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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

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

An agency of the European Union

IN THIS ISSUE

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

Antivirals/anti-infectives

New information on authorised medicines

- Xydalba (*dalbavancin)* - extension of indication
  Treatment of acute bacterial skin and skin structure infections

Cancer

New information on authorised medicines

- Brukinsa (*zanubrutinib)* - extension of indication
  Treatment of chronic lymphocytic leukaemia (a blood cancer)
- Libtayo (*cemiplimab)* C - extension of indication
  Treatment of cervical cancer

Key to symbols used

O Orphan medicine | Generic medicine | Biosimilar medicine | C Conditional approval | E Exceptional circumstances

Positive CHMP opinions on new medicines

- Ebvallo (*tabelecleucel)* O E
  Treatment of Epstein-Barr virus positive post-transplant lymphoproliferative disease (a blood cancer that can occur after transplantation)
- Locametz (*gozetotide)*
  Diagnosis of prostate cancer
- Pemetrexed Baxter (*pemetrexed*) generic of Alimta
  Treatment of the lung lining cancer and non-small cell lung cancer
- Plerixafor Accord (*plerixafor)* generic of Mozobil
  Treatment of blood cancer after bone marrow (blood stem cell) transplantation
- Pluvicto (*lutetium (177Lu) vipivotide tetraxetan)*
  Treatment of prostate cancer

New medicines authorised

- Opdualag (*relatlimab/nivolumab)*
  Treatment of melanoma (a type of skin cancer)
- Thalidomide Lipomed (*thalidomide)*
  Treatment of multiple myeloma (a cancer of the bone marrow)

Withdrawal of applications for new medicines

- Hervelous (*trastuzumab)*
  Treatment of certain forms of breast cancer and gastric (stomach) cancer
- Tuznue (*trastuzumab)*
  Treatment of certain forms of breast cancer and gastric (stomach) cancer

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

- Livmarli (*maralixibat chloride*) O E
  Treatment of itching sensation caused by a condition called Alagille syndrome which affects the liver
- Spevigo (*spesolimab*)
  Treatment of generalised pustular psoriasis (GPP), an inflammatory skin disease

New information on authorised medicines

- Xydalba (*dalbavancin)* - extension of indication
  Treatment of acute bacterial skin and skin structure infections

Diabetes

New information on authorised medicines

- Lyumjev (previously Liumjev) (*insulin lispro)*
  Treatment of diabetes mellitus

Key to symbols used

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Supply shortages

- Ozempic (semaglutide)
  Treatment of Diabetes mellitus

Direct Healthcare Professional Communication (DHPC)

- Ozempic (semaglutide): Solution for injection in pre-filled pen - supply shortage
  Treatment of Diabetes mellitus

Hepatology

Positive CHMP opinions on new medicines

- Livmarli (*maralixibat chloride*) O E
  Treatment of itching sensation caused by a condition called Alagille syndrome which affects the liver

Hormone system

Supply shortages

- Natpar (*parathyroid hormone*)
  Treatment of hypoparathyroidism (a condition in which the parathyroid glands do not produce enough parathyroid hormone)

Direct Healthcare Professional Communication (DHPC)

- Natpar (*parathyroid hormone*): Discontinuation of manufacturing at the end of 2024 and update on 100mcg shortage
  Treatment of hypoparathyroidism (a condition in which the parathyroid glands do not produce enough parathyroid hormone)

Immune system

Positive CHMP opinions on new medicines

- Spevigo (*spesolimab*)
  Treatment of generalised pustular psoriasis (GPP), an inflammatory skin disease

Nervous system

Positive CHMP opinions on new medicines

- Dimethyl fumarate Teva (*dimethyl fumarate*) generic of Tecfidera
  Treatment of multiple sclerosis

New medicines authorised

- Amvuttra (*vutrisiran*) O
  Treatment of hereditary transthyretin-mediated amyloidosis (a disease in which abnormal proteins build up in tissues around the nerves)
- Rayvow (*lasmiditan*)
  Treatment of migraine with or without aura (unusual visual or other sensory experiences)

Key to symbols used

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Ophthalmology (eye conditions)

