



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

COVID-19 vaccines and treatments	1
Antivirals/anti-infectives	2
Cancer	2
Cardiovascular system	2
Dermatology	3
Diabetes	3
Gynaecology & Obstetrics	3
Haematology	3
Hepatology	3
Immune system	4
Nephrology	4
Nervous system	4
Ophthalmology	5
Respiratory system	5
Rheumatology	5
Other medicines	5
Medicines under additional monitoring	5
Other information	6
Guidelines	6
Scientific committee and working party activities	6
Other publications on Covid-19	6
Other publications	6
Events	8
Explanation of terms used	9

Key to symbols used

Orphan medicine Generic medicine Biosimilar medicine Conditional approval Exceptional circumstances

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 information on authorised medicines



- [Cominaty](#) (tozinameran / riltozinameran and tozinameran / famtozinameran and tozinameran / COVID-19 mRNA Vaccine (nucleoside modified))- extension of indication Prevention of COVID-19

New medicines authorised

- [VidPrevtyn Beta](#) (recombinant, adjuvanted)
Prevention of COVID-19 in adults

Antivirals/anti-infectives

New medicines authorised


- [Ertapenem SUN](#) (*ertapenem*)  generic of Invanz
Treatment of various infections in patients aged 3 months and above
- [Livtency](#) (*maribavir*) 
Treatment of illness caused by cytomegalovirus in adults

New information on authorised medicines

- [Xofluza](#) (*baloxavir marboxil*) - change of indication
Treatment of influenza in patients aged 1 year and above.

Cancer

New medicines authorised

- [Sorafenib Accord](#) (*sorafenib*)  generic of Nexavar
Treatment of liver and kidney cancer

New information on authorised medicines

- [Enhertu](#) (*trastuzumab deruxtecan*) - new indication
Treatment of stomach cancer
- [Imfinzi](#) (*durvalumab*) - new indication
Treatment of biliary tract cancer (cancer of the bile ducts in liver and digestive system)
- [Lynparza](#) (*olaparib*) - new indication
Treatment of a type of prostate cancer in patients who cannot have chemotherapy

Withdrawal of applications for new medicines

- [Febseftiq](#) (*infigratinib*)
Treatment of bile ducts cancer (cancer of the bile ducts in liver and digestive system)

Withdrawal of applications for extension of indication

- [Gavreto](#) (*pralsetinib*)
Treatment of certain types of thyroid cancer

Cardiovascular system

New information on authorised medicines

- [DuoPlavin](#) (*clopidogrel / acetylsalicylic acid*) - change of indication
Prevention of clotting problems after a heart attack
- [Iscover](#) (*clopidogrel*) - change of indication
Prevention of clotting problems after a heart attack
- [Plavix](#) (*clopidogrel*) - change of indication
Prevention of clotting problems after a heart attack

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Withdrawal of applications for new medicines

- [Orepaxam](#) (*treprostinil diolamine*)
Treatment of high blood pressure in the lungs

Dermatology (skin conditions)

New information on authorised medicines

- [Dupixent](#) (*dupilumab*) - new indication
Treatment of chronic skin disorder that causes itchy nodules

Diabetes

New medicines authorised

- [Mounjaro](#) (*tirzepatide*)
Treatment of type 2 diabetes

Gynaecology & Obstetrics (pregnancy and female reproductive)

Direct Healthcare Professional Communication (DHPC)

- [Nomegestrol and chlormadinone containing medicines](#) (*nomegestrol / chlormadinone*)
Contraception and treatment of gynaecological conditions

Haematology (blood conditions)

New medicines authorised


- [Cevenfacta](#) (*Eptacog beta (activated)*)
Treatment and prevention of bleeding in patients with haemophilia A and B

New information on authorised medicines

- [Ceprotin](#) (*human protein C*) - extension of indication
Prevention and treatment of clotting problems in patients with a condition known as congenital protein C deficiency

Hepatology

New medicines authorised

- [Sorafenib Accord](#) (*sorafenib*)  generic of Nexavar
Treatment of liver and kidney cancer

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Safety update

- Review of [Terlipressin-containing medicinal products indicated in the treatment of hepatorenal syndrome](#) - CMDh position (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)

