

# **HUMAN MEDICINES**

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



IN THIS ISSUE	
COVID-19 vaccines	1
Antivirals/anti-infectives	2
Cancer	2
Cardiovascular system	2
Haematology	2
HIV	3
Ophthalmology	3
Respiratory system	3
Rheumatology	3
Medicines under additional monitoring	4
Guidelines	4
Scientific committee and working party activities	4
COVID-19	4
Other publications	5
Explanation of terms used	6

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 guide 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

## COVID-19 vaccines and treatments

## New vaccines authorised

- COVID-19 Vaccine AstraZeneca (COVID-19 Vaccine (ChAdOx1-S [recombinant]) Prevention of coronavirus disease 2019 (COVID-19)
- COVID-19 Vaccine Moderna (COVID-19 mRNA Vaccine (nucleoside modified)) Prevention of coronavirus disease 2019 (COVID-19)

## Safety update

- Comirnaty (COVID-19 mRNA Vaccine (nucleoside modified)) Prevention of coronavirus disease 2019 (COVID-19)
- COVID-19 Vaccine Moderna: EPAR Risk-management-plan

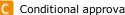














## Antivirals/anti-infectives

#### New medicines authorised

- Rekambys (rilpivirine) Treatment of HIV-1
- Vocabria (cabotegravir) Treatment of HIV-1
- Xofluza (baloxavir marboxil) Treatment and prevention of flu

## Direct healthcare professional communication (DHPC)

Kaletra (lopinavir/ritonavir) oral solution, 2 bottle pack containing 2-ml oral dosing syringes: Presence of amide particles in 2-ml oral dosing syringes

## Cancer

## New medicines authorised

- Elzonris (tagraxofusp) Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), a type of blood cancer that can affect the skin
- Phesqo (pertuzumab / trastuzumab) Treatment of breast cancer
- Tecartus (Autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured) 0

Treatment of mantle cell lymphoma (type of blood cancer)

## Cardiovascular system

## New medicines authorised

Legvio (inclisiran)

Treatment of primary hypercholesterolaemia or mixed dyslipidaemia (abnormal levels of fats in blood)

# Haematology (blood conditions)

#### New medicines authorised

**Elzonris** (tagraxofusp)

Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), a type of blood cancer that can affect the skin

Tecartus (Autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured)

Treatment of mantle cell lymphoma (type of blood cancer)

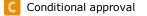
## Key to symbols used











## HIV

#### New medicines authorised

- Rekambys (rilpivirine) Treatment of HIV-1
- Vocabria (cabotegravir) Treatment of HIV-1

## Direct healthcare professional communication (DHPC)

Kaletra (Iopinavir/ritonavir) oral solution, 2 bottle pack containing 2-ml oral dosing syringes: Presence of amide particles in 2-ml oral dosing syringes

# Ophthalmology (eye conditions)

#### New medicines authorised

Roclanda (latanoprost / netarsudil) Reduction of pressure in the eye in patients with glaucoma or ocular hypertension

## Respiratory system

#### New medicines authorised

Trixeo Aerosphere (formoterol / glycopyrronium bromide/ budesonide) Treatment of chronic obstructive pulmonary disease (COPD)

## Supply shortages

Nucala (mepolizumab) Treatment of asthma

## Direct healthcare professional communication (DHPC)

Shortage of Nucala (mepolizumab) Pre-Filled Pen (EU/1/15/1043/003, EU/1/15/1043/004)

## Rheumatology (immune and inflammatory conditions)

## New medicines authorised

Livogiva (teriparatide) Treatment of osteoporosis (a disease that makes bones fragile)

## Withdrawal of authorised medicines

Outavina (teriparatide) Intended for treatment of osteoporosis (a disease that makes bone fragile)













# Medicines under additional monitoring

Updated list of medicines under additional monitoring

# Other information

## Guidelines

#### Guidelines open for consultation

Parallel application for EU-M4all (Article 58) opinion and Centralised Marketing Authorisation procedure Deadline for comments: 15 February 2021

## Scientific committee and working party activities

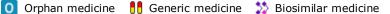
- Medicinal products for human use: monthly figures December 2021
- CAT agendas, minutes and reports
- CHMP agendas, minutes and highlights
- CHMP applications for new human medicines: January 2021
- COMP agendas, minutes and meetings reports
- HMPC agendas, minutes and meetings reports
- PDCO agendas, minutes and meeting reports
- PRAC agendas, minutes and highlights
- PRAC statistics: January 2021
- PRAC recommendations on safety signals
- Meeting summary: PCWP/HCPWP meeting with all eligible organisations: COVID-19 pandemic updated

## COVID-19

- Clarification of Comirnaty dosage interval
- Extra dose from vials of Comirnaty COVID-19 vaccine
- EMA receives application for conditional marketing authorisation of COVID-19 Vaccine AstraZeneca
- EMA recommends COVID-19 Vaccine Moderna for authorisation in the EU
- Global regulators highlight key role of healthcare professionals in fostering confidence in COVID-19 vaccines
- Leaflet: Inforcard for patients: Reporting suspected side effects of medicines in patients with COVID-19











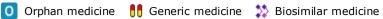


# Other publications

- Cyberattack on EMA update 4
- Cyberattack on EMA update 5
- Cyberattack on EMA update 6
- Leaflet: EU-M4all Promoting parallel application for EU-M4all opinion and centralised marketing authorisation procedure
- Report: Highlight report Fifth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines
- Human medicines: highlights of 2020
- Report: European Medicines Agency budget for 2021
- Report: Summary report EU big data stakeholder virtual forum
- Report: European Medicines Agency's interaction with industry stakeholders Biennial report 2018-19

## **Events**

- SME and academia Clinical Trials Information System (CTIS) two-part training webinar: Day 1, virtual meeting, 22 February 2021
- SME and academia Clinical Trials Information System (CTIS) two-part training webinar: Day 2, virtual meeting, 4 March 2021
- European Medicines Agency and European Healthcare Distribution Association (GIRP) bilateral meeting, virtual meeting, 18 January 2021 - Agenda
- European Medicines Agency and Medicines for Europe fourth bilateral meeting, virtual meeting, 26 January 2021 - Agenda
- Real world research on medicines: contribution of the European Network of Centres in Pharmacoepidemiology and Pharmacovigilance (ENCePP), virtual meeting, 8 March 2021











## 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

