



# HUMAN MEDICINES HIGHLIGHTS

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

An agency of the European Union



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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

### 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

Orphan medicine Generic medicine Biosimilar medicine Conditional approval Exceptional circumstances

### Withdrawal of applications for new medicines

- [Garsun](#) (*artesunate*)   
Intended for treatment of severe malaria

## Cancer

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### 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

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### Positive CHMP opinions on new medicines

- [Dabigatran Etxilate Accord](#) (*dabigatran etexilate*)  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 abdomen

### 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

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#### Key to symbols used

 Orphan medicine    Generic medicine    Biosimilar medicine    Conditional approval    Exceptional circumstances

## Dermatology (skin conditions)

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### New information on authorised medicines

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

## Diabetes

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### Supply shortages

- [Ozempic](#) (*semaglutide*)  
Treatment of diabetes

## Haematology (blood conditions)

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### Positive CHMP opinions on new medicines

- [Epysqli](#) (*eculizumab*)   
Treatment of paroxysmal nocturnal haemoglobinuria (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)

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### 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

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### Key to symbols used

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## HIV

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### Withdrawal of applications for new medicines

- [Raltegravir Viatris](#) (*raltegravir potassium*)  
Intended for treatment of HIV type 1 virus

## Immune system

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### Positive CHMP opinions on new medicines

- [Epysqli](#) (*eculizumab*)   
Treatment of paroxysmal nocturnal haemoglobinuria (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

- [Ultomiris](#) (*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

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### Supply shortages

- [Myalepta](#) (*metreleptin*)    
Treatment of abnormal distribution of fat in patients with a condition known as leptin deficiency

## Nephrology (kidney conditions)

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### 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

- [Ultomiris](#) (*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

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### Key to symbols used

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## Nervous system

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### 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 [Topiramate](#) (*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)

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### Arbitration procedures

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

## Respiratory system

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### 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)

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### New medicines authorised

- [Kauliv](#) (*teriparatide*)   
Treatment of osteoporosis (a disease that makes bones fragile)

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### Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

### Withdrawal of applications for new medicines

- [Onteoo \(INN\)](#)  
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

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### New information on authorised medicines

- [Wegovy \(semaglutide\)](#) - extension of indication  
Treatment of obesity

## Medicines under additional monitoring

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- [Updated list of medicines under additional monitoring](#)

## Other information

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### Scientific committee and working party activities

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- [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

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- [DARWIN EU® has completed its first studies and is calling for new data partners](#)
- [Public engagement highlights](#)

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#### Key to symbols used

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## Events

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- [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](#)

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### Key to symbols used

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## Explanation of terms used

### **O** 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.

### **G** 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')

### **B** 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)

### **C** 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.

### **E** 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.

### **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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[Healthcare professionals](#)

[European public assessment reports](#)

If you have a question relating to the content of this Newsletter, please send it via [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

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