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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 information on authorised medicines

- Comirnaty (*COVID-19 mRNA vaccine (nucleoside-modified)*) C - extension of indication Prevention of COVID-19 - extension to young people aged 12-15

Ongoing evaluations

- EMA starts rolling review of COVID-19 Vaccine (Vero Cell) Inactivated
- EMA starts rolling review of sotrovimab (VIR-7831) for COVID-19

Safety update

- COVID-19 vaccine safety update for Comirnaty: 11 May 2021
- COVID-19 vaccine safety update for COVID-19 Vaccine Moderna: 11 May 2021

Key to symbols used

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

- COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 21 May 2021
- COVID-19 vaccine safety update for COVID-19 Vaccine Janssen: 11 May 2021

Cancer

New medicines authorised

- Abiraterone Accord (*abiraterone*) generic of Zytiga
  Treatment of metastatic prostate cancer
- Copiktra (*duvelisib*)
  Treatment of chronic lymphocytic leukaemia and follicular lymphoma (blood cancers)
- Jemperli (*dostarlimab*) C
  Treatment of different types of endometrial cancer (cancer of the womb)
- Nexpovio (selinexor)
  Treatment of multiple myeloma (a cancer of the bone marrow)
- Pemazyre (*pemigatinib*) O C
  Treatment of cholangiocarcinoma (biliary tract cancer or cancer of the bile ducts)

New information on authorised medicines

- Blincyto (*blinatumomab*) O - new indication
  Treatment of precursor cell lymphoblastic leukemia-lymphoma (a blood cancer)
- Darzalex (*daratumumab*) O - extension of indication
  Treatment of multiple myeloma (a cancer of the bone marrow)
- Keytruda (*pembrolizumab*) - new indication
  Treatment of different types of cancers
- Libtayo (*cemiplimab*) C - new indication
  Treatment of skin cancer called cutaneous squamous cell carcinoma
- Opdivo (*nivolumab*) - new indication
  Treatment of different types of cancers
- Yervoy (*pilimumab*) - new indication
  Treatment of melanoma (skin cancer)

Other information

- EMA reminds physicians to use Tecentriq with nab-paclitaxel for treating breast cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- Verquvo (*vericiguat*)
  Treatment of symptomatic chronic heart failure

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

- Klisyri (*tirbanibulin*)
  Treatment of actinic keratosis (abnormal skin growths caused by over exposure to sunlight)

New information on authorised medicines

- Libtayo (*cemiplimab*) C - new indication
  Treatment of skin cancer called cutaneous squamous cell carcinoma
- Yervoy (*pilimumab*) - new indication
  Treatment of melanoma (skin cancer)

Diabetes

New information on authorised medicines

- Eucreas (*vildagliptin/metformin*) - change of indication
  Treatment of diabetes mellitus, type 2
- Galvus (*vildagliptin*) - change of indication
  Treatment of diabetes mellitus, type 2
- Icandra (previously Vildagliptin / metformin hydrochloride Novartis) (*vildagliptin/metformin*) - change of indication
  Treatment of diabetes mellitus, type 2
- Jalra (*vildagliptin*) - change of indication
  Treatment of diabetes mellitus, type 2
- Jardiance (*empagliflozin*) - new indication
  Treatment of diabetes mellitus, type 2
- Xiliarx (*vildagliptin*) - change of indication
  Treatment of diabetes mellitus, type 2
- Zomarist (*vildagliptin/metformin*) - change of indication
  Treatment of diabetes mellitus, type 2

Gastro-intestinal system

New medicines authorised

- Pemazyre (*pemigatinib*) O C
  Treatment of cholangiocarcinoma (biliary tract cancer or cancer of the bile ducts)

Gynaecology & Obstetrics (pregnancy and female reproductive)

Positive CHMP opinions on new medicines

- Ryeqo (*relugolix / estradiol / norethisterone acetate*)
  Treatment of symptoms of uterine fibroids