Immune system

New information on authorised medicines



- [Dupixent](#) (*dupilumab*) - new indication
Treatment of chronic skin disorder that causes itchy nodules

Withdrawal of applications for extension of indication

- [Ilaris](#) (*canakinumab*)
Treatment of a rare long-term inflammatory disease causing urticaria (hives)

Nephrology (kidney conditions)

New medicines authorised



- [Sorafenib Accord](#) (*sorafenib*)   generic of Nexavar
Treatment of liver and kidney cancer

Safety update





- Review of [Terlipressin-containing medicinal products indicated in the treatment of hepatorenal syndrome](#) - CMDh position (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)

Nervous system

Positive CHMP opinions on new medicines

- [Sugammadex Amomed](#) (*sugammadex*)   generic of Bridion
Reversal of the effects of the certain muscle relaxants

New medicines authorised


- [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

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Ophthalmology (eye conditions)

New medicines authorised


- [Ximluci](#) (*ranibizumab*) 
Treatment of sight problems caused by damage to the retina

New information on authorised medicines

- [Eylea](#) (*aflibercept*) - new indication
Treatment an eye condition that can affect prematurely born babies

Respiratory system

Positive CHMP opinions on new medicines


- [Pirfenidone Viatris](#) (*pirfenidone*)  generic of Esbriet
Treatment of idiopathic pulmonary fibrosis (IPF), a condition in which fibrous scar tissue forms in the lungs

New medicines authorised

- [Bevfortus](#) (*nirsevimab*)
Prevention of serious lung disease caused by respiratory syncytial virus (RSV) in newborns

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- [Kauliv](#) (*teriparatide*) 
Treatment of osteoporosis

Safety update

- Review of [Janus Kinase inhibitors \(JAKi\)](#) (tofacitinib; abrocitinib; baricitinib; upadacitinib; filgotinib) - CHMP Opinion (Art. 20)
Risk of serious side effects (cardiovascular conditions, blood clots, cancer and serious infections)

Other medicines

Safety update

- Review of [Amfepramone-containing medicinal products](#) - CMDh position (Art.31)
Risk of serious side effects (high blood pressure in the lungs, dependency)

Medicines under additional monitoring

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

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Other information

Guidelines

Guidelines open for consultation

- [Reflection paper on criteria to be considered for the evaluation of new active substance \(NAS\) status of biological substances](#)

Deadline for comments: 31 May 2023

Scientific committee and working party activities

- Download here <https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/medicine-evaluation-figures>
- [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](#)
- [Meeting of the CTTI/FDA Patient Engagement Collaborative \(PEC\) and EMA Patients and Consumers Working Party \(PCWP\) - 15 July 2022 - Minutes](#)
- [European Medicines Agency \(EMA\) Patients' and Consumers' \(PCWP\) and Healthcare Professionals' \(HCPWP\) Working Parties meeting with all eligible organisations - 15 November 2022 - Agenda](#)

Other publications on COVID-19

- [COVID-19 vaccines safety update](#)
- [EMA recommends approval of VidPrevtyn Beta as a COVID 19 booster vaccine](#)
- [Guidance for medicine developers and other stakeholders on COVID-19](#)
- [List of critical medicines for COVID-19 public health emergency \(PHE\) under Regulation \(EU\) 2022/123](#)

