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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

- Comirnaty (*tozinameran / riltozinameran and tozinameran / famtozinameran and tozinameran / COVID-19 mRNA Vaccine (nucleoside modified))* - EMA recommends approval of a adapted COVID-19 vaccine targeting Omicron XBB.1.5
  Prevention of COVID-19Cancer

**Key to symbols used**

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

# Cancer

### Withdrawal of applications for new medicines

- Lutholaz (*pegfilgrastim*)
  Intended to reduce the duration of neutropenia (low levels of neutrophils, a type of white blood cell) in cancer patients

### Supply shortages

- Abraxane (*paclitaxel*)
  Treatment of different types of cancer
- Methotrexate (*methotrexate*)
  Treatment of different types of cancer

### Direct Healthcare Professional Communication (DHPC)

- Potential missing package leaflet in folding boxes of RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab), Phesgo (pertuzumab / trastuzumab) and Tecentriq (atezolizumab)
  Treatment of various conditions

# Diabetes

### Supply shortages

- Saxenda (*liraglutide*)
  Treatment of obesity and weight-related complications such as type 2 diabetes
- Tresiba (*insulin degludec)*
  Treatment of diabetes type 1 and 2
- Victoza (*liraglutide)*
  Treatment of diabetes type 2 in addition to diet and exercise

# Hematology (blood conditions)

### Direct Healthcare Professional Communication (DHPC)

- Potential missing package leaflet in folding boxes of RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab), Phesgo (pertuzumab / trastuzumab) and Tecentriq (atezolizumab)
  Treatment of various conditions

# Metabolic disorders

### Supply shortages

- Saxenda (*liraglutide*)
  Treatment of obesity and weight-related complications such as type 2 diabetes

# Nervous system

### New medicines authorised

- Aquipta (*atogepant*)
  Prevention of migraine

### Safety update

- Review of Valproate-containing medicines - EMA review of data on paternal exposure to valproate
  Treatment of epilepsy and bipolar disorder

# Ophthalmology (eye conditions)

### Withdrawal of applications for new medicines

- Lumevoq (*lenadogene nolparvovec*)
  Intended for treatment of loss of vision due to an eye condition known as Leber hereditary optic neuropathy

# Rheumatology (immune and inflammatory conditions)

### Supply shortages

- Methotrexate (*methotrexate*)
  Treatment of different types of inflammatory diseases

### Direct Healthcare Professional Communication (DHPC)

- Potential missing package leaflet in folding boxes of RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab), Phesgo (pertuzumab / trastuzumab) and Tecentriq (atezolizumab)
  Treatment of various conditions

# Medicines under additional monitoring

- Updated list of medicines under additional monitoring

# Other information

## Guidelines

**Guidelines open for consultation**

- Concept paper on the development of a Reflection Paper on modern manufacturing techniques used for herbal preparations
  Deadline for comments: 15 November 2023

## Scientific committee and working party activities

- Medicinal products for human use: monthly figures - July 2023
- 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
- HCPWP

## Other publications

- EMA's response to the COVID-19 pandemic
- EMA mourns passing of Noël Wathion

## Events

- Strengthening life-sciences innovation across Europe: EU-Innovation Network conference - 21 November 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

In particular, you may be interested in these links:

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