

HUMAN MEDICINES

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



IN THIS ISSUE COVID-19 vaccines and treatments Cancer 1 Cardio vascular system 2 2 Haematology 3 Hepatology 3 HIV 3 Hormone system Immune system 3 Metabolic disorders 3 4 Nephrology 4 Nervous system 4 Ophthalmology Respiratory system 4 Rheumatology 4 5 Urology 5 Vaccines 5 Other medicines Medicines under additional monitorina Guidelines Scientific committee and working party activities 5 6 Other publications Other publications on COVID-19 6 Other publications 6 on Monkeypox **Events** 6

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 dick 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 quide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

You can find details on how to cancel / unsubscribe to an RSS feed on the RSS reader tool that you are using, for example Unsubscribe from an RSS Feed for users of Microsoft Outlook.

For further information on the processing of your personal data, please find EMA's Privacy statement regarding the sending of electronic newsletters click here.

Information on medicines

COVID-19 vaccines and treatments

Withdrawal of applications for extension of indication

Olumiant (baricitinib) Intended for treatment of patients hospitalized with Covid-19

Cancer

Positive CHMP opinions on new medicines

- Imjudo (tremelimumab) Treatment of liver cancer
- <u>Tremelimumab AstraZeneca</u> (tremelimumab) Treatment of non-small cell lung cancer



New medicines authorised

- Locametz (gozetotide) Treatment of prostate cancer
- Padcev (enfortumab vedotin) Treatment of bladder and urinary tract cancer
- Pluvicto (lutetium (177Lu) vipivotide tetraxetan) Treatment of prostate cancer

New information on authorised medicines

- Enhertu (trastuzumab deruxtecan) new indication Treatment of breast cancer
- Imfinzi (durvalumab) new indication Treatment of liver cancer

Negative CHMP opinions on new medicines

Omblastys (iodine (131I) omburtamab) Intended for treatment of a rare type of cancer which forms from immature nerve cells

Cardiovascular system

New information on authorised medicines

- Adcirca (previously Tadalafil Lilly) (tadalafil) new indication Treatment of pulmonary arterial hypertension (high blood pressure in lungs)
- Edistride (dapagliflozin) extension of indication Treatment of symptomatic chronic heart failure
- Forxiga (dapagliflozin) extension of indication Treatment of symptomatic chronic heart failure

Arbitration procedures

Rambis and associated names (ramipril, bisoprolol fumarate) - outcome Treatment of certain long-term heart conditions and high blood pressure

Haematology (blood conditions)

Positive CHMP opinions on new medicines

Hemgenix (etranacogene dezaparvovec) Treatment of inherited bleeding disorder

New medicines authorised

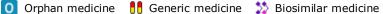
Pyrukynd (mitapivat) Treatment of a disease that causes red blood cells to break down faster than normal

New information on authorised medicines

Hemlibra (emicizumab) - extension of indication Prevention of bleeding in patients with haemophilia A (a blood clotting disorder)















Hepatology (liver conditions)

New information on authorised medicines

Imfinzi (durvalumab) - new indication Treatment of liver cancer

Positive CHMP opinions on new medicines

Imjudo (tremelimumab) Treatment of liver cancer

Direct Healthcare Professional Communication (DHPC)

<u>Terlipressin</u> (terlipressin) Treatment of hepatorenal syndrome (serious kidney problems in people with advanced liver disease)

HIV

New information on authorised medicines

Triumeq (abacavir sulfate / dolutegravir sodium / lamivudine) - new pharmaceutical form Treatment of HIV in children weighing between 14 to 25kg

Hormone system

New medicines authorised

Mycapssa (octreotide) Treatment of acromegaly (excess growth of body tissues due to excessive growth hormone)

Immune system

New information on authorised medicines

Dupixent (dupilumab) - new indication Treatment of an inflammatory condition affecting the oesphagus, or food pipe

Metabolic disorders

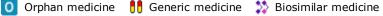
Positive CHMP opinions on new medicines

Livmarli (Maralixibat chloride) Treatment of intense itching due to a build-up of bile in patients aged 2 months and older

Pombiliti (cipaglucosidase alfa) Treatment of glycogen storage disease (a disease that causes the build up of glycogen, a complex sugar, in organs and muscles)









Nephrology (kidney conditions)

New information on authorised medicines

Kerendia (finerenone) - extension of indication Treatment of chronic kidney disease

Withdrawal of applications for new medicines

Imbarkyd (bardoxolone methyl) Treatment of chronic kidney disease caused by an inherited disease called Alport syndrome

Direct Healthcare Professional Communication (DHPC)

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

Nervous system

Positive CHMP opinions on new medicines

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

New information on authorised medicines

Fintepla (fenfluramine) - new indication Treatment of seizures associated with Lennox-Gastaut syndrome (a severe form of epilepsy that starts in childhood)

Ophthalmology (eye conditions)