Other publications

- [EMA recommends measures to minimise risk of serious side effects with Janus kinase inhibitors for chronic inflammatory disorders](#)
- [Consolidated 3-year work plan for the Non-clinical domain](#)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Applications for new human medicines under evaluation by the CHMP: 27 October 2022](#)
- [Medicinal products for human use: monthly figures - October 2022](#)
- [Regulatory update - EMA encourages companies to submit type I variations for 2022 by end of November](#)
- [Consolidated 3-year work plan for the Cardiovascular Working Party \(CVWP\)](#)
- [Composition of the Emergency Task Force \(ETF\) for the therapeutic response to the COVID-19 and Monkeypox Public Health Emergencies](#)
- [EMA confirms recommendation to withdraw marketing authorisations for amfepramone medicines](#)
- [New recommendations for terlipressin-containing medicines in the treatment of hepatorenal syndrome](#)
- [Advanced therapy classification](#)
- [Recommendations on eligibility to PRIME scheme](#)
- [Criteria to be considered for the evaluation of new active substance \(NAS\) status of biological substances](#)
- [Report - Multistakeholder workshop on EMA's extended mandate](#)
- [Ex ante publicity of a negotiated procedure: EMA/2022/15/CO – On demand supply of books \(print and digital\)](#)
- [Antimicrobial resistance - Infocards](#)
- [European Antibiotic Awareness Day 2022: Preventing antimicrobial resistance together](#)
- [Committee for Medicinal Product for Human Use: Rules of Procedure](#)
- [Best practices to fight antimicrobial resistance](#)
- [Annual Report of the Good Clinical Practice \(GCP\) Inspectors Working Group \(IWG\) 2021](#)
- [New Quality Innovation Expert Group \(QIG\) supports medicine innovation](#)
- [Key performance indicators \(KPIs\) to monitor the European clinical trials environment](#)
- [Guidance for applicants on Simultaneous National Scientific Advice \(SNSA\) Briefing book format and content](#)
- [Application form to request a Simultaneous National Scientific Advice \(SNSA\)](#)
- [Scientific Advice on medicines for Human use in the EU medicines regulatory network](#)
- [List of NCA's participating in the Simultaneous National Scientific Advice \(SNSA\) pilot phase 2](#)
- [Guidance for applicants on Simultaneous National Scientific Advice \(SNSA\) phase 2 pilot \(from October 2022\) – Optimized process](#)
- [Accelerating Clinical Trials in the EU \(ACT EU\)](#)
- [DARWIN EU welcomes first data partners](#)
- [Records of data processing activity \(public\) regarding the processing of personal data in the Clinical Trials Information System \(CTIS\)](#)
- [DARWIN EU: Data Partners onboarded in Phase I](#)
- [Training and resources for patients and consumers](#)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Events

- [Second Cancer Medicines Forum](#) - 28 June 2022 - [Minutes](#)
- [ACT EU multi-stakeholder meeting on decentralised clinical trials](#) - 4 October 2022
- [European Medicines Agency - Parenteral Drug Association \(PDA\) bilateral meeting](#) - 5 October 2022
- [Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products \(MSSG\)](#) - 5 October 2022 - [Minutes](#)
- [First European Medicines Agency - European Confederation of Pharmaceutical Entrepreneurs \(EUCOPE\) bilateral meeting](#) - 11 October 2022
- [Second bi-annual Big Data Steering Group and industry stakeholders meeting](#) - 3 November 2022
- [Seventeenth industry stakeholder platform - operation of European Union \(EU\) pharmacovigilance](#) - 7 November 2022 - [Agenda](#)
- [Human Variations eAF Form training session](#) - 8 November 2022 - [Agenda](#)
- [Human variations eAF Form \(DADI\) training session](#) - 8 November 2022
- [Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products \(MSSG\)](#) - 11 November 2022
- [European Medicines Agency \(EMA\) Patients' and Consumers' \(PCWP\) and Healthcare Professionals' \(HCPWP\) Working Parties meeting with all eligible organisations](#) - 15 November 2022
- [Second European Medicines Agency and Affordable Medicines Europe bilateral meeting](#) - 16 November 2022
- [Third Industry Standing Group \(ISG\) meeting](#) - 22 November 2022
- [Third Industry Standing Group \(ISG\) meeting](#) - 22 November 2022 - [Agenda](#)
- [EMA regular press briefing on public health emergencies](#) - 24 November 2022
- [Organisation Management System \(OMS\) Trouble Shooting Session for CTIS users](#) - 24 November 2022
- [Ninth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines](#) - 24 November 2022 - [Agenda](#)
- [Human Variations electronic application forms Q&A Clinics – Session 3 \(focus: access management\)](#) - 29 November 2022
- [EU Big Data Stakeholder Forum](#) - 1 December 2022 - [Agenda](#)
- [EMA and FATRIS webinar on support for academic and non-profit ATMP developers](#) - 1 December 2022
- [Clinical Trials Information System \(CTIS\) bitesize talk: Annual safety report \(ASR\)](#) - 15 December 2022
- [Quarterly system demo - Q4 2022](#) - 21 December 2022
- [Quality Review of Documents \(QRD\) working group plenary meeting dates](#) - year 2023

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

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>

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 www.ema.europa.eu/contact

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

An agency of the European Union

