



# HUMAN MEDICINES HIGHLIGHTS

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

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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 information on authorised medicines

- [Comirnaty](#) (*tozinameran / riltozinameran and tozinameran / famtozinameran and tozinameran / COVID-19 mRNA Vaccine (nucleoside modified)*) - conversion of conditional marketing authorisation to standard marketing authorisation  
Prevention of COVID-19
- [Spikevax](#) (previously COVID-19 Vaccine Moderna) (*elasomeran/imelasomeran and elasomeran / COVID-19 mRNA vaccine (nucleoside-modified)*) - conversion of conditional marketing authorisation to standard marketing authorisation  
Prevention of COVID-19
- [Evusheld](#) (*tixagevimab / cilgavimab*) - extension of indication  
Treatment of COVID-19
- [Veklury](#) (*remdesivir*) - extension of indication  
Treatment of COVID-19


#### Key to symbols used

Orphan medicine Generic medicine Biosimilar medicine Conditional approval Exceptional circumstances


## Antivirals/anti-infectives

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### Positive CHMP opinions on new medicines

- [Livtency](#) (*maribavir*)   
Treatment of cytomegalovirus infection

### New medicines authorised

- [Ertapenem SUN](#) (*ertapenem*)  generic of Invanz  
Treatment of different types of bacterial infections




### New information on authorised medicines

- [Vaxneuvance](#) (*pneumococcal polysaccharide conjugate vaccine (adsorbed)*) - extension of indication  
Prevention of pneumococcal infections (infections caused by bacteria called *Streptococcus pneumoniae*)


## Cancer

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### Positive CHMP opinions on new medicines

- [Sorafenib Accord](#) (*sorafenib*)  generic of Nexavar  
Treatment of hepatocellular carcinoma (a liver cancer) and renal cell carcinoma (a kidney cancer)
- [Zynlonta](#) (*loncastuximab tesirine*)    
Treatment of diffuse large B-cell lymphoma and high-grade B-cell lymphoma (blood cancers)

### New medicines authorised

- [Scemblix](#) (*asciminib*)   
Treatment of myeloid leukaemia (cancer of white blood cells) in the 'chronic' phase (this is when the condition is developing slowly and the patient has few or no symptoms)

### New information on authorised medicines

- [Brukinsa](#) (*zanubrutinib*) - new indication  
Treatment of marginal zone lymphoma (a kind of blood cancer)
- [Xalkori](#) (*crizotinib*) - new indication  
Treatment of non-small cell lung cancer, a type of lung cancer
- [Yescarta](#) (*axicabtagene ciloleuce*) - extension of indication  
Treatment of different types of blood cancers

### Withdrawal of applications for new medicines

- [Exkivity](#) (*mobocertinib*)  
Treatment of non-small cell lung cancer, a type of lung cancer
- [Sevsury](#) (*surufatinib*)  
Treatment of progressive neuroendocrine tumours, cancers which affect the cells that release hormones

### Direct Healthcare Professional Communication (DHPC)

- [Rubraca](#) (*rucaparib*): restriction of indication  
Treatment for cancers of the ovary, fallopian tubes (the tubes connecting ovaries to the uterus) or peritoneum (the membrane lining the abdomen)

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#### Key to symbols used

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## Cardiovascular system

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### Supply shortages

- [Actilyse](#) (*alteplase*)  
Treatment of myocardial infarction (heart attacks)
- [Metalyse](#) (*tenecteplase*)  
Treatment of myocardial infarction (heart attacks)

### Direct Healthcare Professional Communication (DHPC)

- [Metalyse](#) (tenecteplase) 8000 units (40 mg) and 10000 units (50 mg) powder and solvent for solution for injection: temporary supply shortage

## Dermatology (skin conditions)

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### New information on authorised medicines

- [Adtralza](#) (*tralokinumab*) - extension of indication  
Treatment of moderate to severe atopic dermatitis (also known as eczema, when the skin is itchy, red and dry)

## Diabetes

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### New medicines authorised

- [Sitagliptin / Metformin hydrochloride Accord](#) (*sitagliptin / metformin hydrochloride*)  generic of Janumet  
Treatment of type 2 diabetes

## Gynaecology & Obstetrics (pregnancy and female reproductive)

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### Supply shortages

- [Cetrotide](#) (*cetorelix acetate*)  
Prevention of premature ovulation (early release of eggs from the ovary)

### Safety update

- Review of [medicines containing nomegestrol and chlormadinone](#) - New measures to minimise risk of meningioma (a non-cancerous tumour) with medicines containing nomegestrol or chlormadinone
- Review of [Topiramate](#) - review started (Art.31)  
Risk of developmental disorders in children exposed in the womb

### Direct Healthcare Professional Communication (DHPC)

- [Cetrotide](#) (*Cetorelix acetate*) 0.25 mg Powder and solvent for injection: Temporary Shortage  
Prevention of premature ovulation (early release of eggs from the ovary)

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### Key to symbols used

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## Haematology (blood conditions)

