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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 medicines authorised

- Regkirona (*regdanvimab*)
  Treatment of COVID-19
- Ronapreve (casirivimab/imdevimab)
  Treatment of COVID-19

Safety update

- COVID-19 vaccine safety update for Spikevax (previously COVID-19 Vaccine Moderna): 11 November 2021
- COVID-19 vaccine safety update for Comirnaty: 11 November 2021
- COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 11 November 2021
- COVID-19 vaccine safety update for COVID-19 Vaccine Janssen: 11 November 2021

Key to symbols used

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

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Tecovirimat SIGA (*tecovirimat*) E
  Treatment of smallpox, monkeypox, cowpox and complications from using vaccinia in smallpox vaccination

New information on authorised medicines

- Epclusa (*sofosbuvir/velpatasvir*) - extension of indication
  Treatment of chronic hepatitis C
- Noxafil (*posaconazole*) - extension of indication
  Treatment of fungal infections

Cancer

Positive CHMP opinions on new medicines

- Lumykras (*sotorasib*) C
  Treatment of non-small cell lung cancer with a mutation known as KRAS G12C

New medicines authorised

- Abiraterone Krka (*abiraterone acetate*) generic of Zytiga
  Treatment of metastatic prostate cancer
- Qinlock (*ripretinib*) O
  Treatment of gastrointestinal stromal tumour, a cancer of the stomach and bowel
- Trodelvy (*sacituzumab govitecan*)
  Treatment of triple-negative breast cancer, a type of breast cancer

Withdrawal of applications for extension of indication

- Cervarix (*human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed)*)
  Intended for the prevention of head and neck cancers that are caused by certain types of human papillomavirus (HPV)

Diabetes

Direct Healthcare Professional Communication (DHPC)

- Forxiga (dapagliflozin) 5mg should no longer be used for the treatment of Type 1 diabetes mellitus

Gastro-intestinal system

New medicines authorised

- Qinlock (*ripretinib*) O
  Treatment of gastrointestinal stromal tumour, a cancer of the stomach and bowel

Withdrawal of authorised medicines

- Flynpovi (*eflornithine / sulindac*)
  Intended for the treatment of familial adenomatous polyposis, a hereditary disease in which polyps (growths) form in the gut

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Tavneos (*avacopan*)
  Treatment of granulomatosis with polyangiitis or microscopic polyangiitis (inflammatory conditions of the blood vessels)

Hormone system

Positive CHMP opinions on new medicines

- Lonapegsomatropin Ascendis Pharma (*lonapegsomatropin*)
  Treatment of growth hormone deficiency

Immune system

Supply shortages

- Kevzara (*sarilumab*)
  Treatment of rheumatoid arthritis

Direct Healthcare Professional Communication (DHPC)

- Supply Constraint of Sarilumab [Kevzara®]

Nervous system

Positive CHMP opinions on new medicines

- Vyepti (*eptinezumab*)
  Treatment of migraine

Ophthalmology (eye conditions)

Positive CHMP opinions on new medicines

- Uplizna (*inebilizumab*)
  Treatment of adult patients with neuromyelitis optica spectrum disorders, inflammatory disorders that affect the nerve connecting the eye to the brain

Negative CHMP opinions on new medicines

- Ipique (*bevacizumab*)
  Intended for treatment of neovascular (wet) age-related macular degeneration, a disease affecting the central part of the retina, at the back of the eye

Supply shortages

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

Direct Healthcare Professional Communication (DHPC)

- Beovu ® (brolucizumab): Updated recommendations to minimise the known risk of intraocular inflammation, including retinal vasculitis and/or retinal vascular occlusion
- Visudyne (verteporfin): Information on the continuing supply restriction until end Q1/2022

Respiratory system

Positive CHMP opinions on new medicines

- Riltrava Aerosphere (*formoterol fumarate dihydrate / glycopyrronium / budesonide*)
  Treatment of chronic obstructive pulmonary disease

New information on authorised medicines

- Kaftrio (*ivacaftor / tezacaftor / elexacaftor*) O - extension of indication
  Treatment of cystic fibrosis
- Kalydeco (*ivacaftor*) - extension of indication
  Treatment of cystic fibrosis

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- Tavneos (*avacopan*) O
  Treatment of granulomatosis with polyangiitis or microscopic polyangiitis (inflammatory conditions of the blood vessels)

Supply shortages

- Kevzara (*sarilumab*)
  Treatment of rheumatoid arthritis

Direct Healthcare Professional Communication (DHPC)

- Supply Constraint of Sarilumab [Kevzara®]

Vaccines

New information on authorised medicines

- Dengvaxia (*sofosbuvir/velpatasvir*) - new indication
  Vaccine to prevent Dengue, a mosquito-borne tropical disease

Withdrawal of applications for extension of indication

- Cervarix (*human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed)*)
  Intended for the prevention of head and neck cancers that are caused by certain types of human papillomavirus (HPV)

Other medicines

Positive CHMP opinions on new medicines

- Voraxaze (*glucarpidase*) E O
  Treatment to reduce toxic plasma methotrexate concentration
- Wegovy (*semaglutide*)
  Treatment of people with obesity or who are overweight in the presence of other related conditions

New medicines authorised

- Sugammadex Mylan (*sugammadex*) generic of Bridion
  Treatment used during some types of operation to make the muscles relax

New information on authorised medicines

- Rapiscan (*regadenoson*) - change of indication
  Medicine used in diagnosis of heart problems

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Adopted guidelines

- Abiraterone acetate tablets 250 mg and 500 mg product-specific bioequivalence guidance - Revision 2

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - October 2021
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: November 2021
- 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 joint meeting - 21-22 September 2021 - Minutes

Other information on COVID-19

- Comirnaty COVID-19 vaccine: EMA recommends approval for children aged 5 to 11
- EMA receives application for marketing authorisation for Lagevrio (molnupiravir) for treating patients with COVID 19
- EMA starts review of Paxlovid for treating patients with COVID-19
- EMA issues advice on use of Lagevrio (molnupiravir) for the treatment of COVID-19
- EMA receives application for marketing authorisation for Xevudy (sotrovimab) for treating patients with COVID-19
- EMA evaluating data on booster dose of COVID-19 Vaccine Janssen
- EMA starts evaluating use of COVID-19 vaccine Spikevax in children aged 6 to 11
- EMA receives application for conditional marketing authorisation of Novavax's COVID-19 vaccine, Nuvaxovid
- COVID-19: EMA and Heads of Medicines Agencies update on molnupiravir
- EMA ends rolling review of the antibodies bamlanivimab and etesevimab for COVID-19 following withdrawal by Lilly

Other publications

- A vision for use of real-world evidence in EU medicines regulation
- European Antibiotic Awareness Day: Fighting the silent pandemic
- Antimicrobial resistance - Join the fight! - Infocards
- Questions and answers from the webinar for industry on integration of EudraGMDP and OMS
- Notification on arrangements for requesting EMA certificates through urgent and standard procedure for December 2021
- 2011-2020: More than 40% decrease in sales of antimicrobials for use in animals

Events

- Seventh industry stakeholder platform on research and development support, 23 November 2021, virtual meeting
- EMA and EATRIS webinar on navigating the regulatory requirements for advanced therapy medicinal products (ATMPs), 29 November 2021, virtual meeting
- Nitrosamine Implementation Oversight Group (NIOG) - second meeting with pharmaceutical industry, 8 December 2021, virtual meeting
- Seventh meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicine, 1 December, virtual meeting - 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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