



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 and treatments

New information on authorised medicines

- [Spikevax: EMA recommendation on booster](#)
- [Comirnaty and Spikevax: EMA recommendations on extra doses and boosters](#)

Safety update

- [COVID-19 vaccine safety update for Comirnaty: 6 October 2021](#)
- [COVID-19 vaccine safety update for COVID-19 Vaccine Janssen: 6 October 2021](#)
- [COVID-19 vaccine safety update for Vaxzevria \(previously COVID-19 Vaccine AstraZeneca\): 6 October 2021](#)
- [COVID-19 vaccine safety update for Spikevax \(previously COVID-19 Vaccine Moderna\): 6 October 2021](#)

Key to symbols used


Orphan medicine
 Generic medicine
 Biosimilar medicine
 Conditional approval
 Exceptional circumstances

Direct Healthcare Professional Communication (DHPC)



- [Vaxzevria \(previously COVID-19 Vaccine AstraZeneca\)](#): risk of thrombocytopenia (including immune thrombocytopenia) with or without associated bleeding
- [COVID-19 Vaccine Janssen](#): Risk for immune thrombocytopenia (ITP) and venous thromboembolism (VTE)

Cancer

Positive CHMP opinions on new medicines

- [Rybrevant](#) (*amivantamab*)  Treatment of non-small cell lung cancer
- [Trodelvy](#) (*sacituzumab govitecan*) Treatment of triple-negative breast cancer

New medicines authorised

- [Imatinib Koanaa](#) (*imatinib*)  generic of Glivec
Treatment of blood cancers and gastrointestinal stromal tumours (tumours in the gut)
- [Koselugo](#) (*selumetinib*)  Treatment of plexiform neurofibromas, (non-cancerous tumours along the nerves)

New information on authorised medicines

- [Keytruda](#) (*pembrolizumab*) - extension of indication
Treatment of several types of cancers
- [Kisplyx](#) (*lenvatinib*) - extension of indication
Treatment of adults with advanced renal cell carcinoma (kidney cancer)
- [Lenvima](#) (*lenvatinib*) - new indication
Treatment of cancer of the lining of the womb

Withdrawal of applications for new medicines

- [Zynyz](#) (*retifanlimab*)
Intended for the treatment of squamous carcinoma of the anal canal, a cancer of the tissues of the anus

Cardiovascular system

New information on authorised medicines


- [Repatha](#) (*evolocumab*) - change of indication
Treatment of hypercholesterolaemia (high levels of blood cholesterol) and dyslipidaemia (abnormal levels of fats, including cholesterol)

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

- [Cibinqo](#) (*abrocitinib*)
Treatment of atopic dermatitis (inflammation of the skin)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

New information on authorised medicines


- [Skyrizi](#) (*risankizumab*) - new indication
Treatment of plaque psoriasis (scaly patches on skin)

Safety update

- [Lidocain/Prilocain Idetec and associated names](#) - CHMP Opinion
Intended for preventing pain during minor surgical or medical procedures, and for the treatment of leg ulcers

Diabetes

Positive CHMP opinions on new medicines


- [Sitagliptin SUN](#) (*sitagliptin fumarate*)  generic of Januvia
Treatment of type 2 diabetes mellitus

New information on authorised medicines

- [Forxiga](#) and [Edistride](#) (*dapagliflozin*) - extension of indication
Treatment of type 1 and 2 diabetes mellitus

Gastro-intestinal system

New medicines authorised

- [Imatinib Koanaa](#) (*imatinib*)  generic of Glivec
Treatment of blood cancers and gastrointestinal stromal tumours (tumours in the gut)

Gynaecology & Obstetrics (pregnancy and female reproductive)

Safety update


- Review of [Nomegestrol and chlormadinone](#) - review started - Art. 31
Treatment of gynaecological disorders and for use as hormone replacement therapy or contraception.

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- [Aspaveli](#) (*pegcetacoplan*)
Treatment of paroxysmal nocturnal haemoglobinuria (a condition where there is an excessive breakdown of red blood cells)

New medicines authorised

- [Imatinib Koanaa](#) (*imatinib*)  generic of Glivec
Treatment of blood cancers and gastrointestinal stromal tumors

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

New information on authorised medicines

- [Hizentra](#) (*human normal immunoglobulin (SCIg)*) - extension of indication
Treatment of immunologic deficiency syndromes (conditions where levels of antibodies in the blood are too low)

Immune system

Positive CHMP opinions on new medicines

- [Cibingo](#) (*abrocitinib*)
Treatment of atopic dermatitis (inflammation of the skin)