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### Positive CHMP opinions on new medicines

- [Enjaymo](#) (*sutimlimab*)   
Treatment of haemolytic anaemia (excess destruction of red blood cells)
- [Pyrukynd](#) (*mitapivat*)   
Treatment of an inherited condition called pyruvate kinase deficiency (a red blood cell disorder)
- [Zynlonta](#) (*loncastuximab tesirine*)   
Treatment of diffuse large B-cell lymphoma and high-grade B-cell lymphoma (blood cancers)

## HIV

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### New medicines authorised

- [Sunlenca](#) (*lenacapavir*)  
Treatment of human immunodeficiency virus type 1 (HIV-1)

### New information on authorised medicines

- [Biktarvy](#) (*bictegravir / emtricitabine / tenofovir alafenamide*) - extension of indication  
Treatment of human immunodeficiency virus type 1 (HIV-1)

## Immune system

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### New medicines authorised

- [Lupkynis](#) (*voclosporin*)  
Treatment of lupus nephritis (a condition in which the body's immune system attacks the kidneys)


### New information on authorised medicines

- [Revolade](#) (*eltrombopag*) - extension of indication  
Treatment of conditions leading to low levels of platelets (thrombocytopenia) and aplastic anaemia (when the bone marrow does not make enough blood cells)
- [Skyrizi](#) (*risankizumab*) - extension of indication  
Treatment of plaque psoriasis (scaly patches on skin), psoriatic arthritis and Crohn's disease

## Metabolic disorders

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### New medicines authorised

- [Nexviadyme](#) (*Avalglucosidase alfa*)  
Treatment of Pompe disease (a rare inherited disorder caused by the lack of an enzyme called alpha-glucosidase)
- [Nulibry](#) (*fosdenopterin*)   
Treatment of molybdenum cofactor deficiency (MoCD) type A (a severe condition which affects the nervous system and is caused by changes in certain genes)

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## Nephrology (kidney conditions)

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### Safety update

- Review of [Terlipressin-containing medicinal products indicated in the treatment of hepatorenal syndrome](#) - PRAC recommendation (Art.31)  
Risk of respiratory failure (severe breathing difficulties that may be life-threatening) and sepsis (when bacteria and their toxins circulate in the blood, leading to organ damage)



### Direct Healthcare Professional Communication (DHPC)

- [Nulojix](#) (belatacept): Risk of medication errors due to change in maintenance dose from 5 mg/kg to 6 mg/kg
- [Nujolix](#) (belatacept): Further extension of the temporary restriction in supply up until 3Q 2023

## Nervous system

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### Positive CHMP opinions on new medicines

- [Melatonin Neurim](#) (*melatonin*)  
Treatment of insomnia
- [Teriflunomide Accord](#) (*teriflunomide*)  generic of Aubagio  
Treatment of multiple sclerosis
- [Teriflunomide Mylan](#) (*teriflunomide*)  generic of Aubagio  
Treatment of multiple sclerosis

## Ophthalmology (eye conditions)

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### Positive CHMP opinions on new medicines

- [Ximluci](#) (*ranibizumab*)   
treatment of several conditions affecting the retina (the light sensitive part of the eye)

### Direct Healthcare Professional Communication (DHPC)

- [Visudyne](#) (verteporfin): Information on the continuing supply limitation until end of 2023  
Treatment of degenerative myopia and macular degeneration (eye conditions that worsen over time)

## Respiratory system

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### Positive CHMP opinions on new medicines

- [Beyfortus](#) (*nirsevimab*)  
Prevention of Respiratory Syncytial Virus lower respiratory tract disease in newborns and infants

### New medicines authorised

- [Tezspire](#) (*tezepelumab*)  
Treatment of severe asthma

### Safety update

- Review of [Pholcodine-containing medicinal products](#) - review started (Art.107i)  
Treatment of non-productive (dry) cough

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## Rheumatology (immune and inflammatory conditions)

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### Positive CHMP opinions on new medicines

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

## Vaccines

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### New information on authorised medicines

- [Vaxneuvance](#) (*pneumococcal polysaccharide conjugate vaccine (adsorbed)*) - extension of indication  
Prevention of pneumococcal infections (infections caused by bacteria called *Streptococcus pneumoniae*)



## Other medicines

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### Positive CHMP opinions on new medicines

- [Pyrukynd](#) (*mitapivat*)   
Treatment of an inherited condition called pyruvate kinase deficiency (a red blood cell disorder)

### New medicines authorised

- [Mycapssa](#) (*octreotide*)   
Treatment of acromegaly (disorder that results from excess growth hormone)
- [Zokinvy](#) (*lonafarnib*)   
Treatment of Hutchinson-Gilford progeria syndrome and processing-deficient progeroid laminopathies (rare diseases in which features resembling aging appear in childhood)

### New information on authorised medicines

- [Exparel liposomal](#) (*bupivacaine*) - extension of indication  
Treatment of pain after certain operations

