



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

New medicines authorised

- [COVID-19 Vaccine Janssen](#) (COVID-19 vaccine (Ad26.COV2-S [recombinant]))^C
Prevention of coronavirus disease 2019 (COVID-19)

Safety update

- [Comirnaty: 29 March 2021](#) (COVID-19 mRNA Vaccine (nucleoside modified))
Prevention of coronavirus disease 2019 (COVID-19)
- [COVID-19 Vaccine Moderna: 29 March 2021](#) (COVID-19 mRNA Vaccine (nucleoside modified))
Prevention of coronavirus disease 2019 (COVID-19)
- [Vaxzevria \(previously COVID-19 Vaccine AstraZeneca\): 29 March 2021](#) (COVID-19 Vaccine (ChAdOx1-S [recombinant]))
Prevention of coronavirus disease 2019 (COVID-19)

Key to symbols used

Orphan medicine Generic medicine Biosimilar medicine Conditional approval Exceptional circumstances

- Direct healthcare professional communication (DHPC): [COVID-19 Vaccine AstraZeneca: Risk of thrombocytopenia and coagulation disorders](#)

Antivirals/anti-infectives

New medicines authorised

- [Heplisav B](#) (*hepatitis B surface antigen*)
Prevention of hepatitis B virus infection

Cancer

Positive CHMP opinions on new medicines

- [Copiktra](#) (*duvelisib*)
Treatment of relapsed or refractory chronic lymphocytic leukaemia and refractory follicular lymphoma (blood cancers)

New medicines authorised

- [Inrebic](#) (*fedratinib*) 
Treatment of myelofibrosis (a rare form of blood cancer)
- [Onbevzi](#) (*bevacizumab*)
Treatment of different types of cancers (colon, lung, kidney, ovary and cervix)

New information on authorised medicines

- [Tecentrig](#) (*atezolizumab*) - new indication
Treatment of different types of cancer
- [Xtandi](#) (*enzalutamide*) - extension of indication
Treatment of prostate cancer

Safety update

- [Review of ifosfamide solutions](#) - PRAC recommendation (Art.31)
Treatment of different types of cancers, including various solid tumours and blood cancers such as lymphomas (cancer of white blood cells)
- Direct healthcare professional communication (DHPC): [Tecentrig \(atezolizumab\): Risk of Severe Cutaneous Adverse Reactions \(SCARs\)](#)

Cardiovascular system

Withdrawal of applications to change the marketing authorisation

- [Brilique](#) (*ticagrelor*)
Intended to be used with aspirin to prevent problems caused by blood clots

Safety update

- Direct healthcare professional communication (DHPC): [Zolgensma \(onasemnogene abeparvovec\): risk for thrombotic microangiopathy](#)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Dermatology (skin conditions)

Safety update

- Direct healthcare professional communication (DHPC): [Tecentriq \(atezolizumab\): Risk of Severe Cutaneous Adverse Reactions \(SCARs\)](#)

Diabetes

New medicines authorised

- [Kixelle](#) (*insulin aspart*)  : biosimilar of NovoRapid
Treatment of diabetes mellitus

Gynaecology & Obstetrics (pregnancy and female reproductive)

Positive CHMP opinions on new medicines

- [Drovelis](#) (*estetrol / drospirenone*)
To be used for oral contraception
- [Lydisilka](#) (*estetrol / drospirenone*)
To be used for oral contraception

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- [Copiktra](#) (*duvelisib*)
Treatment of relapsed or refractory chronic lymphocytic leukaemia and refractory follicular lymphoma (blood cancers)

New medicines authorised

- [Inrebic](#) (*fedratinib*) 
Treatment of myelofibrosis (a rare form of blood cancer)

Negative CHMP opinions on new medicines

- [Gamifant](#) (*emapalumab*)
Intended for the treatment of primary haemophagocytic lymphohistiocytosis (HLH), a disorder that results in an overactive immune system

Withdrawal of applications to change the marketing authorisation

- [Brilique](#) (*ticagrelor*)
Intended to be used with aspirin to prevent problems caused by blood clots

Safety update

- [Review of Zynteglo \(*betibeglogene autotemcel*\)](#) - review started (Art. 20)
Treatment of a blood disorder known as beta thalassaemia

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Hormone system

Positive CHMP opinions on new medicines

- [Drovelis](#) (*estetrol / drospirenone*)
To be used for oral contraception
- [Efmody](#) (*hydrocortisone*) 
Treatment of congenital adrenal hyperplasia (genetic disorder that affects hormones)
- [Lydisilka](#) (*estetrol / drospirenone*)
To be used for oral contraception

Immune system

Negative CHMP opinions on new medicines

- [Gamifant](#) (*emapalumab*)
Intended for the treatment of primary haemophagocytic lymphohistiocytosis (HLH), a disorder that results in an overactive immune system

Safety update

- Direct healthcare professional communication (DHPC): [Strimvelis® \(autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase \[ADA\] cDNA sequence\): first case of lymphoid T cell leukaemia after insertional oncogenesis](#)
- Direct healthcare professional communication (DHPC): [Xeljanz \(tofacitinib\): Initial clinical trial results of increased risk of major adverse cardiovascular events and malignancies \(excluding NMSC\) with use of tofacitinib relative to TNF-α inhibitors](#)

Musculoskeletal system

Safety update

- Direct healthcare professional communication (DHPC): [Zolgensma \(onasemnogene abeparvovec\): risk for thrombotic microangiopathy](#)

