



HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
Published monthly by the European Medicines Agency

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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

Safety update




- [COVID-19 vaccine safety update for Spikevax \(previously COVID-19 Vaccine Moderna\): 11 August 2021](#)
- [COVID-19 vaccine safety update for COVID-19 Vaccine Janssen: 11 August 2021](#)
- [COVID-19 vaccine safety update for Vaxzevria \(previously COVID-19 Vaccine AstraZeneca\): 11 August 2021](#)
- [COVID-19 vaccine safety update for Comirnaty: 11 August 2021](#)

Key to symbols used

Orphan medicine Generic medicine Biosimilar medicine Conditional approval Exceptional circumstances

Cancer

New medicines authorised

- [Abecma](#) (*idecabtagene vicleucel*)  
Treatment of multiple myeloma (cancer of the bone marrow)
- [Abiraterone Mylan](#) (*abiraterone acetate*)  generic of Zytiga
Treatment of metastatic prostate cancer

Dermatology (skin conditions)

New medicines authorised

- [Bimzelx](#) (bimekizumab)
Treatment of plaque psoriasis (scaly patches on skin)

Haematology (blood conditions)

New medicines authorised

- [Evrenzo](#) (*roxadustat*)
Treatment of anaemia symptoms (low red blood cell counts) caused by chronic kidney failure

Immune system

New medicines authorised

- [Bimzelx](#) (bimekizumab)
Treatment of plaque psoriasis (scaly patches on skin)

Nephrology (kidney conditions)

New medicines authorised


- [Evrenzo](#) (*roxadustat*)
Treatment of anaemia symptoms (low red blood cell counts) caused by chronic kidney failure

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Nervous system

New medicines authorised

- [Fingolimod Mylan](#) (fingolimod)  generic of Gilenya
Treatment of adults and children over 10 year of age with multiple sclerosis (RRMS)

Medicines under additional monitoring

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

Other information

Guidelines

Adopted guidelines

- [Dissemination guidelines for training materials: CTIS training programme](#)

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - July 2021](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: August 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](#)
- [European Medicines Agency \(EMA\) Patients' and Consumers' \(PCWP\) and Healthcare Professionals' \(HCPWP\) Working Parties joint meeting](#) - virtual meeting - 21 September to 22 September 2021 [Agenda](#)

Key to symbols used

-  Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances



COVID-19 publications

- [ECDC and EMA update on COVID-19](#)
- [EMA starts evaluating use of RoActemra in hospitalised adults with severe COVID-19](#)
- [Increase in vaccine manufacturing capacity for COVID-19 vaccines from BioNTech / Pfizer and Moderna](#)

Other publications

- [Interoperability of track and trace systems: key to public health protection](#)
- [Six-month countdown to go-live for the Clinical Trials Information System \(CTIS\)](#)
- [Artificial intelligence in medicine regulation](#)
- Work programme: [Workplan 2021-2023 - HMA / EMA joint Big Data Steering Group](#)

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:

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[Patients and carers](#)

[Healthcare professionals](#)

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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

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