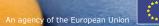


# JMAN MEDICIN

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



## **IN THIS ISSUE** COVID-19 vaccines and treatments 1 Antivirals/anti-infectives 1 2 Cardiovascular system 2 Dermatology 3 Diabetes 3 Haematology 3 Hepatology (liver conditions) 3 HIV 3 Immune system 3 Metabolic disorders 4 4 Nephrology Nervous system 5 Ophthalmology 5 5 Respiratory system Rheumatology (immune and inflammatory conditions) Other medicine Medicines under additional monitoring

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.

To receive each new issue of the newsletter, please click here RSS feeds, choose 'Human medicines highlights newsletter' and then click on 'Subscribe to this feed'. Please note, in order to be able to view RSS feeds you need one of the following: a modern web browser; a web-based news reader or a desktop news reader. For a list of RSS readers please refer to our RSS guide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

You can find details on how to cancel / unsubscribe to an RSS feed on the RSS reader tool that you are using, for example Unsubscribe from an RSS Feed for users of Microsoft Outlook.

For further information on the processing of your personal data, please find EMA's Privacy statement regarding the sending of electronic newsletters click here.

# Information on medicines

## COVID-19 vaccines and treatments

#### New medicines authorised

Bimervax (COVID-19 Vaccine (recombinant, adjuvanted)) Prevention of COVID-19 disease

## Antivirals/anti-infectives

## New information on authorised medicines

Tenkasi (previously Orbactiv) (oritavancin) - extension of indication Treatment of infections of the skin and tissues beneath the skin

### Key to symbols used

Explanation of terms used

Scientific committee and

working party activities

Other publications



**Events** 

6

7

## Withdrawal of applications for new medicines

Garsun (artesunate) Intended for treatment of severe malaria

## Cancer

## Positive CHMP opinions on new medicines

- Pedmarqsi (sodium thiosulfate) Prevention of development of hearing loss caused by cisplatin cancer treatment
- Qaialdo (spironolactone) Treatment of persistent swelling caused by cardiovascular, liver and kidney problems or by cancer in the abdomen

#### New medicines authorised

Imjudo (tremelimumab) Treatment of a type of liver cancer

## New information on authorised medicines

Breyanzi (lisocabtagene maraleucel) - new indication Treatment of lymphomas ( cancers of certain types of blood cells)

## **Direct Healthcare Professional Communication (DHPC)**

Janus kinase inhibitors (JAKi) (abrocitinib, filgotinib, baricitinib, upadacitinib, tofacitinib) Updated recommendations to minimize risk of cancer, heart problems and blood clots

## Cardiovascular system

## Positive CHMP opinions on new medicines

- <u>Dabigatran Etexilate Accord</u> (dabigatran etexilate) <sup>10</sup> generic of Pradaxa Treatment and prevention of blood clots
- Qaialdo (spironolactone)

Treatment of persistent swelling caused by cardiovascular, liver and kidney problems or by cancer in the

## New information on authorised medicines

- Neparvis (sacubitril / valsartan) new indication and new pharmaceutical form Treatment of chronic heart failure in children
- Entresto (sacubitril / valsartan) new indication and new pharmaceutical form Treatment of chronic heart failure in children over one year of age

#### **Direct Healthcare Professional Communication (DHPC)**

Janus kinase inhibitors (JAKi) (abrocitinib, filgotinib, baricitinib, upadacitinib, tofacitinib) Updated recommendations to minimize risk of cancer, heart problems and blood clots













# Dermatology (skin conditions)

#### New information on authorised medicines

Tenkasi (previously Orbactiv) (oritavancin) - extension of indication Treatment of infections of the skin and tissues beneath the skin

## Diabetes

## Supply shortages

Ozempic (semaglutide) Treatment of diabetes

# Haematology (blood conditions)

## Positive CHMP opinions on new medicines

Epysgli (eculizumab)

Treatment of paroxysmal nocturnal heamoglobinuria (a rare immune condition in which there is haemoglobin (red pigment) in the urine due to the excessive breakdown of red blood cells.)

#### New information on authorised medicines

Ultomiris (ravulizumab) - new indication and new pharmaceutical form Treatment of paroxysmal nocturnal haemoglobinuria (PNH) and atypical haemolytic uraemic syndrome (aHUS), life-threatening blood conditions caused by an overactive immune system

## Withdrawal of applications for new medicines

Feraheme (ferumoxytol) Intended for treatment of iron deficiency anaemia

### Safety update

Review of Pseudoephedrine-containing medicinal products (pseudoephedrine) - review started Treatment of nasal congestion

## **Direct Healthcare Professional Communication (DHPC)**

Janus kinase inhibitors (JAKi) (abrocitinib, filgotinib, baricitinib, upadacitinib, tofacitinib) Updated recommendations to minimize risk of cancer, heart problems and blood clots

