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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

COVID-19 vaccines and treatments

New medicines authorised

- Paxlovid ((*PF-07321332/ritonavir*) C
  Treatment of coronavirus disease (COVID-19)

Safety update

- Comirnaty
- Nuvaxovid
- Spikevax (previously COVID-19 Vaccine Moderna)
- Vaxzevria (previously COVID-19 Vaccine AstraZeneca)
- COVID-19 Vaccine Janssen

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Breyanzi (*lisocabtagene maraleucel*)
  Treatment of lymphoma (a blood cancer)
- Dasatinib Accord (*dasatinib*) generic of Sprycel
  Treatment of leukaemia (a blood cancer)
- Dasatinib Accordpharma (*dasatinib*) generic of Sprycel
  Treatment of leukaemia (a blood cancer)
- Stimufend (pegfilgrastim) biosimilar of Neulasta
  Treatment of neutropenia (low levels of neutrophils, a type of white blood) after chemotherapy.

New information on authorised medicines

- Ayvakyt (*avapritinib*) - new indication
  Treatment of gastrointestinal stromal tumour (cancer of the stomach and bowels) and systemic mastocytosis (accumulation of mast cells, a type of white blood cell, in the body)

Withdrawal of applications for new medicines

- Aliqopa (*copanlisib*)
  Treatment of previously treated marginal zone lymphoma (a blood cancer)

Withdrawal of authorised medicines

- Tookad (*padeliporfin*)
  Treatment of prostate cancer

Cardiovascular system

Withdrawal of applications for extension of indication

- Brilique (*ticagrelor)*
  Prevention of stroke after a previous stroke or transient ischaemic attack

Diabetes

Positive CHMP opinions on new medicines

- Vildagliptin / Metformin hydrochloride Accord (*vildagliptin/metformin hydrochloride*) generic of Eucreas
  Treatment of type 2 diabetes mellitus

New information on authorised medicines

- Jardiance (*empagliflozin*) - extension of indication
  Treatment of type 2 diabetes mellitus

Gastro-intestinal system

New information on authorised medicines

- Ayvakyt (*avapritinib*) O - new indication
  Treatment of gastrointestinal stromal tumour (cancer of the stomach and bowels) and systemic mastocytosis (accumulation of mast cells, a type of white blood cell, in the body)

Gynaecology & Obstetrics (pregnancy and female reproductive system)

New information on authorised medicines

- Senshio (*ospemifene*) - extension of indication
  Treatment of vulvar and vaginal atrophy in post-menopausal women

Haematology (blood conditions)

Positive CHMP opinions on new medicines

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  Treatment of lymphoma (a blood cancer)
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Withdrawal of applications for new medicines

- Aliqopa (*copanlisib*)
  Treatment of previously treated marginal zone lymphoma (a blood cancer)

Hepatology

Safety update

- Review of terlipressin (*terlipressin*) - review started (Scope of safety referral) *for Art.31*
  Treatment of liver disease

Immune system

New information on authorised medicines

- Dupixent (*dupilumab*) - extension of indication
  Treatment of asthma

Withdrawal of applications for new medicines

- Abylqis (*arachis hypogaea extract*)
  Treatment of peanut allergy

Nephrology (kidney conditions)

Safety update

- Review of terlipressin (*terlipressin*) - review started (Scope of safety referral) *for Art.31*
  Treatment of liver disease

Direct Healthcare Professional Communication (DHPC)

- Nulojix (*belatacept*)
  Prevention of kidney transplant rejection

Nervous system

New information on authorised medicines

- Briviact (*brivaracetam*) - extension of indication
  Treatment of epilepsy
- Lacosamide UCB (*lacosamide*) - extension of indication
  Treatment of epilepsy
- Vimpat (lacosamide) - extension of indication
  Treatment of epilepsy

Withdrawal of applications for extension of indication

- Brilique (*ticagrelor)*
  Prevention of stroke after a previous stroke or transient ischaemic attack

