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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

Positive CHMP opinions on new medicines

- Hepcludex (*bulevirtide*)
  Treatment of chronic hepatitis delta virus infection in patients with compensated liver disease
- Xenleta (*lefamulin*)
  Treatment of community-acquired pneumonia

New medicines authorised

- Fetcroja (*cefiderocol*)
  Treatment of infections due to aerobic Gram-negative bacteria

Cancer

Positive CHMP opinions on new medicines

- Piqray (*alpelisib*)
  Treatment of locally advanced or metastatic breast cancer

Key to symbols used

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

- Rozlytrek (*entrectinib*)
  Treatment of solid tumours and non-small cell lung cancer
- Zercepac (*trastuzumab*)
  Treatment of breast and gastric cancer

New information on authorised medicines

- Lynparza (*olaparib*) - new indication
  Treatment of ovarian cancer

Supply shortages

- Direct healthcare professional communication (DHPC): Polivy (*polatuzumab vedotin*) - Potential shortages

Safety update

- Direct healthcare professional communication (DHPC): Brivudine - Fatal interactions
- Review of leuprorelin-containing depot medicinal products - PRAC recommendation (new measures to avoid handling errors)
  Medicines used to control hormone levels in certain cancers and in disorders of the female reproductive system

Withdrawal of applications for new medicines

- Erlotinib Accord (*erlotinib*)
  Intended for treatment of lung cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- Apixaban Accord (*apixaban*)
  Treatment and prevention of blood clots and prevention of stroke

New information on authorised medicines

- Ofev (*nintedanib*) - new indication
  Treatment of pulmonary fibrosis (IPF), a long-term lung disease

Dermatology (skin conditions)

New information on authorised medicines

- Sivextro (*tedizolid phosphate*) - change of indication
  Treatment of infections of the skin and tissue around the skin
- Taltz (*ixekizumab*) - new indication
  Treatment of plaque psoriasis (scaly patches on skin)

Diabetes

New medicines authorised

- Rybelsus (*semaglutide*)
  Treatment of type 2 diabetes

New information on authorised medicines

- Invokana (*canagliflozin*) - change of indication
  Treatment of type 2 diabetes

Gynaecology & Obstetrics (pregnancy and female reproductive system)

New information on authorised medicines

- Lynparza (*olaparib*) - new indication
  Treatment of ovarian cancer

Safety update

- Review of leuprorelin-containing depot medicinal products - PRAC recommendation (new measures to avoid handling errors)
  Medicines used to control hormone levels in certain cancers and in disorders of the female reproductive system

Hormone system

Safety update

- Review of leuprorelin-containing depot medicinal products - PRAC recommendation (new measures to avoid handling errors)
  Medicines used to control hormone levels in certain cancers and in disorders of the female reproductive system

Immune system

New information on authorised medicines

- Taltz (*ixekizumab*) - new indication
  Treatment of plaque psoriasis (scaly patches on skin)

Musculoskeletal system

New medicines authorised

- Zolgensma (*onasemnogene abeparvovec*) O C
  Treatment of babies and young children who have a rare, serious inherited condition called spinal muscular atrophy

Nervous system

New medicines authorised

- Zeposia (*ozanimod*)
  Treatment of relapsing remitting multiple sclerosis
- Zolgensma (*onasemnogene abeparvovec*) O C
  Treatment of babies and young children who have a rare, serious inherited condition called spinal muscular atrophy

Withdrawal of applications for new medicines

- Fingolimod Mylan (*fingolimod*)
  Intended for treatment of multiple sclerosis

Respiratory system

New information on authorised medicines

- Ofev (*nintedanib*) O - new indication
  Treatment of pulmonary fibrosis (IPF), a long-term lung disease

Rheumatology (immune and inflammatory conditions)

Withdrawal of authorised medicines

- Public statement: Osseor - Withdrawal of the marketing authorisation in the European Union

Vaccines

Positive CHMP opinions on new medicines

- Mvabea *(Ebola vaccine (MVA-BN-Filo [recombinant])*
  Prevention of Zaire ebolavirus disease
- Zabdeno (*Ebola vaccine (Ad26.ZEBOV-GP [recombinant])*
  Prevention of Zaire ebolavirus disease

New medicines authorised

- Fluad Tetra (*influenza vaccine (surface antigen, inactivated, adjuvanted)*)
  Intended to protect people aged from 65 years against influenza (flu)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - April 2020
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: May 2020
- 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: May 2020
- PRAC recommendations on safety signals
- PCWP & HCPWP - European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties Joint: Agenda

COVID-19

- European medicines regulatory network fully mobilised in fight against COVID-19
- EU actions to support availability of medicines during COVID-19 pandemic – update #5
- EU actions to support availability of medicines during COVID-19 pandemic – update #6
- Global regulators work towards alignment on policy approaches and regulatory flexibility during COVID-19 – update #3
- Global regulators work towards alignment on policy approaches and regulatory flexibility during COVID-19 – update #2
- Global regulators work towards alignment on policy approaches and regulatory flexibility during COVID-19
- Global regulators commit to cooperate on observational research in the context of COVID-19
- International coordination needed to encourage conduct of large, decision-relevant COVID-19 clinical trials
- COVID-19: reminder of the risks of chloroquine and hydroxychloroquine
- COVID-19: how EMA fast-tracks development support and approval of medicines and vaccines
- EMA recommends expanding remdesivir compassionate use to patients not on mechanical ventilation
- EMA calls for high-quality observational research in context of COVID-19

- Prospective dialogue between developers and regulators makes for better evidence generation
- EMA commissions independent research to prepare for real-world monitoring of COVID-19 vaccines

Other publications

- Update of EU recommendations for 2020/2021 seasonal flu vaccine composition

Events

- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties Joint - Agenda - Virtual meeting - 2 June 2020
- ICH E6(R3) Good Clinical Practice workshop with Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties - Agenda - Virtual meeting - 3 June 2020

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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