## Hepatology (liver conditions)

## Positive CHMP opinions on new medicines

Qaialdo (spironolactone)

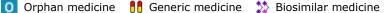
Treatment of persistent swelling caused by cardiovascular, liver and kidney problems or by cancer in the abdomen

## New medicines authorised

Imjudo (tremelimumab) Treatment of a type of liver cancer

## Key to symbols used





## HIV

## Withdrawal of applications for new medicines

Raltegravir Viatris (raltegravir potassium) Intended for treatment of HIV type 1 virus

## Immune system

## Positive CHMP opinions on new medicines

Epysqli (eculizumab)

Treatment of paroxysmal nocturnal heamoglobinuria (a rare immune condition in which there is haemoglobin (red pigment) in the urine due to the excessive breakdown of red blood cells.)

Omvoh (mirikizumab)

Treatment of an inflammation of the large intestine causing ulceration and bleeding

#### New information on authorised medicines

<u>Ultomiris</u> (ravulizumab) - new indication and new pharmaceutical form Treatment of a disease in which the immune system causes damage leading to anaemia, thrombocytopenia (a decrease in the number of platelets, components that help the blood to clot) and kidney failure

#### Safety update

Review of Pseudoephedrine-containing medicinal products (pseudoephedrine) - review started Treatment of nasal congestion

## Metabolic disorders

## Supply shortages

Myalepta (metreleptin) Treatment of abnormal distribution of fat in patients with a condition known as leptin deficiency

# Nephrology (kidney conditions)

## Positive CHMP opinions on new medicines

Qaialdo (spironolactone)

Treatment of persistent swelling caused by cardiovascular, liver and kidney problems or by cancer in the abdomen

#### New information on authorised medicines

<u>Ultomiris</u> (ravulizumab) - new indication and new pharmaceutical form Treatment of a disease in which the immune system causes damage leading to anaemia, thrombocytopenia (a decrease in the number of platelets, components that help the blood to clot) and kidney failure





## Nervous system

## Positive CHMP opinions on new medicines

- Briumvi (ublituximab)
  - Treatment of multiple sclerosis
- Lacosamide Adroig (lacosamide) generic of Vimpat Treatment of epilepsy
- Sugammadex Adroig (sugammadex) generic of Bridion Used to reverse the effect of the muscle relaxants

### Safety update

- Review of Pseudoephedrine-containing medicinal products (pseudoephedrine) review started Treatment of nasal congestion
- Review of <u>Topiramate</u> (topiramate) review started Prevention of epileptic seizures, treatment of epilepsy, prevention of migraine and, in some countries, used in combination with phentermine for body weight reduction

## Ophthalmology (eye conditions)

## Arbitration procedures

Gelisia and associated names (timolol maleate) - outcome Treatment of high pressure inside the eye

## Respiratory system

## Safety update

- Pholcodine-containing medicinal products (pholcodine) outcome Treatment of dry cough (in combination with other active substances for treatment of) symptoms of cold and flu
- Review of Pseudoephedrine-containing medicinal products (pseudoephedrine) review started Treatment of nasal congestion

## **Direct Healthcare Professional Communication (DHPC)**

Pholcodine-containing medicinal products (pholcodine) Treatment of dry cough (in combination with other active substances for treatment of) symptoms of cold and flu

# Rheumatology (immune and inflammatory conditions)

## New medicines authorised

Kauliv (teriparatide) Treatment of osteoporosis (a disease that makes bones fragile)

## Key to symbols used







## Withdrawal of applications for new medicines

Onteeo (INN) Intended for treatment of various inflammatory conditions and COVID-19

## **Direct Healthcare Professional Communication (DHPC)**

Janus kinase inhibitors (JAKi) (abrocitinib, filgotinib, baricitinib, upadacitinib, tofacitinib) Updated recommendations to minimize risk of cancer, heart problems and blood clots

## Other medicines

#### New information on authorised medicines

Wegovy (semaglutide) - extension of indication Treatment of obesity

# Medicines under additional monitoring

Updated list of medicines under additional monitoring

# Other information

## 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
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - 3 March 2023 - Agenda

# Other publications

- DARWIN EU® has completed its first studies and is calling for new data partners
- Public engagement highlights

Key to symbols used



# **HUMAN MEDICINES**

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





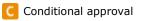
## **Events**

- EMA multi-stakeholder workshop on qualification of novel methodologies 17-18 April 2023
- Fourth Industry Standing Group (ISG) meeting 21 March 2023 Agenda
- Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) 15 March 2023
- HMA/EMA multi-stakeholder workshop on shortages 1-2 March 2023
- Fifth EMA-EFPIA annual bilateral meeting 7 February 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.

## **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:

About us

Patients and carers

Healthcare professionals

European public assessment reports

If you have a question relating to the content of this Newsletter, please send it via <a href="https://www.ema.europa.eu/contact">www.ema.europa.eu/contact</a>

## **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

