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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 vaccines authorised

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

Key to symbols used

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

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*) O
  Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), a type of blood cancer that can affect the skin
- Phesgo (*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*) O
  Treatment of mantle cell lymphoma (type of blood cancer)

Cardiovascular system

New medicines authorised

- Leqvio (*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)

HIV

New medicines authorised

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

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

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

- Qutavina (*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 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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European Medicines Agency

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