

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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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

Ongoing evaluations

- [COVID-19 treatments: under evaluation](#)
- [EMA starts review of VIR-7831 for treating patients with COVID-19](#)
- [EMA starts evaluating use of Olumiant in hospitalised COVID-19 patients requiring supplemental oxygen](#)

Safety update

- [COVID-19 vaccine safety update for COVID-19 Vaccine Janssen: 22 April 2021](#)
- [COVID-19 Vaccine Janssen: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets](#)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [AstraZeneca's COVID-19 vaccine: EMA to provide further context on risk of very rare blood clots with low blood platelets](#)

Direct Healthcare Professional Communication (DHPC)

- Direct healthcare professional communication (DHPC): [COVID-19 Vaccine Janssen: link between the vaccine and the occurrence of thrombosis in combination with thrombocytopenia](#)
- Direct healthcare professional communication (DHPC): [Vaxzevria \(previously COVID-19 Vaccine AstraZeneca\): link between the vaccine and the occurrence of thrombosis in combination with thrombocytopenia](#)


Antivirals/anti-infectives

New information on authorised medicines



- [Maviret](#) (*glecaprevir / pibrentasvir*) - extension of indication
Treatment of chronic hepatitis C in children aged 3 years and older

Cancer

Positive CHMP opinions on new medicines

- [Abiraterone Krka](#) (*abiraterone acetate*)  generic of Zytiga
Treatment of prostate cancer
- [Onureg](#) (*azacitidine*)
Treatment of acute myeloid leukemia (blood cancer)

New medicines authorised

- [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
- [Sunitinib Accord](#) (*sunitinib*)  generic of Sutent
Treatment of metastatic cancers of the breast, kidneys and pancreas

New information on authorised medicines

- [Opdivo](#) (*nivolumab*) - new indication
Treatment of pleural mesothelioma (cancer of the lung lining)
- [Tagrisso](#) (*osimertinib*) - new indication
Treatment of non-small cell lung cancer
- [Venclyxto](#) (*venetoclax*) - new indication
Treatment of acute myeloid leukaemia (blood cancer)
- [Yervoy](#) (*ipilimumab*) - new indication
Treatment of pleural mesothelioma (cancer of the lung lining)

Key to symbols used

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Cardiovascular system

Positive CHMP opinions on new medicines

- [Evkeeza](#) (*evinacumab*)
Treatment of high levels of cholesterol (a type of fat in the blood)

New medicines authorised

- [Vazkepa](#) (*icosapent ethyl*)
Prevention of cardiovascular events, such as heart attack and stroke

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

- [Adtralza](#) (*tralokinumab*)
Treatment of atopic dermatitis (inflammation of the skin)

Haematology (blood conditions)

Positive CHMP opinions on new medicines


- [Onureg](#) (*azacitidine*)
Treatment of acute myeloid leukemia (blood cancer)

New information on authorised medicines

- [Venclyxto](#) (*venetoclax*) - new indication
Treatment of acute myeloid leukaemia (blood cancer)

Immune system

Positive CHMP opinions on new medicines

- [Ensprynq](#) (*satralizumab*) 
Treatment of neuromyelitis optica spectrum disorders (inflammatory disorders of spinal cord and main nerve of the eye)
- [Adtralza](#) (*tralokinumab*)
Treatment of atopic dermatitis (inflammation of the skin)
- [Jayempi](#) (*azathioprine*)
Prevention of transplant rejection

New medicines authorised

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

New information on authorised medicines

- [BiResp Spiromax](#) and [DuoResp Spiromax](#) (*budesonide / formoterol*) - extension of indication
Treatment of asthma in adolescents (12 years and older)


Key to symbols used

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- [Nulojix](#) (*belatacept*) - extension of indication
Prevention of kidney transplant rejection

Metabolic disorders

New medicines authorised





- [Sogroya](#) (*somapacitan*) 
Treatment of growth hormone deficiency

Nephrology (kidney conditions)

- [Nulojix](#) (*belatacept*) - extension of indication
Prevention of kidney transplant rejection

Nervous system

Positive CHMP opinions on new medicines

- [Ensprynq](#) (*satralizumab*) 
Treatment of neuromyelitis optica spectrum disorders (inflammatory disorders of spinal cord and main nerve of the eye)
- [Koselugo](#) (*selumetinib*)  
Treatment of children with neurofibromatosis (disorder of the nervous system affecting development of nerve cell tissues)
- [Celsunax](#) (*ioflupane (123I)*) 
Diagnostic agent for parkinsonian syndromes and dementia

New medicines authorised


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

New information on authorised medicines

- [Aubagio](#) (*teriflunomide*) - extension of indication
Treatment of multiple sclerosis

Ophthalmology (eye conditions)



Positive CHMP opinions on new medicines

- [Ensprynq](#) (*satralizumab*) 
Treatment of neuromyelitis optica spectrum disorders (inflammatory disorders of spinal cord and main nerve of the eye)

Direct Healthcare Professional Communication (DHPC)

- Direct healthcare professional communication (DHPC): [Eylea 40 mg/mL \(aflibercept solution for intravitreal injection\): Higher risk of intraocular pressure increase with the pre-filled syringe](#)

Key to symbols used

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Respiratory system

New medicines authorised

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

New information on authorised medicines

- [BiResp Spiromax](#) and [DuoResp Spiromax](#) (*budesonide / formoterol*) - extension of indication
Treatment of asthma in adolescents (12 years and older)
- [Opdivo](#) (*nivolumab*) - new indication
Treatment of pleural mesothelioma (cancer of the lung lining)
- [Tagrisso](#) (*osimertinib*) - new indication
Treatment of non-small cell lung cancer
- [Yervoy](#) (*ipilimumab*) - new indication
Treatment of pleural mesothelioma (cancer of the lung lining)

Other medicines

New medicines authorised

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

Medicines under additional monitoring

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

Other information

Guidelines






Adopted guidelines

- [Dasatinib product-specific bioequivalence guidance](#)

Other scientific recommendations

- [Classification of advanced therapy medicinal products \(ATMs\)](#)

Key to symbols used

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Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - March 2021](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: April 2021](#)
- [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](#)

COVID-19

- [EMA and ECDC join forces for enhanced post-marketing monitoring of COVID-19 vaccines in Europe](#)
- [Increase in vaccine manufacturing capacity and supply for COVID-19 vaccines from BioNTech/Pfizer and Moderna](#)
- [AstraZeneca's COVID-19 vaccine: benefits and risks in context](#)


Other publications

- [Academia collaboration matrix action plan 2021-2023](#)
- [Clinical Trials Information System reaches major milestone towards go-live and application of the Clinical Trial Regulation](#)
- [Stakeholder engagement highlights 2020](#)

Events

- [EMA press briefing to update on analysis of data on Vaxzevria, the COVID-19 vaccine from AstraZeneca](#)
- Virtual meeting - 23 April 2021
- [Risk management information day 2021](#)
- Virtual meeting - 15 June 2021

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.

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<http://www.ema.europa.eu>

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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

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