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EUROPEAN MEDICINES AGENCY
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HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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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

Withdrawal of applications for new medicines

- Lagevrio (*molnupiravir*)
  Intended for treatment of COVID-19

Direct Healthcare Professional Communication (DHPC)

- Quinolones and fluoroquinolones containing medicinal products (*fluoroquinolones*)
  Treatment of bacterial infections

Cancer

New medicines authorised

- Akeega (*niraparib / abiraterone acetate*)
  Treatment of patients with castration-resistant prostate cancer

Key to symbols used

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

- Pedmarqsi (*sodium thiosulfate*)
  Medicine used to reduce risk of hearing loss caused by the cancer medicine crisplatin in children under 18 years of age

New information on authorised medicines

- Imjudo (*tremelimumab*) - new indication
  Treatment of metastatic non-small cell lung cancer
- Lonsurf (*trifluridine / tipiracil*) - new indication
  Treatment of metastatic colorectal cancer
- Trodelvy (*sacituzumab govitecan*) - new indication
  Treatment of breast cancer

Withdrawal of applications for new medicines

- Dyrupeg (*pegfilgrastim*)
  Intended to reduce the duration of neutropenia (low levels of neutrophils, a type of white blood cells) in cancer patients
- Zefylti (*filgrastim*)
  Intended to stimulate the production of white blood cells

Supply shortages

- Pazenir (*paclitaxel*)
  Treatment of various types of cancer

Direct Healthcare Professional Communication (DHPC)

- Gavreto (*pralsetinib*) C
  Treatment of non-small cell lung cancer

Haematology (blood conditions)

Positive CHMP opinions on new medicines

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

New information on authorised medicines

- Mircera (methoxy polyethylene glycol-epoetin beta) - extension of indication
  Treatment of anaemia associated with chronic kidney disease in children
- Refixia (*nonacog beta pegol*) - extension of indication
  Treatment of haemophilia B

Withdrawal of applications for new medicines

- Dyrupeg (*pegfilgrastim*)
  Intended to reduce the duration of neutropenia (low levels of neutrophils, a type of white blood cells in cancer patients)
- Zefylti (*filgrastim*)
  Intended to stimulate the production of white blood cells

Direct Healthcare Professional Communication (DHPC)

- Adakveo (*crizanlizumab*) O
  Prevention of painful crises in patients with sickle cell disease

HIV

Withdrawal of applications for new medicines

- Zefylti (*filgrastim*)
  Intended to stimulate the production of white blood cells, including in patients with HIV

Immune system

New information on authorised medicines

- Soliris (*eculizumab*) - extension of indication O
  Treatment of generalized myasthenia gravis (a chronic autoimmune neuromuscular disease that causes weakness in the skeletal muscles)

Musculoskeletal system

New medicines authorised

- Sugammadex Adroiq (*sugammadex*)
  Reversing the effect of the muscle relaxants at the end of the operation

Nephrology (kidney conditions)

Positive CHMP opinions on new medicines

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

New information on authorised medicines

- Jardiance (*empagliflozin*) - new indication
  Treatment of chronic kidney disease
- Mircera (methoxy polyethylene glycol-epoetin beta) - extension of indication
  Treatment of anaemia associated with chronic kidney disease in paediatric patients

Nervous system

Negative CHMP opinions on new medicines

- Albrioza (sodium phenylbutyrate / Ursodoxicoltaurine) O
  Intended for treatment of amyotrophic lateral sclerosis, a disease of the nervous system that causes muscle weakness and paralysis

Ophthalmology (eye conditions)

Supply shortages

- Visudyne (*verteporfin*)
  Treatment of the 'wet' form of age-related macular degeneration (a disease that affects the central part of the retina at the back of the eye)

Respiratory system

New medicines authorised

- Arexvy (*Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E*)
  Prevention of lower respiratory tract disease for adults 60 years and older

Vaccines

New medicines authorised

- Arexvy (*Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E*)
  Prevention of lower respiratory tract disease for adults 60 years and older
- Comirnaty Priginal/Omicron BA.4-5 (tozinameran / riltozinameran and tozinameran / famtozinameran and tozinameran / COVID-19 mRNA Vaccine (nucleoside modified)) - extension of indication
  Prevention of COVID-19 in children from 6 months of age who have had no primary vaccination

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on revision of the Guideline on clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome
  Deadline for comments: 31 July 2023
- ICH E6 (R3) Guideline on good clinical practice (GCP)
  Deadline for comments: 26 September 2023
- Concept Paper on the development of a Guideline on the quality aspects of mRNA vaccines
  Deadline for comments: 30 September 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 clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus

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
- PCWP
- HCPWP

Other publications

- Quinolone- and fluoroquinolone-containing medicinal products
- ACT EU: creating a better environment for clinical trials through collaboration
- EMA and ECDC statement on updating COVID-19 vaccines to target new SARS-CoV-2 virus variants
- Report: How EU ensured safety of medicines during COVID-19
- Use of real-world evidence in regulatory decision making – EMA publishes review of its studies
- EMA Management Board: highlights of June 2023 meeting

Events

- Meeting of the Executive Steering Group on Shortages of Medical Devices (MDSSG) - 19 June 2023 - Agenda
- ACT EU multi-stakeholder platform kick-off workshop - 22-23 June 2023 - Agenda
- Tenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines - 27 June 2023 - Agenda
- 10th anniversary of European Medicines Agency (EMA) Healthcare Professionals' (HCPWP) Working Party meeting - 27 June 2023 - Agenda
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) Working Party meeting - 27 June 2023 - Agenda
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - 28 June 2023 - Agenda
- ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 - Public Consultation - 13-14 July 2023 - Agenda

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Website www.ema.europa.eu **Telephone** +31 (0)88 871 6000

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