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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

Cancer

New medicines authorised

- Pemetrexed Baxter (*pemetrexed*) generic of Alimta
  Treatment of lung cancer
- Zynlonta (*loncastuximab tesirine*)
  Treatment of different types of blood cancer
- Celdoxome pegylated liposomal (*doxorubicin hydrochloride*)
  Treatment of various cancers: breast cancer, ovarian cancer, Kaposi's sarcoma and multiple myeloma

New information on authorised medicines

- Nubeqa (*darolutamide*) - new indication
  Treatment of prostate cancer

Key to symbols used

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

- Trecondi (*treosulfan*) - extension of indication
  Treatment to remove the bone marrow cells before blood stem cell transplantation

Withdrawal of applications for new medicines

- Febseltiq (*infigratinib*)
  Intended as a treatment of bile duct cancer

Withdrawal of applications for extension of indication

- Imbruvica (*ibrutinib*)
  Intended for treatment of previously untreated mantle cell lymphoma (a type of blood cancer)

Direct Healthcare Professional Communication (DHPC)

- Pazenir (*paclitaxel*)
  Treatment of breast cancer
- Lymphoseek (*tilmanocept*)
  Diagnostic medicine used to identify different types of cancer

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

- Sotyktu (*deucravacitinib*)
  Treatment of plaque psoriasis (a disease causing red, scaly patches on the skin)

Diabetes

Positive CHMP opinions on new medicines

- Dapagliflozin Viatris (*dapagliflozin*) generic of Forxiga
  Treatment of type 2 diabetes

New medicines authorised

- Sitagliptin / Metformin hydrochloride Sun (*sitagliptin / metformin hydrochloride*) generic of Janumet
  Treatment of diabetes mellitus

New information on authorised medicines

- Trulicity (*dulaglutide*) - extension of indication
  Treatment of diabetes mellitus in patients 10 years of age and above

Direct Healthcare Professional Communication (DHPC)

- INSUMAN RAPID / INSUMAN BASAL / INSUMAN COMB 25 (*insulin human*)
  Treatment of diabetes (type 1 and 2)

Haematology (blood conditions)

New information on authorised medicines

- Reblozyl (*luspatercept*) - extension of indication
  Treatmemt of anaemia in patients with beta - thalassaemia (a blood disorder)

Safety update

- Review of Adakveo (crizanlizumab) - review started (Scope of safety referral)
  Prevention of painful crises in patients with sickle cell disease

Hormone system

Positive CHMP opinions on new medicines

- Tolvaptan Accord (*tolvaptan*) generic of Samsca
  Treatment of low sodium levels in patients with the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

Immune system

Positive CHMP opinions on new medicines

- Sotyktu (*deucravacitinib*)
  Treatment of plaque psoriasis (a disease causing red, scaly patches on the skin)

Musculoskeletal system

Negative CHMP opinions on new medicines

- Sohonos (*palovarotene*)
  Intended to reduce the abnormal formation of bones in joints, muscles, tendons and ligaments

Nervous system

New information on authorised medicines

- Wakix (*pitolisant*) - extension of indication
  Treatment of long-term sleep disorder called narcolepsy in children and adolescents from 6 years of age

Rheumatology (immune and inflammatory conditions)

Safety update

- Review of Janus Kinase inhibitors (JAKi) (tofacitinib; abrocitinib; baricitinib; upadacitinib; filgotinib) - CHMP Recommendation (Art. 20)
  Risk of serious side effects (cardiovascular conditions, blood clots, cancer and serious infections)

New information on authorised medicines

- Byfavo (*remimazolam)* - new pharmaceutical form
  Intravenous induction and maintenance of general anaesthesia

Safety update

- Review of Amfepramone-containing medicinal products (*amfepramone*) - CMDh Position (Artide 31 referral)
  Treatment of obesity

Vaccines

New medicines authorised

- Odenga (*dengue tetravalent vaccine (live, attenuated*)) - extension of indication
  Prevention of dengue disease

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Adopted guidelines

- ICH guideline Q13 on continuous manufacturing of drug substances and drug products
- ICH guideline M10 on bioanalytical method validation and study sample analysis - Questions and Answers
- Procedural advice for vaccine platform technology master file (vPTMF) certification
- Guideline on clinical evaluation of vaccines

Scientific committee and working party activities

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

- Safety of COVID-19 vaccines

Other publication

- PRAC recommendations on signals adopted at the 28 November - 1 December 2022 PRAC meeting
- Outcome of written procedures finalised during the period from 30 September 2022 to 05 December 2022
- CTIS newsflash – 22 December 2022
- Medical devices
- ICH guideline Q13 on continuous manufacturing of drug substances and drug products - Scientific guideline
- Exemptions to labelling and package-leaflet obligations
- Coordination of pharmacovigilance inspections
- Task Forces
- Information package for certificates of medicinal products issued by the European Medicines Agency (EMA)
- Certification of medicinal products
- Big Data Steering Group (BDSG): 2022 report
- 2022-2025 Work plan for the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP)
- Mandatory use of CTIS from 31 January 2023 for all new clinical trial applications
- Report on development of a harmonised approach to human dietary exposure
- Assessment of human dietary exposure to residues of veterinary medicines in the EU
- Maximum residue limits (MRL)
- Public health threats
- Joint statement by Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) on shortages of antibiotic medicines
- Shortage of Insuman Rapid, Basal and Comb 25 (insulin human)
- Medical devices
- European Medicines Agency's Data Protection Notice
- Statement on the amended policy on orphan designations for inherited retinal dystrophies
- Eligible patients and consumers organisations

- CTIS Evaluation Timelines
- Advanced therapy medicinal products: Overview
- Shortage of Pazenir (paclitaxel)
- EMA update on shortages of antibiotics in the EU
- EMA Committee for Advanced Therapies elects Ilona Reischl as its new Chair
- Shortage of amoxicillin and amoxicillin/clavulanic acid
- Biosimilar medicines: Overview
- Substance and product data management services
- Use of Clinical Trials Information System becomes mandatory for new clinical trial applications in the EU
- Q&A on the protection of commercially confidential information and personal data while using CTIS
- Clinical Trials Information System: training and support
- Clinical trials in human medicines

Events

- Regulatory and scientific virtual conference on RNA-based medicines - 2 February 2023 - Agenda
- EIC / EMA Info Day: Regulatory support for the development of innovative medicines and technologies - 31 January 2023
- Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 26 January 2023
- Information session on the pilot for expert panels' scientific advice to manufacturers of high-risk medical devices - 25 January 2023 - Agenda
- Clinical Trials Information System (CTIS): Readiness for mandatory use of the Clinical Trials Regulation from 31 January 2023 - 20 January 2023
- EMA virtual workshop on myocarditis post COVID-19 vaccination - 16 January 2023 - Agenda
- Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 11 January 2023 - Agenda

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

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