### Safety update

- [Amfepramone-containing medicinal products](#) - PRAC recommendation  
Treatment of obesity

## Medicines under additional monitoring

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

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# Other information

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## Guidelines

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### Guidelines open for consultation

- [Concept paper on the establishment of a guideline on the development and manufacture of synthetic peptides](#)  
Deadline for comments: 20 December 2022
- [Concept paper on the establishment of a guideline on the development and manufacture of synthetic oligonucleotides](#)  
Deadline for comments: 20 December 2022

## Scientific committee and working party activities

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- [Medicinal products for human use: monthly figures - July 2022](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines](#): September 2022
- [COMP - agendas, minutes and meetings reports](#)
- [HMPC - agendas, minutes and meetings reports](#)
- [PDCO - agendas, minutes and meeting reports](#)
- [PRAC - agendas, minutes and highlights](#)
- [PRAC statistics: September 2022](#)
- [PRAC recommendations on safety signals](#)
- [PCWP & HCPWP joint meeting](#) - 22 September 2022 - [Agenda](#)
- [Methodology Working Party](#)
- [3Rs Working Party](#)
- [Non-clinical Working Party](#)

## Other publications on COVID-19

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- [EMA recommends standard marketing authorisations for Comirnaty and Spikevax COVID-19 vaccines](#)
- [First adapted COVID-19 booster vaccines recommended for approval in the EU](#)
- [EMA starts review of conditional marketing authorisation application for Skycovion COVID-19 vaccine](#)
- [Adapted vaccine targeting BA.4 and BA.5 Omicron variants and original SARS-CoV-2 recommended for approval](#)

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- [ECDC-EMA statement on booster vaccination with Omicron adapted bivalent COVID-19 vaccines](#)
- [Composition of the Emergency Task Force \(ETF\) for the therapeutic response to the COVID-19 and Monkeypox Public Health Emergencies](#) We put this on both COVID-19 and Monkeypox, but please feel free to advise what is better.

## Other publications on Monkeypox

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- [EMA's Emergency Task Force advises on intradermal use of Imvanex / Jynneos against monkeypox | European Medicines Agency](#)
- [List of critical medicines for Monkeypox public health emergency \(PHE\) under Regulation \(EU\) 2022/123](#)
- [Composition of the Emergency Task Force \(ETF\) for the therapeutic response to the COVID-19 and Monkeypox Public Health Emergencies](#)

## Other publications

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- [Have your say on EMA's communications – how are we doing?](#)
- [New co-chairs elected for working parties for healthcare professionals and for patients and consumers](#)
- [Biosimilar medicines can be interchanged](#)
- [EMA pilot offers enhanced support to academic and non-profit developers of advanced therapy medicinal products](#)
- [CTIS Evaluation Timelines](#)
- [Key performance indicators \(KPIs\) to monitor the European clinical trials environment](#)
- [European Medicine Agency's Data Protection Notice for the Interactive Regulatory Information System \(IRIS\)](#)
- [Terms of reference of the HMA/EMA task force on availability of authorised medicines for human and veterinary use](#)
- [Decision of the Management Board on amending budget No. 01, amending appropriations in budget 2022](#)
- [Regulatory information – adjusted fees for pharmacovigilance applications from 3 October 2022](#)

## Events

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- [Risk management information day 2022](#) - 9 December 2022 - [Agenda](#)
- [EU Big Data Stakeholder Forum](#) - 1 December 2022
- [Clinical Trials Information System \(CTIS\) Webinar - 9 months on and going forward](#) - 16 November 2022 - [Agenda](#)
- [Training session for patients, consumers and healthcare professionals involved in medicine regulatory activities](#) - 17 October 2022 - [Agenda](#)
- [ACT EU multi-stakeholder meeting on decentralised clinical trials](#) - 4 October 2022 - [Agenda](#)
- [Second Industry Standing Group \(ISG\) meeting](#) - 26 September 2022

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- [Multi-stakeholder workshop: Patient experience data in medicines development and regulatory decision-making](#) - 21 September 2022 - [Agenda](#)
- [EMA regular press briefing on COVID-19 and monkeypox](#) - 20 September 2022
- [Fifth European Medicines Agency - Medicines for Europe bilateral meeting](#) - 15 September 2022 - [Agenda](#)
- [Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products \(MSSG\)](#) - 14 September 2022 - [Agenda](#)
- [Webinar on requesting access to and using EMA's substance, product, organisation and referential \(SPOR\) application programming interface \(API\)](#) - 13 September 2022
- [Product Management Services \(PMS\) Sub-Groups \(SG\) Webinar](#) - 9 September 2022
- [EMA regular press briefing on COVID-19 and monkeypox](#) - 2 September 2022
- [Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products \(MSSG\)](#) - 2 September 2022 - [Minutes](#)
- [Seventh Nitrosamines Implementation Oversight Group](#) - 14 July 2022 - [minutes](#)
- [Enpr-EMA Coordinating Group meeting](#) - 30 June 2022 - [Minutes](#)

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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.
- 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)
- 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>

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