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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

New information on authorised medicines

- Recarbrio (*imipenem / cilastatin / relebactam*) - new indication
  Treatment of infections caused by aerobic Gram-negative bacteria

Withdrawal of authorised medicines

- Vepacel (*prepandemic influenza vaccine H5N1 (whole virion, vero cell derived, inactivated)*)
  Prophylaxis of H5N1 subtype of influenza A

Safety update

- Direct healthcare professional communication (DHPC): Systemic and inhaled fluoroquinolones: risk of heart valve regurgitation/incompetence

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Lenalidomide Mylan (*lenalidomide*)
  Treatment of multiple myeloma and follicular lymphoma (blood cancers)
- Tecartus (*autologous anti-CD19-transduced CD3+ cells*)
  Treatment of relapsed or refractory mantle cell lymphoma (blood cancer)

New medicines authorised

- Arsenic trioxide medac (*arsenic trioxide*)
  Treatment of acute promyelocytic leukaemia (blood cancer)
- Cabazitaxel Accord (*cabazitaxel*)
  Treatment of prostate cancer
- Equidacent (*bevacizumab*)
  Treatment of several types of cancers
- Rozlytrek (*entrectinib*)
  Treatment of solid tumours and non-small cell lung cancer

New information on authorised medicines

- Blincyto (*blinatumomab*) - extension of indication
  Treatment of B-precursor acute lymphoblastic leukaemia (blood cancer)
- Opdivo (*nivolumab*) - new indication
  Treatment of several types of cancers

Safety update

- Direct healthcare professional communication (DHPC): Leuprorelin-containing depot products: need to strictly follow instructions for reconstitution and administration to reduce the risk of handling errors that may result in lack of efficacy - Referral art. 31

Cardiovascular system

Positive CHMP opinions on new medicines

- Leqvio (*inclisiran*)
  Treatment of primary hypercholesterolaemia or mixed dyslipidaemia (abnormal levels of fats in blood)

New information on authorised medicines

- Edistride and Forxiga (*dapagliflozin*)- new indication
  Treatment of diabetes

Dermatology (skin conditions)

New information on authorised medicines

- Dupixent (*dupilumab*) - extension of indication
  Treatment of atopic dermatitis in children (also known as atopic eczema, when the skin is itchy, red and dry)

Diabetes

New information on authorised medicines

- Edistride and Forxiga (*dapagliflozin*)- new indication
  Treatment of diabetes

Gastro-intestinal system

New information on authorised medicines

- Humira (*adalimumab*) - new indication
  treatment of ulcerative colitis (a disease causing inflammation and ulcers in the lower part of the gut) in children

Gynaecology & Obstetrics (pregnancy and female reproductive)

Safety update

- Direct healthcare professional communication (DHPC): Leuprorelin-containing depot products: need to strictly follow instructions for reconstitution and administration to reduce the risk of handling errors that may result in lack of efficacy - Referral art. 31

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Lenalidomide Mylan (*lenalidomide*)
  Treatment of multiple myeloma and follicular lymphoma (blood cancers)

New medicines authorised

- Arsenic trioxide medac (*arsenic trioxide*)
  Treatment of acute promyelocytic leukaemia (blood cancer)

New information on authorised medicines

- Blincyto (*blinatumomab*) - extension of indication
  Treatment of B-precursor acute lymphoblastic leukaemia (a type of blood cancer)

Safety update

- Direct healthcare professional communication (DHPC): Esbriet (pirfenidone): Important safety update and new recommendations to prevent Drug-Induced Liver Injury (DILI)

Key to symbols used

Orphan medicine | Generic medicine | Biosimilar medicine | Conditional approval | Exceptional circumstances

HIV

Positive CHMP opinions on new medicines

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

Hormone system

Safety update

- Direct healthcare professional communication (DHPC): Leuprorelin-containing depot products: need to strictly follow instructions for reconstitution and administration to reduce the risk of handling errors that may result in lack of efficacy - Referral art. 31

Immune system

Positive CHMP opinions on new medicines

- Palforzia (*defatted powder of Arachis hypogaea L., semen (peanuts)*)
  Treatment for desensitising children and adolescents to peanut allergy

