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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

- Recarbrio (*imipenem/cilastatin/relebactam*)
  Treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options

New medicines authorised

- Ervebo (*Ebola Zaire Vaccine* [*rVSVΔG-ZEBOV-GP, live*])
  Prevention of Ebola virus disease
- Quofenix (*delafloxacin*)
  Treatment of bacterial skin infections

New information on authorised medicines

- Sirturo (*bedaquiline*) O - extension of indication
  Treatment of tuberculosis

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Azacitidine Accord (*azacitidine*) generic of Vidaza
  Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia (blood cancers)

New medicines authorised

- Pegfilgrastim Mundipharma (*pegfilgrastim*) biosimilar of Neulasta
  Treatment of neutropenia (low level of some white blood cells) due to chemotherapy

New information on authorised medicines

- Akynzeo (*netupitant /palonosetron*)- change of indication
  Prevention of nausea and vomiting during chemiotherapy
- Cyramza (*ramucirumab*)- change of indication
  Treatment of advanced gastric (stomach) cancer, metastatic colorectal (bowel) cancer, non-small cell lung cancer and hepatocellular (liver) cancer
- Darzalex (*daratumumab*) O - extension of indication
  Treatment of multiple myeloma (cancer of the bone marrow)
- Erleada (*apalutamide*)- extension of indication
  Treatment of prostate cancer

Dermatology

New medicines authorised

- Quofenix (*delafloxacin*)
  Treatment of bacterial skin infections

New information on authorised medicines

- Stelara (*ustekinumab*) - extension of indication
  Treatment of plaque psoriasis (scaly patches on skin), psoriatic arthritis and Crohn's disease

Diabetes

New medicines authorised

- Qtrilmet (*metformin hydrochloride/saxagliptin/dapagliflozin*)
  Treatment of diabetes mellitus

Gastro-intestinal system

New information on authorised medicines

- Akynzeo (*netupitant /palonosetron*) - change of indication
  Prevention of nausea and vomiting during chemiotherapy

- Dificlir (*fidaxomicin*) - extension of indication and new pharmaceutical form
  Treatment of infections of the gut caused by bacteria called *Clostridium difficile*
- Stelara (*ustekinumab*) - extension of indication
  Treatment of plaque psoriasis (scaly patches on skin), psoriatic arthritis and Crohn's disease

Haematology

Positive CHMP opinions on new medicines

- Azacitidine Accord (*azacitidine*) generic of Vidaza
  Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia (blood cancers)

New medicines authorised

- Pegfilgrastim Mundipharma (*pegfilgrastim*) biosimilar of Neulasta
  Treatment of neutropenia (low level of some white blood cells) due to chemotherapy

Immune system

Positive CHMP opinions on new medicines

- Amsparity (*adalimumab*) biosimilar of reference product Humira
  Treatment of inflammatory and autoimmune disorders

New information on authorised medicines

- Stelara (*ustekinumab*) - extension of indication
  Treatment of plaque psoriasis, psoriatic arthritis and Crohn's disease

Nervous system

Positive CHMP opinions on new medicines

- Dexmedetomidine Accord (*dexmedetomidine*) generic of Dexdor
  Sedation of patients in intensive care units or undergoing medical or surgical procedures

New medicines authorised

- Spravato (*esketamine*)
  Treatment of major depressive disorder

New information on authorised medicines

- Vyndaqel (*tafamidis*) O - new indication
  Treatment of wild-type or hereditary transthyretin amyloidosis (a condition that affects the nervous system)

Ophthalmology

Positive CHMP opinions on new medicines

- Beovu (*brolucizumab*)
  Treatment of neovascular (wet) age-related macular degeneration (AMD)

New medicines authorised

- Rhokiinsa (*netarsudil*)
  Treatment of glaucoma or ocular hypertension (increased pressure in the eye)

Rheumatology

New information on authorised medicines

- Vyndaqel (*tafamidis*) O - new indication
  Treatment of wild-type or hereditary transthyretin amyloidosis (a condition that affects the nervous system)

Vaccines

New medicines authorised

- Ervebo (*Ebola Zaire Vaccine* [*rVSVΔG-ZEBOV-GP, live*])
  Prevention of Ebola virus disease

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 - November 2019
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: December 2019
- 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: December 2019
- PRAC recommendations on safety signals
- Annual Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) meeting with all eligible organisations, 20 November 2019 - Minutes

Other publications

- Management Board meeting: 3 October 2019 - Minutes
- EMA Management Board: highlights of December 2019 meeting
- European authorities working to avoid shortages of medicines due to Brexit – questions and answers
- European Medicines Agency's Privacy Statement concerning requests for information or access to documents
- EMA update on metformin diabetes medicines
- How will pharmacovigilance look in 2030?
- Report on pharmacovigilance tasks from EU Member States and the European Medicines Agency (EMA), 2015-2018
- 4-year overview of pharmacovigilance activities in the EU shows robust and effective medicines safety system
- Six-year review shows success of the EU signal management system in improving safe use of medicines
- EMA issues alert on the risk of dosing errors with the cancer medicine Trisenox
- Launch of international pilot programme on inspection of manufacturers of sterile medicines
- International collaboration on GMP inspections
- Social Media and M-Health Data

Events

- Third international awareness session on science and regulation for animal health and welfare, public health and the environment - 02/04/2020 to 03/04/2020
- Multi-stakeholder workshop on draft 'Regulatory Science to 2025' strategy (stakeholders for veterinary medicines) - 5 and 6 December 2019

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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