

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 and treatments	1
Antivirals/anti-infectives	2
Cancer	2
Cardiovascular system	3
Gynaecology & Obstetrics	4
Haematology	4
HIV	4
Immune system	5
Metabolic disorders	5
Musculoskeletal system	5
Nephrology	5
Nervous system	5
Respiratory system	6
Urology	6
Vaccines	6
Other medicines	6
Medicines under additional monitoring	7
Guidelines	7
Scientific committee and working party activities	7
Other publications	8
Explanation of terms used	9

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

Information on medicines

COVID-19 vaccines and treatments

New medicines authorised

- [COVID-19 Vaccine AstraZeneca](#) (COVID-19 Vaccine (ChAdOx1-S [recombinant]))
Prevention of coronavirus disease 2019 (COVID-19)

Ongoing evaluations

- [EMA starts rolling review of CureVac's COVID-19 vaccine \(CVnCoV\)](#)
Prevention of coronavirus disease 2019 (COVID-19)
- [EMA starts rolling review of Novavax's COVID-19 vaccine \(NVX-CoV2373\)](#)
Prevention of coronavirus disease 2019 (COVID-19)
- [EMA starts evaluating use of Veklury in COVID-19 patients not requiring supplemental oxygen](#)
Prevention of coronavirus disease 2019 (COVID-19)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [EMA starts rolling review of Celltrion antibody regdanvimab for COVID-19](#)
Treatment of coronavirus disease 2019 (COVID-19)
- [EMA reviewing data on monoclonal antibody use for COVID-19 \(casirivimab, imdevimab, bamlanivimab and etesevimab\)](#)
Treatment of coronavirus disease 2019 (COVID-19)

Safety update

- [COVID-19 vaccine safety update for COVID-19 Vaccine Moderna: February 2021](#)
Prevention of coronavirus disease 2019 (COVID-19)
- [REGN-COV2 antibody combination \(casirivimab / imdevimab\) - CHMP Opinion \(EMA issues advice on use of REGN-COV2 antibody combination\)](#)
Treatment of coronavirus disease 2019 (COVID-19)

Antivirals/anti-infectives

New medicines authorised







- [Rukobia \(fostemsavir\)](#)
Treatment of HIV-1

New information on authorised medicines






- [Quofenix \(delafloxacin\)](#) - extension of indication
Treatment of community-acquired pneumonia (CAP)
- [Sirturo \(bedaquiline\)](#) - extension of indication
Treatment of pulmonary multidrug-resistant tuberculosis (MDR-TB) in paediatric patients




Cancer

Positive CHMP opinions on new medicines





- [Abevmy \(bevacizumab\)](#) 
Treatment of colon or rectum cancer, breast cancer, non-small cell lung cancer, renal cell cancer, ovarian cancer, fallopian tube cancer, primary peritoneal cancer and cervical cancer
- [Abiraterone Accord \(abiraterone\)](#)  generic of Zytiga
Treatment of prostate cancer
- [Alymsys \(bevacizumab\)](#) 
Treatment of colon or rectum cancer, breast cancer, non-small cell lung cancer, renal cell cancer, ovarian cancer, fallopian tube cancer, primary peritoneal cancer and cervical cancer
- [Jemperli \(dostarlimab\)](#) 
Treatment of endometrial cancer (uterus or womb lining)
- [Lextemy \(bevacizumab\)](#) 
Treatment of colon or rectum cancer, breast cancer, non-small cell lung cancer, renal cell cancer, ovarian cancer, fallopian tube cancer, primary peritoneal cancer and cervical cancer
- [Nexpovio \(selinexor\)](#) 
Treatment of multiple myeloma (cancer of the bone marrow)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Oyavas](#) (*bevacizumab*)  Treatment of colon or rectum cancer, breast cancer, non-small cell lung cancer, renal cell cancer, ovarian cancer, fallopian tube cancer, primary peritoneal cancer and cervical cancer
- [Pemazyre](#) (*pemigatinib*)  Treatment of cholangiocarcinoma (bile duct cancer)
- [Thiotepa Riemser](#) (*thiotepa*)  generic of Tepadina
Treatment prior to blood-stem cell transplantation