New medicines authorised

- Ranivisio (*ranibizumab*)
  Treatment of sight problems caused by damage to the retina (the light-sensing layer at the back of the eye)
- Vabysmo (*faricimab)*
  Treatment of sight problems caused by damage to the retina (the light-sensing layer at the back of the eye)

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- Eladynos (*abaloparatide)*
  Treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Vaccines

Positive CHMP opinions on new medicines

- Odenga (*dengue tetravalent vaccine)*
  Prevention of dengue disease (a mosquito-borne tropical disease)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- ICH Guideline Q5A(R2) on viral safety evaluation of biotechnology products derived from cell lines of human or animal origin
  Deadline for comments: 10 February 2023
- ICH M11 guideline
  Deadline for comments: 26 February 2023

Adopted guidelines

- ICH guideline E19 on a selective approach to safety data collection in specific late-stage pre-approval or post-approval clinical trials
- ICH guideline S1B(R1) on testing for carcinogenicity of pharmaceuticals

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - September 2022
- CAT - agendas, minutes and reports
- CAT quarterly highlights and approved ATMPs
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: October 2022
- 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 2022
- PRAC recommendations on safety signals
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting with all eligible organisations - 15 November 2022 - Agenda
- Meeting of the CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients and Consumers Working Party (PCWP) - 15 July 2022 - Minutes

Other publications on COVID-19

- Covid-19: latest updates
- EMA recommends approval of second adapted Spikevax vaccine
- Treatments and vaccines for COVID-19

Other publications

- Call for expression of interest for civil society representatives to participate in the work of EMA's Paediatric Committee - deadline 3 November 2022
- Chair of the European Network of Paediatric Research at EMA re-elected
- High-quality data to empower data-driven medicines regulation in the European Union

- HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use (TFAAM): Steering Committee composition
- DRAFT Qualification opinion for the iBox Scoring System as a secondary efficacy endpoint in clinical trials investigating novel immunosuppressive medicines in kidney transplant patients - deadline for comments 17 November 2022
- Notification on arrangements for requesting EMA certificates through urgent and standard procedure for December 2022
- EMA mid-year report 2022
- Key performance indicators (KPIs) to monitor the European clinical trials environment
- European Medicines Agency's Data Protection Notice
- Records of data processing activity for the raw data proof-of-concept pilot

Events

- Management Board meeting - 15-16 June 2022 - Minutes
- Management Board meeting - 6 October 2022 - Agenda, Highlights
- Multi-stakeholder workshop: Patient experience data in medicines development and regulatory decision-making - 21 September 2022
- Meeting of the Nitrosamine Implementation Oversight Group - 30 November 2022
- Human Variations electronic appplication forms Q&A Clinics – Session 3 - 29 November 2022
- Human Variations electronic appplication forms Q&A Clinics – Session 2 - 22 November 2022
- Ninth Meeting of the Nitrosamine Implementation Oversight Group - 21 November 2022
- Human Variations electronic appplication forms Q&A Clinics – Session 1 - 15 November 2022
- Human Variations electronic appplication forms training session - 8 November 2022
- Digital application dataset integration (DADI) Q&A webinar - go-live of variations form for human medicinal products - 27 October 2022
- EMA regular press briefing on COVID-19 and monkeypox - 26 October 2022
- Extraordinary meeting of the Committee for Medicinal Products for Human Use (CHMP) - 19 October 2022
- Webinar on the draft Data Quality Framework for EU medicines regulation - 18 October 2022
- First European Medicines Agency - European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) bilateral meeting - 11 October 2022 - Agenda
- Second European Medicines Agency and Nuclear Medicines Europe bilateral meeting - 11 October 2022
- EMA Account Management training webinar - 3 October 2022
- Clinical Trials Information System (CTIS) bitesize talk: Notifications - Part 1 - 28 September 2022
- Clinical Trials Information System (CTIS): Walk-in clinic - 20 September 2022
- Fifth European Medicines Agency - Medicines for Europe bilateral meeting - 15 September 2022 - Highlights

- DARWIN EU Advisory Board meeting - 8 September 2022 - Agenda
- IRIS for Good Pharmacovigilance practice (GVP) inspections training session for industry users - 7 September 2022
- DADI PDF electronic application forms (eAF) training webinar - 2 September 2022
- European Medicines Agency/European Network for Health Technology Assessment meeting - 17 June 2022 - Minutes

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.

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