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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

COVID-19 vaccines and treatments

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
  Booster protection in children aged 6 to 11 years with adapted BA.4-5 vaccine
- Ronapreve (*casirivimab / imdevimab*) - extension of indication
  Treatment of COVID-19 disease in patients with a negative antibody test receiving oxygen

Key to symbols used

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

Antivirals/anti-infectives

New information on authorised medicines

- Vemlidy (*tenofovir alafenamide*) - extension of indication
  Treatment of chronic hepatitis B in children

Cancer

Positive CHMP opinions on new medicines

- Columvi (*glofitamab*) O C
  Treatment of blood cancer
- Jaypirca (*pirtobrutinib*) O C
  Treatment of blood cancer
- Lytgobi (*futibatinib*) O C
  Treatment of bile duct cancer

New medicines authorised

- Tremelimumab AstraZeneca (*tremelimumab*)
  Treatment of non-small cell lung cancer

New information on authorised medicines

- Opdivo (*ipilimumab*) - extension of indication
  Treatment of advanced skin cancer
- Yervoy (*nivolumab*) - extension of indication
  Treatment of advanced skin cancer

Withdrawal of applications for new medicines

- Tidhesco (*ivosidenib*)
  Intended for treatment of blood cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- Camzyos (*mavacamten*)
  Treatment of symptomatic obstructive hyperthropic cardiomyopathy (a condition in which the heart muscles thicken)

New medicines authorised

- Dapagliflozin Viatris (*dapagliflozin*)
  Treatment of chronic heart failure

Dermatology (skin conditions)

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of hidradenitis suppurativa (an inflammatory skin condition)

Diabetes

New medicines authorised

- Dapagliflozin Viatris (*dapagliflozin*)
  Treatment of type 2 diabetes

Gastro-intestinal system

New information on authorised medicines

- Revestive (*teduglutide*) - extension of indication
  Treatment of Short Bowel syndrome (condition where part of intestine is removed or does not absorb nutrients properly) in children

Gynaecology & Obstetrics (pregnancy and female reproductive)

Supply shortages

- Menopur (*menotropin*)
  Treatment of female and male infertility

Direct Healthcare Professional Communication (DHPC)

- Menopur (menotropin)
  Treatment of male and female infertility

Haematology (blood conditions)

New information on authorised medicines

- Adempas (*riociguat*) - new indication
  Treatment of high blood pressure in lungs in children

Safety update

- Review of Adakveo (*crizanlizumab*) - review started
  Treatment of painful crises in patients with sickle cell disease

HIV

Withdrawal of applications for new medicines

- Raltegravir Viatris (*raltegravir potassium*)
  Intended for treatment of HIV

Immune system

New information on authorised medicines

- Bimzelx (*bimekizumab*) - new indication
  Treatment of psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints)

Metabolic disorders

Positive CHMP opinions on new medicines

- Opfolda (*miglustat*)
  Treatment of glycogen storage disease type II (Pompe disease)

Musculoskeletal system

Positive CHMP opinions on new medicines

- Sugammadex Piramal (*sugammadex*) generic of Bridion
  Used to reverse the effects of muscle relaxants

Nephrology (kidney conditions)

New medicines authorised

- Dapagliflozin Viatris (*dapagliflozin*)
  Treatment of chronic kidney disease

Direct Healthcare Professional Communication (DHPC)

- Simulect (*basiliximab*)
  Prevention of rejection of newly transplanted kidneys

Nervous system

Positive CHMP opinions on new medicines

- Sugammadex Piramal (*sugammadex*) generic of Bridion
  Used to reverse the effects of muscle relaxants

Ophthalmology (eye conditions)

Withdrawal of applications for new medicines

- Lumevoq (*lenadogene nolparvovec*)
  Intended for treatment of loss of vision due to an eye condition known as Leber hereditary optic neuropathy

Respiratory system

Positive CHMP opinions on new medicines

- Adempas (*riociguat*) - new indication
  Treatment of high blood pressure in lungs in children
- Arexvy (*recombinant, adjuvanted*)
  Prevention of lower respiratory tract disease caused by a virus known as the respiratory syncytial virus (RSV)

New information on authorised medicines

- Orkambi (*lumacaftor / ivacaftor*) - extension of indication and new pharmaceutical form
  Treatment of cystic fibrosis
- Ronapreve (*casirivimab / imdevimab*) - extension of indication
  Treatment of COVID-19 disease in patients with a negative antibody test receiving oxygen

Rheumatology (immune and inflammatory conditions)

New information on authorised medicines

- Bimzelx (*bimekizumab*) - new indication
  Treatment of axial spondyloarthritis (inflammation of the spine causing back pain)

Vaccines

Positive CHMP opinions on new medicines

- Arexvy (*recombinant, adjuvanted*)
  Prevention of lower respiratory tract disease caused by a virus known as the respiratory syncytial virus (RSV)
- Qdenga (*dengue tetravalent vaccine (live, attenuated*))
  Prevention of dengue disease

Other medicines

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of hidradenitis suppurativa (an inflammatory skin condition)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Questions and answers on data requirements when replacing hydrofluorocarbons as propellants in oral pressurised metered dose inhalers
  Deadline for comments: 31 May 2023
- Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation
  Deadline for comments: 30 September 2023

Adopted guidelines

- Guideline on influenza vaccines – submission and procedural requirements
- ICH S12 Guideline on nonclinical biodistribution considerations for gene therapy products

Scientific committee and working party activities

- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- 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

- Reducing risks to human and animal health from exposure to N-methyl pyrrolidone in veterinary medicines
- Report on divergent opinion between EFSA and EMA on bisphenol-A
- Availability of medicines during COVID-19 pandemic
- Single-arm trials as pivotal evidence for the authorisation of medicines in the EU
- Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

Events

- Second European Medicines Agency & MedTech Europe bilateral meeting - 11 April 2023 - Agenda
- ACT EU multi-stakeholder platform kick-off workshop - 22-23 June 2023
- LinkedIn Live interview with Peter Arlett: Real-world evidence in medicines regulation - 20 April 2023
- EMA multi-stakeholder workshop on qualification of novel methodologies - 17-18 April 2023
- Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 20 April 2023 - Agenda
- Fourth EMA and Association of the European Self-Medication Industry (AESGP) annual bilateral meeting - 18 April 2023
- ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 - Public Consultation - 13-14 July 2023
- Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party - 18 April 2023
- ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 - Public Consultation - 13-14 July 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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