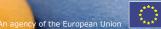


HUMAN MEDICIN

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.

To receive each new issue of the newsletter, please click here RSS feeds, choose 'Human medicines highlights newsletter' and then click on 'Subscribe to this feed'. Please note, in order to be able to view RSS feeds you need one of the following: a modern web browser; a web-based news reader or a desktop news reader. For a list of RSS readers please refer to our RSS guide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

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Information on medicines

COVID-19 vaccines and treatments

Negative CHMP opinions on new medicines

Lagevrio (molnupiravir) Intended for the treatment of COVID-19 in adults

Direct Healthcare Professional Communication (DHPC)

Spikevax bivalent Original/Omicron BA.1 (elasomeran; imelasomeran and elasomeran; davesomeran and elasomeran; COVID-19 mRNA vaccine (nucleoside-modified)) Prevention of COVID-19 virus infection

Explanation of terms used

Events

7

Antivirals/anti-infectives

Supply shortages

Amoxicillin and amoxicillin/clavulanic acid (amoxicillin) Treatment of wide range of bacterial infections

Cancer

Positive CHMP opinions on new medicines

- Akeega (niraparib / abiraterone acetate) Treatment of prostate cancer
- Hyftor (sirolimus) Treatment of angiofibroma, a type of non-cancerous tumour that occurs in the nasal cavity
- Tibsovo (ivosidenib) Treatment of myeloid leukaemia, a type of blood cancer
- Tidhesco (ivosidenib) Treatment of myeloid leukaemia, a type of blood cancer

New medicines authorised

Plerixafor Accord (plerixafor) generic of Mozobil Medicine used in cancer patients to obtain cells from the bone marrow for use in transplantation

New information on authorised medicines

<u>Libtayo</u> (cemiplimab) - new indication Treatment of non-small cell lung cancer

Withdrawal of applications for new medicines

Aligopa (copanlisib) Intended for treatment of a type of white blood cells cancer

Supply shortages

Fasturtec (rasburicase) Prevention of high levels of uric acid in cancer patients order to prevent kidney failure

Direct Healthcare Professional Communication (DHPC)

- Caprelsa (vandetanib) Treatment of thyroid cancer
- Neofordex (dexamethasone) Treatment of multiple myeloma (cancer of the bone marrow)
- Xalkori (crizotinib) Treatment of non-small cell lung cancer







Cardiovascular system

Safety update

Review of pseudoephedrine-containing medicines (pseudoephedrine) - review started Works by stimulating nerve endings to release the chemical noradrenaline, which causes the blood vessels to constrict (narrow)

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

Opzelura (ruxolitinib)

Treatment of vitiligo, a chronic skin condition in which skin loses its pigment

New medicines authorised

Spevigo (spesolimab)

Treatment of psoriasis (inflammatory condition of the skin)

Gastro-intestinal system

New information on authorised medicines

Rinvog (upadacitinib) - new indication Treatment of Crohn's disease, a small intestine inflammatory disease

Gynaecology & Obstetrics (pregnancy and female reproductive)

Supply shortages

Cetrotide (cetrorelix acetate) Prevention of premature ovulation

Haematology (blood conditions)

Positive CHMP opinions on new medicines

Bekemv (eculizumab)

Treatment of paroxysmal nocturnal haemoglobinuria, (rare condition in which there is excessive breakdown of red blood cells and hemoglobin (red pigment) in the urine.)

Tibsovo (ivosidenib)

Treatment of myeloid leukaemia, a type of blood cancer

Tidhesco (ivosidenib)



Treatment of myeloid leukaemia, a type of blood cancer

Vafseo (vadadustat)

Treatment of anaemia associated with chronic kidney disease

Key to symbols used





New medicines authorised

Plerixafor Accord (plerixafor) generic of Mozobil Medicine used in cancer patients to obtain cells from the bone marrow for use in transplantation

Direct Healthcare Professional Communication (DHPC)

- Adakveo (crizanlizumab)
 - Treatment of anaemia
- Neofordex (dexamethasone)

Treatment of multiple myeloma (cancer of the bone marrow)

Hepatology

Direct Healthcare Professional Communication (DHPC)

Terlipressin-containing medicines (terlipressin) Treatment of hepatorenal syndrome (serious kidney problems in people with advanced liver disease)

Immune system

New medicines authorised

Spevigo (spesolimab) Treatment of psoriasis (inflammatory condition of the skin)

Withdrawal of applications for extension of indication

Ilaris (canakinumab)

Treatment of Schnitzler syndrome (a rare long-term inflammatory disease causing urticaria (hives), recurrent fever, bone and joint pain, and swollen lymph nodes)

Metabolic disorders

Positive CHMP opinions on new medicines

Elfabrio (pegunigalsidase alfa) Treatment of Fabry disease, a rare condition that affects the metabolism of fats in the body

Musculoskeletal system

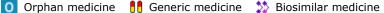
Negative CHMP opinions on new medicines

Sohonos (palovarotene)

Intended for treatment of Fibrodysplasia ossificans progressiva (FOP), a disorder in which bone forms in other tissues







Nephrology (kidney conditions)

