

# HUMAN MEDICINES

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



IN THIS ISSUE	
Cancer	1
Dermatology	2
Diabetes	2
Haematology	3
Hormone system	3
Immune system	3
Musculoskeletal system	3
Nervous system	3
Rheumatology	3
Vaccines	4
Other medicines	4
Medicines under additional monitoring	4
Guidelines	4
Scientific committee and working party activities	4
Other publications on Covid-19	5
Other publications	5
Events	6
Explanation of terms used	7

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

## Cancer

#### New medicines authorised

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

#### New information on authorised medicines

Nubega (darolutamide) - new indication Treatment of prostate cancer

#### Key to symbols used



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

#### Withdrawal of applications for new medicines

Febseltig (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

Dapaqliflozin 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

<u>Trulicity</u> (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

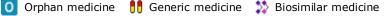
Review of Janus Kinase inhibitors (JAKi) (tofacitinib; abrocitinib; baricitinib; upadacitinib; filgotinib) -CHMP Recommendation (Art. 20)

Risk of serious side effects (cardiovascular conditions, blood clots, cancer and serious infections)

#### Key to symbols used













#### 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

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 quideline Q13 on continuous manufacturing of drug substances and drug products
- ICH quideline 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

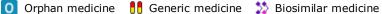
## Scientific committee and working party activities

- 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

#### Key to symbols used













- PDCO agendas, minutes and meeting reports
- PRAC agendas, minutes and highlights
- PRAC recommendations on safety signals

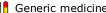
# Other publications on COVID-19

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
- 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
- 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













Page 6

- **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
- 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 - <u>Agenda</u>

## 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:

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 <a href="https://www.ema.europa.eu/contact">www.ema.europa.eu/contact</a>

#### **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



