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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

Ongoing evaluations

- EMA evaluating the use of COVID-19 Vaccine Moderna in young people aged 12 to 17
- COVID-19 Vaccine Janssen: authorities in EU take steps to safeguard vaccine quality
- COVID-19 vaccines: update on ongoing evaluation of myocarditis and pericarditis
- Vaxzevria: EMA advises against use in people with history of capillary leak syndrome

Safety update

- COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 18 June 2021
- COVID-19 vaccine safety update for Comirnaty: 18 June 2021
- COVID-19 vaccine safety update for COVID-19 Vaccine Janssen: 18 June 2021

Key to symbols used

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

- COVID-19 vaccine safety update for Spikevax (previously COVID-19 Vaccine Moderna): 18 June 2021

Direct Healthcare Professional Communication (DHPC)

- Risk of thrombosis in combination with thrombocytopenia - Updated information
- Vaxzevria (previously COVID-19 Vaccine AstraZeneca): contraindication in individuals with previous capillary leak syndrome

Cancer

Positive CHMP opinions on new medicines

- Abecma (*idecabtagene vicleucel)*
  Treatment of multiple myeloma (cancer of the bone marrow)
- Abiraterone Mylan (*abiraterone acetate*) generic of Zytiga
  Treatment of metastatic prostate cancer
- Minjuvi (*tafasitamab*) O
  Treatment of relapsed or refractory diffuse large B-cell lymphoma (blood cancer)

New medicines authorised

- Inrebic (*fedratinib*) O
  Treatment of myelofibrosis (a rare form of blood cancer)
- Onureg (*azacitidine*)
  Treatment of acute myeloid leukaemia (a cancer of white blood cells)
- Nexpovio (*selinexor*)
  Treatment of multiple myeloma (a cancer of the bone marrow)
- Phelinun (*melphalan*)
  Treatment of different types of cancer

New information on authorised medicines

- Opdivo (*nivolumab*) - new indication
  Treatment of several types of cancer

Direct Healthcare Professional Communication (DHPC)

- Venclyxto - (venetoclax) film coated tablets: Updated recommendations on tumour lysis syndrome (TLS) in CLL patients

Dermatology (skin conditions)

Positive CHMP opinions on new medicines

- Bimzelx (*bimekizumab*)
  Treatment of plaque psoriasis (scaly patches on skin)

New medicines authorised

- Adtralza (*tralokinumab*)
  Treatment of moderate to severe atopic dermatitis (also known as eczema, when the skin is itchy, red and dry)

Diabetes

New information on authorised medicines

- Edistride and Forxiga (dapagliflozin) - new indication
  Treatment of diabetes mellitus, type 1 and 2

Gastro-intestinal system

Negative CHMP opinions on new medicines

- Flynpovi (*eflornithine / sulindac*) O
  Intended for the treatment of familial adenomatous polyposis (growths in the large intestine that can become cancerous)

Haematology (blood conditions)

Positive CHMP opinions on new medicines

- Evrenzo (*roxadustat)*
  Treatment of anaemia symptoms in patients with chronic kidney disease

New medicines authorised

- Inrebic (*fedratinib*) O
  Treatment of myelofibrosis (a rare form of blood cancer)
- Onureg (*azacitidine*)
  Treatment of acute myeloid leukaemia, a cancer of white blood cells

Hormone system

New medicines authorised

- Drovelis (*estetrol /drospirenone*)
  Combined contraceptive pill
- Lydisilka (*estetrol/drospirenone*)
  Combined contraceptive pill

Immune system

New medicines authorised

- Enspryng (*satralizumab*) O
  Treatment of neuromyelitis optica spectrum disorders (inflammatory disorders that affect mainly the optic nerve which connects the eye to the brain, and the spinal cord)
- Orladeyo (*berotralstat*)
  Treatment of hereditary angioedema (swelling beneath the skin)

New information on authorised medicines

- Rinvoq (*upadacitinib*) - new indication
  Treatment of rheumatoid arthritis (a disease that causes inflammation of the joints)
- Xeljanz (*tofacitinib)* - new indication
  Treatment of rheumatoid arthritis (a disease that causes inflammation of the joints) and psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints)

Metabolic disorders

New information on authorised medicines

- Galafold (*migalastat*) O - extension of indication
  Treatment of Fabry Disease (a rare lysosomal storage disorder)

Nephrology (kidney conditions)

Positive CHMP opinions on new medicines

- Evrenzo (*roxadustat)*
  Treatment of anaemia symptoms in patients with chronic kidney disease