Nervous system

Positive CHMP opinions on new medicines

- [Ponvory](#) (*ponesimod*)
Treatment of active relapsing forms of multiple sclerosis

Respiratory system

New information on authorised medicines

- [Kaftrio](#) (*ivacaftor / tezacaftor / elexacaftor*)  - extension of indication
Treatment of cystic fibrosis

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [Kalydeco \(ivacaftor\)](#)  - extension of indication
Treatment of cystic fibrosis

Supply shortages

- Direct healthcare professional communication (DHPC): [Respreeza \(human alpha-1-proteinase inhibitor\): Sterility issue with the infusion device co-packed with Respreeza 4.000 mg and 5.000 mg](#)

Rheumatology (immune and inflammatory conditions)

New information on authorised medicines

- [Benlysta \(belimumab\)](#) - new indication
Add-on treatment of systemic lupus erythematosus (a disease in which the immune system, the body's natural defences, attacks normal cells and tissues, causing inflammation and organ damage)

Safety update

- Direct healthcare professional communication (DHPC): [Xeljanz \(tofacitinib\): Initial clinical trial results of increased risk of major adverse cardiovascular events and malignancies \(excluding NMSC\) with use of tofacitinib relative to TNF- \$\alpha\$ inhibitors](#)

Vaccines

New medicines authorised

- [Hepelisav B \(hepatitis B surface antigen\)](#)
Prevention of hepatitis B virus infection

Other medicines

New information on authorised medicines

- [Saxenda \(liraglutide\)](#) - extension of indication
Treatment of obesity

Withdrawal of applications to change the marketing authorisation

- [Brilique \(ticagrelor\)](#)
Intended to be used with aspirin to prevent problems caused by blood clots

Medicines under additional monitoring

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

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

Other information

Guidelines

Adopted guidelines

- Scientific guideline: [Reflection paper on the use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the European Union: development of resistance and impact on human and animal health - First version](#)
- Scientific guideline: [Reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products - First version](#)

Scientific committee and working party activities

- [Medicinal products for human use: monthly figures - January 2021](#)
- [Medicinal products for human use: monthly figures - February 2021](#)
- [CAT - agendas, minutes and reports](#)
- [CHMP - agendas, minutes and highlights](#)
- [CHMP - applications for new human medicines: March 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: March 2021](#)
- [PRAC recommendations on safety signals](#)

COVID-19 publications

- [AstraZeneca COVID-19 vaccine: review of very rare cases of unusual blood clots continues](#)
- [Increase in vaccine manufacturing capacity and supply for COVID-19 vaccines from AstraZeneca, BioNTech/Pfizer and Moderna](#)
- [EMA issues advice on use of regdanvimab for treating COVID-19](#)
- [COVID-19 Vaccine AstraZeneca – Update on ongoing evaluation of blood clot cases](#)
- [COVID-19 Vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low blood platelets](#)
- [Investigation of COVID-19 Vaccine AstraZeneca and thromboembolic events continues](#)
- [EMA's safety committee continues investigation of COVID-19 Vaccine AstraZeneca and thromboembolic events – further update](#)

Key to symbols used

 Orphan medicine  Generic medicine  Biosimilar medicine  Conditional approval  Exceptional circumstances

- [COVID-19 Vaccine AstraZeneca: PRAC investigating cases of thromboembolic events - vaccine's benefits currently still outweigh risks - Update](#)
- [COVID-19 Vaccine AstraZeneca: PRAC preliminary view suggests no specific issue with batch used in Austria](#)
- [EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials](#)
- [EMA starts rolling review of Eli Lilly antibodies bamlanivimab and etesevimab for COVID-19](#)
- [EMA starts rolling review of the Sputnik V COVID-19 vaccine](#)
- [EMA and Health Canada publish clinical data used to support their authorisations of the Moderna COVID-19 vaccine](#)
- [EMA issues advice on use of antibody combination \(bamlanivimab / etesevimab\)](#)
- [EMA review of regdanvimab for COVID-19 to support national decisions on early use](#)
- Other: [Reply to open letter concerning vaccines for COVID-19](#)

Other publications

- [EMA Management Board – highlights of March 2021 meeting](#)
- [Management Board meeting](#): 16-17 December 2020 , European Medicines Agency, Amsterdam, the Netherlands - [Minutes](#)
- [EU recommendations for 2021-2022 seasonal flu vaccine composition](#)
- Other: [Decision of the Executive Director on fee reductions for scientific advice requests on products for the prevention and/or treatment of COVID-19](#)
- [EMA medical terms simplifier - Plain - language description of medical terms related to medicines use](#)
- [EMA working on COVID-19 over holiday period](#)

Events

- [Public stakeholder meeting: approval, safety monitoring and impact of COVID-19 vaccines in the EU](#), virtual event, 26 March 2021 - [Recording](#)
- [Press briefing on the conclusion of the investigation of COVID-19 Vaccine AstraZeneca and thromboembolic events by the Pharmacovigilance Risk Assessment Committee \(PRAC\)](#), virtual event , 18 March 2021
- [Joint HMA/EMA workshop on artificial intelligence in medicines regulation](#), virtual event, 19 and 20 April 2021 - [Agenda](#)
- [Data standards strategy workshop](#), virtual event, 18 May 2021

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.

G 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.

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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

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