New medicines authorised

- [Enhertu](#) (*trastuzumab deruxtecan*)  Treatment of metastatic breast cancer
- [Lenalidomide KrKa](#) (*lenalidomide*)  generic of Revlimid
Treatment of multiple myeloma and follicular lymphoma (blood cancers)
- [Lenalidomide KrKa d.d.](#) (*lenalidomide*)  generic of Revlimid
Treatment of multiple myeloma, myelodysplastic syndromes, and follicular lymphoma (blood cancers)
- [Lenalidomide KrKa d.d. Novo mesto](#) (*lenalidomide*)  generic of Revlimid
Treatment of multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma and follicular lymphoma (blood cancers)
- [Tukysa](#) (*tucatinib*)
Treatment of locally advanced or metastatic breast cancer

New information on authorised medicines

- [Cabometyx](#) (*cabozantinib*) - extension of indication
Treatment of advanced renal cell carcinoma (kidney cancer)
- [Opdivo](#) (*nivolumab*) - extension of indication
Treatment of advanced renal cell carcinoma (kidney cancer)
- [Keytruda](#) (*pembrolizumab*) - extension of indication
Treatment of advanced Hodgkin lymphoma (blood cancer)
- [Sarclisa](#) (*isatuximab*) - extension of indication
Treatment of multiple myeloma (blood cancer)

Withdrawal of applications for new medicines





- [Tecentriq](#) (*atezolizumab*)
Intended for the treatment of metastatic urothelial cancer (cancer of the bladder and urinary system)

Cardiovascular system

Positive CHMP opinions on new medicines


- [Vazkepa](#) (*icosapent ethyl*)
Prevention of cardiovascular events

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances



Gynaecology & Obstetrics (pregnancy and female reproductive)

Positive CHMP opinions on new medicines




- [Jemperli](#) (*dostarlimab*)  Treatment of endometrial cancer (uterus or womb lining)

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- [Nexpvio](#) (*selinexor*)  Treatment of multiple myeloma (cancer of the bone marrow)
- [Thiotepa Riemser](#) (*thiotepa*)  generic of Tepadina Treatment prior to blood-stem cell transplantation

New medicines authorised

- [Lenalidomide KrKa](#) (*lenalidomide*)  generic of Revlimid Treatment of multiple myeloma and follicular lymphoma (blood cancers)
- [Lenalidomide KrKa d.d.](#) (*lenalidomide*)  generic of Revlimid Treatment of multiple myeloma, myelodysplastic syndromes, and follicular lymphoma (blood cancers)
- [Lenalidomide KrKa d.d. Novo mesto](#) (*lenalidomide*)  generic of Revlimid Treatment of multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma and follicular lymphoma (blood cancers)

New information on authorised medicines

- [Sarclisa](#) (*isatuximab*) - extension of indication Treatment of multiple myeloma (blood cancer)

Withdrawal of authorised medicines

- [Udenyca](#) (*pegfilgrastim*) Treatment of neutropenia (low level of white blood cells)

Other information

- [Precautionary marketing suspension of thalassaemia medicine Zyteglo](#) (*betibeglogene autotemcel*)

Direct Healthcare Professional Communication (DHPC)


- [Lojuxta \(lomitapide\): Reminder to monitor the liver function of patients treated with Lojuxta and to avoid use in pregnancy](#)

HIV

New medicines authorised


- [Rukobia](#) (*fostemsavir*) Treatment of HIV-1

Key to symbols used


 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Immune system

Positive CHMP opinions on new medicines



- [Orladeyo](#) (*berotralstat*) 
Prevention of hereditary angioedema (swelling beneath the skin)
- [Seffalair Spiromax](#) / [BroPair Spiromax](#) (*salmeterol / fluticasone*)
Treatment of asthma

New medicines authorised

- [Yuflyma](#) (*adalimumab*) 
Treatment of inflammatory and autoimmune disorders