Positive CHMP opinions on new medicines

Gelisia and associated names (timolol maleate) Treatment of high pressure inside the eye

Respiratory system

Safety update

Review of Pholcodine-containing medicinal products (pholcodine) - PRAC recommendation Treatment of dry cough and (in combination with other active substances for treatment of) symptoms of cold and flu

Rheumatology (immune and inflammatory conditions)

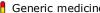
New medicines authorised

Eladynos (abaloparatide)

Treatment of osteoporosis in women in menopause with increased risk of bone fractures

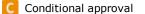












HIGHLIGHTS

Urology

New medicines authorised

- Locametz (gozetotide) Treatment of prostate cancer
- Padcev (enfortumab vedotin) Treatment of bladder and urinary tract cancer
- Pluvicto (lutetium (177Lu) vipivotide tetraxetan) Treatment of prostate cancer

Vaccines

New medicines authorised

Odenga (dengue tetravalent vaccine (live, attenuated)) Protection against dengue disease in patients from 4 years of age

Other medicines

Safety update

Review of Synchron (INN) - European Commission final decision (Scope of safety referral) Suspension of medicines over flawed studies

Medicines under additional monitoring

Updated list of medicines under additional monitoring

Other information

Guidelines

Adopted guidelines

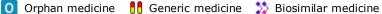
- Liposomal amphotericin B product-specific bioequivalence guidance Scientific guideline
- Lanreotide acetate, prolonged-release solution for injection in prefilled syringe 60, 90 and 120 mg product-specific bioequivalence quidance - Scientific quideline

Scientific committee and working party activities

Download here https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/medicine -evaluation-figures

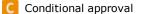














HIGHLIGHTS

- CAT agendas, minutes and reports
- CHMP agendas, minutes and highlights
- 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 on COVID-19

- COVID -19 vaccines safety update
- COVID-19 vaccines: key facts
- ETF concludes that bivalent original/Omicron BA.4-5 mRNA vaccines may be used for primary vaccination
- ETF warns that monoclonal antibodies may not be effective against emerging strains of SARS-CoV-2

Other publications on Monkeypox

Possible use of the medicinal product TPOXX for the treatment of monkeypox

Other publications

- EMA recommends withdrawal of pholcodine medicines from EU market
- Synchron Research Service: re-examination confirms suspension of medicines over flawed studies
- ECDC and EMA collaborate on vaccine safety and effectiveness monitoring studies
- Letter of support for TREAT-NMD Core Dataset for Spinal Muscular Atrophy (SMA).
- Big Data Highlights Issue 4
- First gene therapy to treat haemophilia B
- Letter of Support of Model-based Clinical Trial Simulation Platform (CTSP) for Duchenne Muscular **Dvstrophy**
- Facilitating Decentralised Clinical Trials in the EU
- Clinical Trials Highlights
- Key performance indicators (KPIs) to monitor the European clinical trials environment
- Questions and answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products









Events

- ACT EU multi-stakeholder meeting on decentralised clinical trials 4 October 2022 Report
- Second European Medicines Agency and Affordable Medicines Europe bilateral meeting 16 November 2022
- Ninth Nitrosamine Implementation Oversight Group (NIOG) meeting 21 November 2022
- Ninth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicine 24 November 2022
- First European Medicines Agency Vaccines Europe meeting 28 November 2022 Highlights
- Ninth industry stakeholder platform on research and development support 5 December 2022
- Management Board meeting 14-15 December 2022 Agenda, Highlights
- Clinical Trials Information System (CTIS) bitesize talk: Annual safety report (ASR) 15 December 2022
- Joint EMA-FDA workshop: Efficacy of monoclonal antibodies in the context of rapidly evolving SARS-CoV-2 variants 15 December 2022
- EMA regular press briefing on public health emergencies 16 December 2022
- Cancer Medicines Forum December 2022 20 December 2022
- Clinical Trials Information System (CTIS): Walk-in clinic 18 January 2023
- Regulatory and scientific virtual conference on RNA-based medicines 2 February 2023 Agenda
- Clinical Trials Information System (CTIS) sponsor end user training programme 7-10 February 2023 Agenda
- eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course February 2023 13-15 February 2023
- Clinical Trials Information System (CTIS): Walk-in clinic 16 February 2023
- HMA/EMA multi-stakeholder workshop on shortages 1-2 March 2023
- Clinical Trials Information System (CTIS): Walk-in clinic 16 March 2023
- Clinical Trials Information System (CTIS) sponsor end user training programme 2-5 May 2023 Agenda
- eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course May 2023 10-12 May 2023
- Clinical Trials Information System (CTIS) sponsor end user training programme 27-30 June 2023 Agenda
- eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course July 2023 3-5 July 2023





Explanation of terms used

Orphan medicine 0

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')

Highly similar 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.

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:

About us

Patients and carers

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

European Medicines Agency

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us Website www.ema.europa.eu Telephone +31 (0)88 871 6000



