 2023

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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http://www.ema.europa.eu

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European Medicines Agency

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