Positive CHMP opinions on new medicines

Vafseo (vadadustat)

Treatment of anaemia associated with chronic kidney disease

Supply shortages

Fasturtec (rasburicase)

Prevention of high levels of uric acid in cancer patients order to prevent kidney failure

Direct Healthcare Professional Communication (DHPC)

Cystagon (mercaptamine bitartrate)

Treatment of kidney cystinosis (rare disease in which excess amounts of cystine, an amino acid, build up within cells of kidneys)

<u>Terlipressin-containing medicines</u> (terlipressin)

Treatment of hepatorenal syndrome (serious kidney problems in people with advanced liver disease)

Nervous system

New medicines authorised

<u>Dimethyl fumarate Accord</u> (dimethyl fumarate) generic of Tecfidera Treatment of multiple sclerosis

New information on authorised medicines

Esbriet (pirfenidone) - change of existing indication Treatment of idiopathic pulmonary fibrosis (a disease in which scar tissue forms in the lungs)

Safety update

- Review of Topiramate (topiramate) review started Prevention of epileptic seizures and migraines
- Review of <u>pseudoephedrine-containing medicines</u> (pseudoephedrine) review started Stimulating of nerve endings to release the chemical noradrenaline, which causes the blood vessels to constrict (narrow)

Direct Healthcare Professional Communication (DHPC)

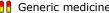
Zolgensma (onasemnogene abeparvovec)

Treatment of spinal muscular atrophy, a condition of the nerves that causes muscle wasting and weakness

Other medicines

New information on authorised medicines

TachoSil (human fibrinogen / human thrombin) - extension of indication Supportive treatment in surgery as a sealant



Withdrawal of applications for extension of indication

Buvidal (buprenorphine) Treatment of opioids dependency

Safety update

Review of <u>pseudoephedrine-containing medicines</u> (pseudoephedrine) - review started Works by stimulating nerve endings to release the chemical noradrenaline, which causes the blood vessels to constrict (narrow)

Direct Healthcare Professional Communication (DHPC)

Amfepramone-containing medicinal products (amfepramone) Treatment of obesity

Medicines under additional monitoring

Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

ICH Guideline M13A on bioequivalence for immediate-release solid oral dosage forms Deadline for comments: 26 May 2023

Adopted guidelines

- Guideline on clinical evaluation of vaccines
- Priority Action 3 concept paper: an EU multi-stakeholder platform for improving clinical trials
- ICH quideline Q9 (R1) on quality risk management
- Paediatric Addendum on the guidelines on clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease
- Adjuvants in vaccines for human use

Scientific committee and working party activities

- Medicinal products for human use: monthly figures January 2023
- CAT agendas, minutes and reports
- CHMP agendas, minutes and highlights







- CHMP applications for new human medicines: February 2023
- 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

Other publications

- Crisis preparedness and management
- Public consultation on a multi-stakeholder platform to improve clinical trials in the EU
- Actions to support the development of medicines for children
- EMA update on shortages of antibiotics in the EU
- Updated EMA emerging health threats plan
- Note on European Medicines Agency's involvement in HORIZON-HLTH-2023-TOOL-05-09: Developing a Data Quality and Utility Label for the European Health Data Space
- Questions and answers Clinical Trials Information System (CTIS) and Clinical Trials Regulation (CTR)
- Multilingualism on the EMA website and in external communications
- Considerations for research / project teams seeking competent authority participation in externally funded regulatory science and public health research projects related to medicinal products
- Mandate, objectives and rules of procedure for the Oncology European Specialised Expert Communities (ESEC)

Events

- Quarterly system demo Q1 2023 22 March 2023
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - 3 March 2023
- HMA/EMA multi-stakeholder workshop on shortages 1 2 March 2023
- Clinical Trials Information System (CTIS) bitesize talk: Document and personal data in CTIS 23 February 2023
- Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) 23 February 2023
- Product Management Service (PMS) Webinar on Data Migration 23 February 2023
- EMA regular press briefing on public health emergencies 15 February 2023
- DARWIN EU Advisory Board meeting 6 February 2023
- EMA virtual technical media briefing on the RNA technology 3 February 2023
- Regulatory and scientific virtual conference on RNA-based medicines 2 February 2023 Agenda

Key to symbols used





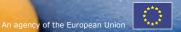




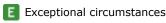


JMAN MEDICINES

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- EIC / EMA Info Day: Regulatory support for the development of innovative medicines and technologies 31 January 2023
- European Union (EU) International Organisation for Standardization (ISO) for identification of medical products (IDMP)/ Substance, Product, Organisation and Referential (SPOR) data Task Force meeting - January 2023 - 26 January 2023
- Information session on the pilot for expert panels' scientific advice to manufacturers of high-risk medical devices 25 January 2023 - Agenda
- Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) 11 January 2023 Minutes
- EMA/HMA Big Data Stakeholder Forum 2022 1 December 2022 Report
- Management Board meeting 14-15 December 2022
- Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) 26 January 2023



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 <u>CHMP</u> to give opinions, in co-operation with the World Health Organization, on <u>medicinal products</u> 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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European Medicines Agency

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