New medicines authorised

- Jemperli (*dostarlimab*) C
  Treatment of different types of endometrial cancer (cancer of the womb)

Haematology (blood conditions)

New medicines authorised

- Copiktra (*duvelisib*)
  Treatment of chronic lymphocytic leukaemia and follicular lymphoma (blood cancers)
- Nexpovio (selinexor)
  Treatment of multiple myeloma (a cancer of the bone marrow)

New information on authorised medicines

- Blincyto (*blinatumomab*) O - new indication
  Treatment of precursor cell lymphoblastic leukemia-lymphoma (a blood cancer)
- Darzalex (*daratumumab*) O - extension of indication
  Treatment of multiple myeloma (a cancer of the bone marrow)

Hepatology

Positive CHMP opinions on new medicines

- Bylvay (*odevixibat*) O
  Treatment of progressive familial intrahepatic cholestasis (a disease in which there is a build up of bile in the liver)

HIV

New information on authorised medicines

- Evotaz (*atazanavir / cobicistat*) - extension of indication
  Treatment of HIV

Immune system

Positive CHMP opinions on new medicines

- Icatibant Accord (*icatibant*) generic of Firazyr
  Treatment of hereditary angioedema (swelling beneath the skin)

Musculoskeletal system

New information on authorised medicines

- Spherox (*spheroids of human autologous matrix-associated chondrocytes*) - extension of indication
  Treatment of cartilage diseases

Nervous system

Positive CHMP opinions on new medicines

- Skysona (*elivaldogene autotemcel*)
  Treatment of early cerebral adrenoleukodystrophy (a severe form of a rare inherited neurological disease that affects the brain)

Urology (urinary tract conditions)

New medicines authorised

- Abiraterone Accord (*abiraterone*) generic of Zytiga
  Treatment of metastatic prostate cancer

Other medicines

Positive CHMP opinions on new medicines

- Imcivree (*setmelanotide*)
  Treatment of obesity caused by genetic disorders
- Ozawade (*pitolisant*)
  Treatment of excessive daytime sleepiness in obstructive sleep apnoea

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Addendum to the ICH guideline S1B on testing for carcinogenicity of pharmaceuticals - Step 2b
  Deadline for comments: 22 October 2021

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - April 2021
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: May 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: May 2021
- PRAC recommendations on safety signals
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint virtual meeting - 1 and 2 June 2021 - Agenda
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint virtual meeting - 2 and 3 March 2021 - Minutes

COVID-19

- Vaxzevria: further advice on blood clots and low blood platelets
- EMA issues advice on use of sotrovimab (VIR-7831) for treating COVID-19
- More flexible storage conditions for BioNTech/Pfizer's COVID-19 vaccine
- EMA starts evaluating use of COVID-19 vaccine Comirnaty in young people aged 12 to 15
- Insufficient data on use of inhaled corticosteroids to treat COVID-19
- Additional measures to allow experts to focus on COVID-19 activities

Other publications

- Management Board meeting - 11 March 2021 - Minutes
- International regulators and WHO call for wider public access to clinical data
- Confidentiality arrangement between EU and Brazilian regulatory authorities
- Medical Device Regulation comes into application
- Reply to open letter to 'Doctors for COVID ethics' concerning COVID-19 vaccines
- Report: Report of the joint HMA/EMA workshop on artificial intelligence in medicines regulation

Events

- EMA regular press briefing on COVID-19 - Virtual event - 27 May 2021
- First EMA regular press briefing on COVID-19 - Virtual event - 12 May 2021
- Webinar on EMA's categorisation of antibiotics used in animals - Virtual event - 23 June 2021
- Clinical Trials Information System (CTIS) webinar: How sponsor organisations can prepare for CTIS - Virtual meeting - 29 July 2021
- Nitrosamine Implementation Oversight Group (NIOG) meeting - Virtual event - 2 June 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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http://www.ema.europa.eu

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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

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