Safety update

- Nasolam and associated names - completed review *(for Art.29)*

Respiratory system

New information on authorised medicines

- Dupixent (*dupilumab*) - extension of indication
  Treatment of asthma

Rheumatology (immune and inflammatory conditions)

Positive CHMP opinions on new medicines

- Sondelbay (*teriparatide*) biosimilar of Forsteo
  Treatment of osteoporosis (a disease that makes bones fragile)

Urology (urinary tract conditions)

Withdrawal of authorised medicines

- Tookad (*padeliporfin*)
  Treatment of prostate cancer

Other medicines

Direct Healthcare Professional Communication (DHPC)

- Nulojix (*belatacept*)
  Prevention of kidney transplant rejection

Withdrawal of applications for new medicines

- Abylqis (*arachis hypogaea extract*)
  Treatment of peanut allergy

Safety update

- Review of Synchron - review started *(for Art.31)*
- Nasolam and associated names - completed review *(for Art.29)*

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials - Revision 2
  Deadline for comments: 31 January 2022

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - November 2022
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: January 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: January 2022
- PRAC recommendations on safety signals
- Report: Meeting summary - Annual Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) meeting with all eligible organisations - 24 November 2021

Other information on COVID-19

- Global regulators discuss path towards regulatory alignment on response to Omicron variant
- Preliminary data indicate COVID-19 vaccines remain effective against severe disease and hospitalisation caused by the Omicron variant
- COVID-19: latest safety data provide reassurance about use of mRNA vaccines during pregnancy
- Increase in manufacturing capacity for Vaxzevria (previously COVID-19 Vaccine AstraZeneca)
- International regulators' recommendations on COVID-19 vaccines and the Omicron variant

Other publications

- A stronger role for EMA
- EMA welcomes EU Commissioner for Health and Food Safety
- Accelerating Clinical Trials in the EU (ACT EU): for better clinical trials that address patients' needs – Regulatory and procedural guideline
- Report:Meeting report - Learnings initiative webinar for optimal use of big data for regulatory purpose
- Procedural note for interim measures regarding notification of pharmacovigilance alerts by marketing authorisation holders under Regulation (EU) 2019/6 - Annex
- Report: Final programming document 2022-2024
- Newsletter: Clinical Trials Information System (CTIS) highlights - January 2022
- Regulatory harmonisation of clinical trials in the EU: Clinical Trials Regulation to enter into application and new Clinical Trials Information System to be launched

Key to symbols used

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- Letter of Support for performing registry-based post authorisation safety studies (PASS) in Multiple Sclerosis (MS) using data of the Big MS Data Network (BMSD)

Events

- Union Pharmacovigilance Database: follow up webinar on signal detection, evaluation and yearly reporting - virtual meeting, 19 January 2022
- EMA regular press briefing on COVID-19 - virtual meeting, 3 February 2022
- EMA regular press briefing on COVID-19 - virtual meeting, 18 January 2022
- EMA regular press briefing on COVID-19 - virtual meeting, 11 January 2022
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting - virtual meeting, 02 and 03 March 2022
- Clinical Trials Information System (CTIS) sponsor end user training programme - virtual meeting, from 20 to 23 June 2022 - Agenda
- Clinical Trials Information System (CTIS) sponsor end user training programme - virtual meeting, from 10 to 13 May 2022 - Agenda
- Clinical Trials Information System (CTIS) sponsor end user training programme - virtual meeting, from 05 to 08 April 2022 - Agenda
- Clinical Trials Information System (CTIS) sponsor end user training programme - virtual meeting, from 01 to 04 March 2022 - Agenda
- Clinical Trials Information System (CTIS) sponsor end user training programme - virtual meeting, from 15 to 18 February 2022 - Agenda
- Joint press briefing - The Clinical Trial Regulation enters into application in the EU - virtual meeting, 25 January 2022

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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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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