New information on authorised medicines

- [Hizentra](#) (*human normal immunoglobulin (SCIg)*) - extension of indication
Treatment of immunologic deficiency syndromes (conditions where levels of antibodies in the blood are too low)
- [Skyrizi](#) (*risankizumab*) - new indication
Treatment of plaque psoriasis (scaly patches on skin)
- [Xeljanz](#) (*tofacitinib*) - extension of indication
Treatment of rheumatoid arthritis and psoriatic arthritis


Nervous system

New information on authorised medicines

- [Zeposia](#) (*ozanimod*) - extension of indication
Treatment of multiple sclerosis

Respiratory system

Positive CHMP opinions on new medicines

- [Rybrevant](#) (*amivantamab*) 
Treatment of non-small cell lung cancer

Rheumatology (immune and inflammatory conditions)

New information on authorised medicines

- [Xeljanz](#) (*tofacitinib*) - extension of indication
Treatment of rheumatoid arthritis and psoriatic arthritis

Vaccines

Positive CHMP opinions on new medicines

- [Vaxneuvance](#) (*pneumococcal polysaccharide conjugate vaccine (adsorbed)*)
Intended for prophylaxis against pneumococcal pneumonia and associated invasive disease

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Medicines under additional monitoring

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

Other information

Guidelines

Guidelines open for consultation

- [ICH guideline M7 on assessment and control of DNA reactive \(mutagenic\) impurities in pharmaceuticals to limit potential carcinogenic risk - Addendum - Step 2b](#)
Deadline for comments: 8 December 2021
- [Reflection paper on the interpretation of Article 72 of Regulation \(EU\) 2019/6 - Environmental safety documentation and environmental risk assessment of certain veterinary medicinal products](#)
Deadline for comments: 31 January 2022
- [Concept paper on scientific guidelines for limited market products deemed not eligible for authorisation under Article 23 of Regulation 2019/6](#)
Deadline for comments: 15 December 2021

Adopted guidelines

- [Guideline on registry-based studies](#)


Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - September 2021](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: October 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 statistics: November 2021](#)
- [PRAC recommendations on safety signals](#)
- [Annual Patients and Consumers Working Party \(PCWP\) and Healthcare Professionals Working Party \(HCPWP\) meeting with all eligible organisations](#), virtual meeting, 24 November 2021 - [Agenda](#)

Other information on COVID-19

- [COVID-19: EMA starts rolling review of molnupiravir](#)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [EMA starts evaluating use of COVID-19 vaccine Comirnaty in children aged 5 to 11](#)
- [EMA starts rolling review of Evusheld \(tixagevimab and cilgavimab\)](#)
- [EMA receives application for marketing authorisation for Ronapreve \(casirivimab / imdevimab\) for treatment and prevention of COVID-19](#)
- [EMA receives application for marketing authorisation for Regkirona \(regdanvimab\) for treating patients with COVID-19](#)
- [EMA ends rolling review of CVnCoV COVID-19 vaccine following withdrawal by CureVac AG](#)
- [A global approach to regulatory flexibility to increase manufacturing capacity during COVID-19](#)
- [New manufacturing sites and new formulation approved for COVID-19 vaccine from BioNTech/Pfizer](#)
- [Additional manufacturing site for COVID-19 Vaccine Janssen](#)
- [EMA working on COVID-19 during closure on 1 and 2 November 2021](#)

Other publications

- [EMA mid-year report 2021](#)
- [Highlights of Management Board – October 2021 meeting](#)
- [Agenda for the 113th meeting of the Management Board](#)
- [EMA welcomes new Head of International Affairs](#)
- [Regulatory update - EMA encourages companies to submit type I variations for 2021 in November 2021](#)
- [Letter of support for International Niemann-Pick Disease Registry \(INPDR\)](#)
- [Final feedback from European Medicine Agency \(EMA\) to the EU Commission request to evaluate the impact of the removal of titanium dioxide from the list of authorised food additives on medicinal products](#)
- [Repurposing of authorised medicines: pilot to support not-for-profit organisations and academia](#)

Events

- [Public stakeholder meeting on COVID-19 vaccines and therapeutics in the EU](#), virtual meeting, 25 November 2021 - [Agenda](#)
- [Training session for patients, consumers and healthcare professionals interested in EMA activities](#), virtual meeting, 24 November 2021
- [Annual Patients and Consumers Working Party \(PCWP\) and Healthcare Professionals Working Party \(HCPWP\) meeting with all eligible organisations](#), virtual meeting, 24 November 2021 - [Agenda](#)
- [EMA press briefing to inform on CHMP discussion on booster doses](#), virtual meeting, 5 October 2021
- [EMA regular press briefing on COVID-19](#), virtual meeting, 21 October 2021

Key to symbols used

 Orphan medicine
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  Biosimilar medicine
  Conditional approval
  Exceptional circumstances

Explanation of terms used

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.

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:

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[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

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