



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

Positive CHMP opinions on new medicines

- [Comirnaty](#) (COVID-19 mRNA vaccine (nucleoside-modified))
Prevention of coronavirus disease 2019 (COVID-19)


Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- [Heplisav B](#) (hepatitis B surface antigen)
Intended for the active immunisation against hepatitis B virus infection

Key to symbols used

Orphan medicine Generic medicine Biosimilar medicine Conditional approval Exceptional circumstances

- [Inrebic](#) (*fedratinib*)  Treatment of primary myelofibrosis and of myelofibrosis secondary to polycythaemia vera or essential thrombocythaemia (blood disorders)
- [Rukobia](#) (*fostemsavir*) Treatment of HIV-1

New information on authorised medicines









- [Veklury](#) (*remdesivir*) - change of indication
Treatment of coronavirus disease 2019 (COVID-19) in patients with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment).

Supply shortages



- [Zerbaxa](#) (*ceftolozane / tazobactam*)
Treatment of severe bacterial infections
- Direct healthcare professional communication (DHPC): [GLOBAL RECALL: Zerbaxa \(ceftolozane / tazobactam\) 1 g/0.5 g powder for concentrate for solution for infusion](#)

Cancer

Positive CHMP opinions on new medicines




- [Enhertu](#) (*trastuzumab deruxtecan*)  Treatment of metastatic breast cancer
- [Lenalidomide KrKa](#) (*lenalidomide*)  generic of Revlimid
Treatment of multiple myeloma and follicular lymphoma (blood cancer)
- [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)
- [Lumoxiti](#) (*moxetumomab pasudotox*)   Treatment of relapsed or refractory hairy cell leukaemia (blood cancer)
- [Retsevmo](#) (*selpercatinib*)  Treatment of cancers that display rearranged during transfection (RET) gene alterations: RET-fusion positive non-small cell lung cancer (NSCLC), RET-fusion positive thyroid cancer and RET-mutant medullary-thyroid cancer (MTC)
- [Sunitinib Accord](#) (*sunitinib*)  generic of Sutent
Treatment of metastatic cancers of the breasts, kidneys and pancreas
- [Tukysa](#) (*tucatinib*)
Treatment of locally advanced or metastatic breast cancer

New medicines authorised

- [Blenrep](#) (*belantamab mafodotin*)   Treatment of relapsed and refractory multiple myeloma (blood cancer)

New information on authorised medicines

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Bavencio](#) (*avelumab*) - new indication
Treatment of Merkel cell carcinoma (a type of skin cancer)
- [Keytruda](#) (*pembrolizumab*) - new indication
Treatment of several types of cancers

Cardiovascular system

New information on authorised medicines

- [Doptelet](#) (*avatrombopag*) - new indication
Treatment of severe thrombocytopenia (low level of blood platelets) in patients with chronic liver disease
- [Iscover](#) (*clopidogrel*) - new indication
Treatment and prevention of blood clots
- [Plavix](#) (*clopidogrel*) - new indication
Treatment and prevention of blood clots







Diabetes

Positive CHMP opinions on new medicines

- [Kixelle](#) (*insulin aspart*)
Treatment of diabetes mellitus
- [Ogluo](#) (*glucagon*)
Treatment of severe hypoglycaemia (low blood glucose levels) in diabetes mellitus

Haematology (blood conditions)






Positive CHMP opinions on new medicines

- [Inrebic](#) (*fedratinib*) 
Treatment of primary myelofibrosis and of myelofibrosis secondary to polycythaemia vera or essential thrombocythaemia
- [Lenalidomide KrKa](#) (*lenalidomide*)  generic of Revlimid
Treatment of multiple myeloma and follicular lymphoma (blood cancers)
- [Lenalidomide KrKa d.d.](#) (*lenalidomide*)  generic of Revlimid
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Treatment of multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma and follicular lymphoma (blood cancers)
- [Lumoxiti](#) (*moxetumomab pasudotox*)  
Treatment of relapsed or refractory hairy cell leukaemia (blood cancer)

New information on authorised medicines

- [Nplate](#) (*romiplostim*) - extension of indication
Treatment of patients with long-term immune thrombocytopenic purpura (ITP), a disease in which the patient's immune system destroys platelets (components in the blood that help it to clot)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Hepatology (liver conditions)

New information on authorised medicines

- [Doptelet](#) (*avatrombopag*) - new indication
Treatment of severe thrombocytopenia (low level of blood platelets) in patients with chronic liver disease


HIV

Positive CHMP opinions on new medicines

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

Immune system

Positive CHMP opinions on new medicines

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

New information on authorised medicines

- [Nordimet](#) (*methotrexate*) - new indication
Treatment of inflammatory conditions such as arthritis (inflammatory condition of joints), psoriasis (scaly patches on skin) and Chron's disease (inflammatory bowel disease)
- [Nplate](#) (*romiplostim*) - extension of indication
Treatment of patients with long-term immune thrombocytopenic purpura (ITP), a disease in which the patient's immune system destroys platelets (components in the blood that help it to clot)
- [Palforzia](#) (*defatted powder of *Arachis hypogaea* L., semen (peanuts)*)
Treatment for desensitising children and adolescents to peanut allergy
- [Rinvog](#) (*upadacitinib*) - extension of indication
Treatment of rheumatoid arthritis, a disease that causes inflammation of the joints


