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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

- COVID-19 vaccine Spikevax approved for children aged 12 to 17 in EU

Ongoing evaluations

- EMA starts rolling review of COVID-19 vaccine Vidprevtyn
- EMA starts evaluating the use of Kineret in adult COVID-19 patients at increased risk of severe respiratory failure

Safety update

- COVID-19 vaccine safety update for Comirnaty: 14 July 2021
- COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 14 July 2021

Key to symbols used

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

- COVID-19 vaccine safety update for COVID-19 Vaccine Janssen: 14 July 2021
- COVID-19 vaccine safety update for Spikevax (previously COVID-19 Vaccine Moderna): 14 July 2021

Direct Healthcare Professional Communication (DHPC)

- COVID-19 mRNA Vaccines Comirnaty and Spikevax: risk of myocarditis and pericarditis
- Champix (varenicline) - lots to be recalled due to presence of impurity N-nitroso-varenicline

Antivirals/anti-infectives

New information on authorised medicines

- Deltyba (*delamanid*) O C - extension of indication
  Treatment of tuberculosis
- Vosevi (*sofosbuvir / velpatasvir / voxilaprevi*) - extension of indication
  Treatment of Hepatitis C

Cancer

Positive CHMP opinions on new medicines

- Imatinib Koanaa (*imatinib*)
  Treatment of leukaemia (blood cancer) and gastrointestinal stromal tumours (cancers of the stomach and bowel)

Withdrawal of applications for extension of indication

- Tecentriq (*atezolizumab*)
  Intended for treatment of advanced triple-negative breast cancer

Cardiovascular system

New information on authorised medicines

- Volibris (*ambrisentan*) - extension of indication
  Treatment of pulmonary arterial hypertension (high blood pressure in the lungs)

Dermatology (skin conditions)

New medicines authorised

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

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Imatinib Koanaa (*imatinib*)
  Treatment of leukaemia (blood cancer) and gastrointestinal stromal tumours (cancers of the stomach and bowel)

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Imatinib Koanaa (*imatinib*)
  Treatment of leukaemia (blood cancer) and gastrointestinal stromal tumours (cancers of the stomach and bowel)

New information on authorised medicines

- Ultomiris (*ravulizumab)* - extension of indication
  Treatment of paroxysmal nocturnal haemoglobinuria and atypical haemolytic uraemic syndrome (blood disorders)

Negative CHMP opinions on extension of indication

- Siklos (*hydroxycarbamide*)
  Intended to extend the use of Siklos to include the treatment of severe chronic (long-term) anaemia (low red blood cell counts) in patients suffering from sickle cell syndrome (a genetic disease where the red blood cells become rigid and sticky, and change from being disc-shaped to being crescent-shaped)

Safety update

- Review of Zynteglo (*betibeglogene autotemcel*) - CHMP Opinion
  Treatment of beta thalassaemia (a blood disorder)

Immune system

Direct Healthcare Professional Communication (DHPC)

- Xeljanz (tofacitinib): increased risk of major adverse cardiovascular events and malignancies with use of tofacitinib relative to TNF-alpha inhibitors

Nervous system

New medicines authorised

- Celsunax (*ioflupane (123I))* *Generic of* DaTSCAN
  Treatment of dementia, radionuclide diagnosing dementia and movement disorders

Negative CHMP opinions on new medicines

- Nouryant (i*stradefylline*)
  Intended for treatment of Parkinson's disease

Rheumatology (immune and inflammatory conditions)

Direct Healthcare Professional Communication (DHPC)

- Xeljanz (tofacitinib): increased risk of major adverse cardiovascular events and malignancies with use of tofacitinib relative to TNF-alpha inhibitors

Other medicines

Positive CHMP opinions on new medicines

- Nexviadyme (*Avalglucosidase alfa*)
  Treatment of glycogen storage disease type II (Pompe disease)

New medicines authorised

- Bylvay (*odevixibat*)
  Treatment of progressive familial intrahepatic cholestasis, a rare type of liver disease in which bile acids build up in the liver
- Imcivree (*setmelanotide*)
  Treatment of obesity and to control hunger caused by genetic conditions that affect how the brain controls feelings of hunger

Supply shortages

- Champix (*arenicline*)
  Intended to help to stop smoking

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials - Revision 2
  Deadline for comments: 31 August 2021
- Draft guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials - Revision 2
  Deadline for comments: 31 August 2021
- ICH guideline Q13 on continuous manufacturing of drug substances and drug products
  Deadline for comments: 20 December 2021
- Draft guideline on core SmPC, labelling and package leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells
  Deadline for comments: 31 October 2021

Adopted guidelines

- Consideration on core requirements for PSURs of COVID-19 vaccines

- Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development
- Reflection paper on good manufacturing practice and marketing authorisation holders

Other scientific recommendations

Classification of advanced therapy medicinal products (ATMPs)

- CAT monthly report of application procedures, guidelines and related documents on advanced therapies Title

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - June 2021
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: July 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: July 2021
- PRAC recommendations on safety signals

COVID-19 publications

- COVID-19 Vaccine Janssen: Guillain-Barré syndrome listed as a very rare side effect
- Increased manufacturing capacity and supply for Spikevax
- Increased manufacturing capacity for COVID-19 Vaccine Janssen
- EMA advises against use of COVID-19 Vaccine Janssen in people with history of capillary leak syndrome
- Comirnaty and Spikevax: possible link to very rare cases of myocarditis and pericarditis
- EMA and ECDC update on COVID-19
- International regulators work towards alignment on development and authorisation of second-generation COVID-19 vaccines

Other publications

- The European Medicines Agency mourns the passing of Jordi Llinares Garcia
- Annual activity report 2020
- EMA finds no evidence linking viral vector in Zynteglo to blood cancer
- Annual accounts: Financial year 2020
- Opinion of the SWP regarding Diethanolamine and coconut oil diethanolamine condensate as excipients
- Genome editing EU-IN Horizon Scanning Report
- Report: Meeting report of the joint meeting of the FDA/CTTI Patient Engagement Collaborative (PEC) and EMA Patients and Consumers Working Party (PCWP) on 1 July 2021

Events

- Meeting of the CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients and Consumers Working Party (PCWP) - Virtual meeting - 1 July 2021 - Agenda
- First European Medicines Agency and Affordable Medicines Europe bilateral meeting - Virtual meeting - 1 July - Agenda
- 2020_EMA_FINAL annual accounts (europa.eu)
- Extraordinary meeting of the Committee for Medicinal Products for Human Use (CHMP) - Virtual meeting - 23 July 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

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