Metabolic disorders

Positive CHMP opinions on new medicines

- [Pemazyre](#) (*pemigatinib*) 
Treatment of cholangiocarcinoma (bile duct cancer)
- [Sogroya](#) (*somapacitan*) 
Treatment of growth hormone deficiency

Musculoskeletal system

Positive CHMP opinions on new medicines

- [Ervysdi](#) (*risdiplam*) 
Treatment of spinal muscular atrophy (muscle weakness)

Nephrology (kidney conditions)

New information on authorised medicines

- [Cabometyx](#) (*cabozantinib*) - extension of indication
Treatment of advanced renal cell carcinoma (kidney cancer)
- [Opdivo](#) (*nivolumab*) - extension of indication
Treatment of advanced renal cell carcinoma (kidney cancer)

Direct Healthcare Professional Communication (DHPC)




- [Risk of acute adrenal insufficiency when switching from crushed or compounded oral hydrocortisone formulations to Alkindi \(hydrocortisone granules in capsules for opening\)](#)

Nervous system

Positive CHMP opinions on new medicines

- [Kesimpta](#) (*ofatumumab*)
Treatment of multiple sclerosis

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Ontozry](#) (*cenobamate*)
Treatment of epilepsy

New information on authorised medicines

- [Epidyolex](#) (*cannabidiol*) - extension of indication
Prevention of seizures
- [Tysabri](#) (*natalizumab*) - extension of indication
Treatment of multiple sclerosis

Respiratory system

Positive CHMP opinion

- [Seffalair Spiromax](#) / [BroPair Spiromax](#) (*salmeterol / fluticasone*)
Treatment of asthma

Negative CHMP opinion on extension of indication


- [Elebrato Ellipta](#) / [Temybric Ellipta](#) / [Trelegy Ellipta](#) (*fluticasone furoate / umecclidinium / vilanterol*)
Intended for the treatment of asthma

Direct Healthcare Professional Communication (DHPC)

- [Respreeza \(human alpha-1-proteinase inhibitor\): batch-specific product recall](#)

Urology (urinary tract conditions)

Positive CHMP opinions on new medicines

- [Abiraterone Accord](#) (*abiraterone*)  generic of Zytiga
Treatment of prostate cancer

Vaccines

New information on authorised medicines

- [Vaxchora](#) (Cholera vaccine) - extension of indication
Immunisation against cholera from 2 years of age

Product update






- Review of [Varilrix](#) (*live attenuated varicella virus (OKA strain)*) - CHMP (changes to the prescribing information)
Prevention of varicella (chickenpox)

Other medicines

Positive CHMP opinions on new medicines

- [Byfavo](#) (*remimazolam*)
Used for procedural sedation

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Safety update

- Review of [amfepramone-containing medicinal products](#) - review (following concerns that require further evaluation)
Treatment of obesity

Medicines under additional monitoring

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

Other information

Guidelines

Guidelines open for consultation

- [Draft toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME marketing authorisation applications](#)
Deadline for comments: 31 July 2021

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - January 2021](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines under evaluation by the CHMP: February 2021](#)
- [COMP - agendas, minutes and meetings reports](#)
- [COMP work plan 2021](#)
- [COMP meeting report on the review of applications for orphan designation: January 2021](#)
- [HMPC - agendas, minutes and meetings reports](#)
- [PDCO - agendas, minutes and meeting reports](#)
- [PRAC - agendas, minutes and highlights](#)
- [PRAC recommendations on safety signals](#)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances






Other publications

- [Pilot phase for CHMP early contact with patient / consumer organisations](#)
- [Adapting COVID-19 vaccines to SARS-CoV-2 variants: guidance for vaccine manufacturers](#)
- [International cooperation to align approaches for regulation of COVID-19 vaccines and medicines](#)
- [International regulators working together to enhance collaboration on COVID-19 observational research](#)

Events

- [Public stakeholder meeting: approval, safety monitoring and impact of COVID-19 vaccines in the EU](#) -
26 March 2021 - virtual meeting

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.

I 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:

[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