Musculoskeletal system

Withdrawal of applications for new medicines






- [Artobend](#) (*autologous human chondrocytes in vitro expanded*)
Intended to repair defects in the cartilage of the knee

Nervous system

New medicines authorised

- [Libmeldy](#) (*autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene*) 
Treatment of children with metachromatic leukodystrophy (a rare inherited metabolic disease that affects the nervous system)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

New information on authorised medicines

- [Spravato](#) (*esketamine*) - extension of indication
Treatment of depressive disorder

Safety update

- Direct healthcare professional communication (DHPC): [Important information on Gliolan \(5-aminolevulinic acid, 5-ALA\): What to do in case of delayed surgery and information on fluorescence in non high-grade glioma](#)

Rheumatology (immune and inflammatory conditions)

New information on authorised medicines

- [Nordimet](#) (*methotrexate*) - new indication
Treatment of inflammatory conditions such as arthritis (inflammatory condition of joints), psoriasis (scaly patches on skin) and Chron's disease (inflammatory bowel disease)
- [Rinvog](#) (*upadacitinib*) - extension of indication
treatment of rheumatoid arthritis, a disease that causes inflammation of the joints

Withdrawal of applications for new medicines


- [Artobend](#) (*autologous human chondrocytes in vitro expanded*)
Intended to repair defects in the cartilage of the knee

Safety update

- Direct healthcare professional communication (DHPC): [Metamizole: Risk of drug-induced liver injury](#)

Urology (urinary tract conditions)

Positive CHMP opinions on new medicines

- [Sibnaval](#) (*potassium citrate / potassium hydrogen carbonate*) 
Treatment of distal renal tubular acidosis (rare type of kidney disease)

Vaccines

Positive CHMP opinions on new medicines

- [Heplisav B](#) (*hepatitis B surface antigen*)
Intended for the active immunisation against hepatitis B virus infection

Safety update

- Review of [Varilrix](#) (*live attenuated varicella virus (OKA strain)*) - under evaluation (Art.30)
Used for protecting individuals against varicella (chickenpox)

Key to symbols used

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Other medicines

New medicines authorised

- [Exparel](#) (*bupivacaine*)
Treatment of post-operative pain

Medicines under additional monitoring

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

Other information

Guidelines

Guidelines open for consultation

- Title: [ICH reflection paper on proposed ICH guideline work to advance patient focused drug Development](#)
Deadline for comments: 7 March 2021



Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - November 2020](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: December 2020](#)
- [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 organises a first public meeting about the new COVID-19 vaccines](#)
- [EMA recommends first COVID-19 vaccine for authorisation in the EU](#)
- [EMA organises a second public meeting about the new COVID-19 vaccines](#)
- [Update on rolling review of AstraZeneca's COVID-19 vaccine](#)

Key to symbols used






-  Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Update on assessment of the BioNTech and Pfizer BNT162b2 vaccine marketing authorisation application](#)
- [EMA receives application for conditional marketing authorisation of COVID-19 mRNA vaccine BNT162b2](#)
- [EMA receives application for conditional marketing authorisation of Moderna COVID-19 vaccine](#)
- [Update on assessment of marketing authorisation application for Moderna's mRNA-1273 COVID-19 vaccine](#)
- [EMA starts rolling review of Janssen's COVID-19 vaccine Ad26.COV2.S](#)
- [EMA speaking points for update on COVID-19 vaccines: Informal videoconference of the Ministers of Health on 2 December 2020](#)

Other publications

- [EMA Management Board: highlights of December 2020 meeting](#)
- [109th Management Board meeting](#) - Virtual meeting - 1 October 2020: [Minutes](#)
- [Stakeholder engagement report 2018-2019](#)
- [Joint strategy sets direction for EMA and EU medicines regulatory agencies to 2025](#) - [Report](#)
- [Analysis and summaries of public consultation results - European Medicines Agencies Network Strategies to 2025](#)
- [Privacy Statement concerning European Medicines Agency's public stakeholder meetings on COVID-19 vaccines](#)
- [Letter from EMA on conditions for making available reports of suspected adverse reactions by EMA to WHO/UMC](#)
- [Response from WHO to letter from EMA on conditions for making available reports of suspected adverse reactions by EMA to WHO/UMC](#)
- [Response from UMC to letter from EMA on conditions for making available reports of suspected adverse reactions by EMA to WHO/UMC](#)
- [Cyberattack on the European Medicines Agency](#)
- [Cyberattack on EMA - update 1](#)
- [Cyberattack on EMA - update 2](#)
- [Cyberattack on EMA - update 3](#)
- [EMA working on COVID-19 and Brexit over holiday period](#)






Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Events

- [Public stakeholder meeting on the approval and roll-out of COVID-19 vaccines in the EU](#) - Virtual meeting - 8 January
- [Press briefing on EU recommendation on first COVID-19 vaccine](#) - Virtual meeting - 21 December 2020
- [Extraordinary meeting of the Committee for Medicinal Products for Human Use \(CHMP\)](#) - 21 December 2020
- [Industry stakeholder webinar on the UK withdrawal from the European Union - End of transition period](#) - Virtual meeting - 30 November 2020 - [Report](#)

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.



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)



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.



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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