Direct Healthcare Professional Communication (DHPC)

- INOmax (nitric oxide): Difficulties in closing the cylinder valves after use: precautions for use when disconnecting the cylinders from pressure regulators

Nervous system

Positive CHMP opinions on new medicines

- Fingolimod Mylan (*fingolimod*) generic of Gilenya
  Treatment of multiple sclerosis

New medicines authorised

- Ponvory (*ponesimod*)
  Treatment of multiple sclerosis

Safety update

- Review of Stresam (*etifoxine*) - review started - *Art.31*
  Treatment of anxiety disorders

Ophthalmology (eye conditions)

Positive CHMP opinions on new medicines

- Byooviz (*ranibizumab*)
  Treatment of eye problems caused by damage to the retina

Respiratory system

Withdrawal of applications for extension of indication

- Esbriet (*pirfenidone*)
  Treatment of idiopathic pulmonary fibrosis (fibrous scar tissue which forms in the lungs, causing persistent cough, frequent lung infections and severe shortness of breath)

Rheumatology (immune and inflammatory conditions)

New information on authorised medicines

- Rinvoq (*upadacitinib*) - new indication
  Treatment of rheumatoid arthritis (a disease that causes inflammation of the joints)
- Xeljanz (*tofacitinib*) - new indication
  Treatment of rheumatoid arthritis (a disease that causes inflammation of the joints) and psoriatic arthritis (red, scaly patches on the skin with inflammation of the joints)

Other medicines

Positive CHMP opinions on new medicines

- Voxzogo (*vosoritide*)
  Treatment of achondroplasia, a condition that impairs bone growth and causes dwarfism.

New medicines authorised

- Efmody (*hydrocortisone*)
  Treatment of an inherited condition called congenital adrenal hyperplasia

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- ICH guideline S12 on nonclinical biodistribution considerations for gene therapy products - Step 2b
  Deadline for comments: 24 October 2021
- Concept paper for the revision of residues guidelines to align with the definitions for withdrawal periods provided in Regulation (EU) 2019/6
  Deadline for comments: 31 July 2021

- Draft guideline on data requirements for vaccine antigen master files (VAMF)

  Deadline for comments: 30 September 2021

Adopted guidelines

- Deferasirox, dispersible tablets (125 mg, 250 mg and 500 mg), film-coated tablets (90 mg, 180 mg, and 360 mg) and granules (90 mg, 180 mg and 360 mg) product-specific bioequivalence guidance
- ICH guideline work to advance Patient Focused Drug Development (PFDD)
- ICH guideline E6 on good clinical practice - Draft ICH E6 principles

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - May 2021
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: June 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: June 2021
- PRAC recommendations on safety signals
- PCWP and HCPWP joint virtual meeting - 1 and 2 June 2021- Minutes

COVID-19

- Additional manufacturing site for COVID-19 Vaccine Janssen
- Additional manufacturing capacity for Moderna's COVID-19 vaccine
- Additional manufacturing capacity for BioNTech/Pfizer's COVID-19 vaccine
- EMA raises awareness of clinical care recommendations to manage suspected thrombosis with thrombocytopenia syndrome
- Advancing international collaboration on COVID-19 real-world evidence and observational studies
- International regulators and WHO address need to boost COVID-19 vaccine confidence

Other publications

- Deputy Executive Director Noël Wathion retires after 25 years of service
- Highlights of Management Board: June 2021 meeting
- EMA and EUnetHTA take stock of their cooperation
- EU regulators develop recommendations to forecast demand of medicines
- Annual report 2020 published
- Use of antibiotics in animals is decreasing
- Update of EU recommendations for 2021–2022 seasonal flu vaccine composition
- Success rate for marketing authorisation applications from SMEs doubles between 2016 and 2020
- Strengthening Training of Academia in Regulatory Science (STARS) overview
- Report on budgetary and financial management: financial year 2020
- Report on budgetary and financial management: financial year 2019
- Report on budgetary and financial management: financial year 2018

Events

- EMA regular press briefing on COVID-19 - Virtual meeting - 1 July 2021
- EMA regular press briefing on COVID-19 - Virtual meeting - 17 June 2021
- Sixth industry stakeholder platform on research and development support - Virtual meeting - 4 June 2021
- ePI information workshop and exploratory workshop - Virtual meeting - From 5 July to 8 July 2021 - Agenda 5 July - Agenda 6 - 8 July
- Sixth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines - virtual meeting - 30 June 2021 - Agenda

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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