

# HUMAN MEDICINES

Key information for patients, consumers and healthcare professionals Published monthly by the European Medicines Agency



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Explanation of terms used

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

# Antivirals/anti-infectives

## Positive CHMP opinions on new medicines

Tecovirimat SIGA (tecovirimat)

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) 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) Treatment of gastrointestinal stromal tumour, a cancer of the stomach and bowel
- <u>Trodelvy</u> (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

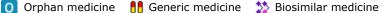
## New medicines authorised

Qinlock (ripretinib)

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 (Ionapegsomatropin) 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**

<u>Ipique</u> (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) 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) 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®]

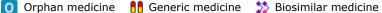
## **Vaccines**

### 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) 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 quidance - 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.

### **ff** 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 <u>CHMP</u> to give opinions, in co-operation with the World Health Organization, on <u>medicinal products</u> 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.

#### Visit our website

Further information about the European Medicines Agency and the work it does is available on our website:

http://www.ema.europa.eu

In particular, you may be interested in these links:

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