New information on authorised medicines

- Desloratadine ratiopharm (*desloratadine*) generic of Aerius - change of classification
  Treatment to relieve the symptoms of allergic rhinitis (inflammation of the nasal passages caused by an allergy) or urticaria (a skin condition caused by an allergy, with symptoms including itching and hives)
- Dupixent (*dupilumab*) - extension of indication
  Treatment of atopic dermatitis (also known as atopic eczema, when the skin is itchy, red and dry)
- Humira (*adalimumab*) - new indication
  treatment of ulcerative colitis (a disease causing inflammation and ulcers in the lower part of the gut) in children
- Tremfya (*guselkumab*) - new indication
  Treatment of plaque psoriasis (disease causing red, scaly patches on the skin)

Nervous system

Positive CHMP opinions on new medicines

- Fintepla (*fenfluramine*)
  Treatment of seizures associated with Dravet syndrome
- Libmeldy (*autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene*)
  Treatment of children with metachromatic leukodystrophy (a rare inherited metabolic disease that affects the nervous system)

New medicines authorised

- Fampridine Accord (*fampridine*)
  Treatment to improve walking of adult patients suffering from multiple sclerosis with walking disability
- Zeposia (*ozanimod*)
  Treatment of relapsing remitting multiple sclerosis

New information on authorised medicines

- Lacosamide UCB (*lacosamide*) - new indication
  Treatment of epilepsy
- Plegridy (*peginterferon beta-1a*) - new route of administration
  Treatment of relapsing remitting multiple sclerosis
- Vimpat (*lacosamide*) - new indication
  Treatment of epilepsy

Respiratory system

Positive CHMP opinions on new medicines

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

Safety update

- Direct healthcare professional communication (DHPC): Esbriet (pirfenidone): Important safety update and new recommendations to prevent drug-induced liver injury (DILI)

Rheumatology (immune and inflammatory conditions)

New information on authorised medicines

- Tremfya (*guselkumab*) - new indication
  Treatment of plaque psoriasis (disease causing red, scaly patches on the skin)

Other medicines

Positive CHMP opinions on new medicines

- Oxlumo (*Ilumasiran*)
  Treatment of primary hyperoxaluria type 1 (rare disorder that affects kidneys)

New medicines authorised

- Zynrelef (*bupivacaine / meloxicam*)
  Treatment of post-operative pain

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Adopted guidelines

- Reflection paper on the pharmaceutical development of medicines for use in the older population

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - September 2020
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: October 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: October 2020
- PRAC recommendations on safety signals

COVID-19

- EMA starts first rolling review of a COVID-19 vaccine in the EU
- EMA starts second rolling review of a COVID-19 vaccine
- Extra transparency measures for COVID-19 vaccines and therapeutics
- EU regulators fully uphold transparency and independence standards for COVID-19 treatments and vaccines
- Strengthening global collaboration on COVID-19 real-world evidence and observational studies
- Reply to the European Ombudsman's letter concerning transparency and independence of the work of the European Medicines Agency in supporting the development and evaluation of COVID-19 medicines

Other publications

- Highlights of Management Board: October 2020 meeting
- EMA mid-year report 2020
- EMA reminds physicians to use Tecentriq with nab-paclitaxel for treating breast cancer
- New online platform for scientific advice
- EMA cancer symposium: New approaches in patient-focused cancer medicine development
- Ah o10th ESVAC report shows continued decrease in sales of veterinary antibiotics
- European Medicines Agency policy on the use of expertise for specific tasks to be undertaken by the Agency
- Regulatory update - EMA encourages companies to submit type I variations for 2020 by end of November
- Records of data processing activity Regulatory Science Strategy interviews (public)

Events

- PCWP/HCPWP meeting with all eligible organisations: COVID-19 pandemic update - Virtual meeting - 16 November 2020 - Agenda
- 25 Years of EMA: building, learning and adapting to new challenges - Virtual meeting - 22 October 2020 - Agenda
- Training session for patients, consumers and healthcare professionals interested in EMA activities - Virtual meeting - 23 October 2020
- Workshop on the draft guideline on registry-based studies - Virtual meeting - 19 October 2020 - Agenda
- EMA cancer symposium: New approaches in patient-focused cancer medicine development - Virtual meeting - 29 October 2020
- EU Big Data Stakeholder Virtual Forum - Virtual meeting - 15 December 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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