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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

- Fetcroja (*cefiderocol*)
  Treatment of infections due to aerobic Gram-negative bacteria
- Tigecycline Accord (*tigecycline*)
  Treatment of complicated skin and soft tissue infections (cSSTI) and complicated intra-abdominal infections (cIAI)

New medicines authorised

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

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Alunbrig (*brigatinib*)
  Treatment of non-small cell lung cancer (NSCLC)

New medicines authorised

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

Withdrawal of authorised medicines

- Zalmoxis (*allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2)*)
  Intended as add-on treatment to restore the immune system in adults who have had a blood stem cell transplant to replace their bone marrow

Withdrawal of applications for extension of indication

- Axumin (*fluciclovine (18F)*)
  Intended for the diagnosis of glioma (a type of brain tumour)
- Opdivo (*nivolumab*)
  Treatment of non-small cell lung cancer
- Yervoy (*nivolumab*)
  Treatment of non-small cell lung cancer

Safety update

- Review of cyproterone-containing medicinal products - PRAC recommendation (meningioma risk with cyproterone medicines)
  Treatment of various androgen-dependent conditions such as excessive hair growth, hair loss, early puberty, lack of menstrual period, acne and prostate cancer

Safety update

- Review of Yondelis (*trabectedin*) - review started (Art.20)
  Treatment of ovarian cancer and soft tissue sarcoma (a type of cancer that develops from the soft, supporting tissues of the body)

Dermatology

Positive CHMP opinions on new medicines

- Tigecycline Accord (*tigecycline*)
  Treatment of complicated skin and soft tissue infections (cSSTI) and complicated intra-abdominal infections (cIAI).

Diabetes

New medicines authorised

- Baqsimi (*glucagon*)
  Treatment of severe hypoglycaemia (low blood sugar) in patients with diabetes

Gastro-intestinal system

New information on authorised medicines

- Entyvio (*vedolizumab*)- new pharmaceutical form
  Treatment of ulcerative colitis and Crohn's disease (types of inflammation of the gut)

Gynaecology & Obstetrics

Safety update

- Review of estradiol containing medicinal products (0.01% w/w) - CMDh Position (Four-week limit for use of high-strength estradiol creams)
  Treatment of vaginal atrophy

Haematology

New medicines authorised

- Amsparity (*adalimumab*) biosimilar of reference product Humira
  Treatment of inflammatory and autoimmune disorders
- Azacitidine Accord (*azacitidine*) generic of Vidaza
  Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia (blood cancers)
- Tavlesse (*fostamatinib*)
  Intended for the treatment of primary immune thrombocytopenia (ITP), a disorder characterised by destruction of platelets and impaired platelet production

Withdrawal of authorised medicines

- Iblias (*octocog alfa*)
  Intended for treatment and prevention of bleeding in patients with haemophilia A (an inherited bleeding disorder caused by lack of a clotting protein called factor VIII)
- Nonafact (*human coagulation factor IX*)
  Intended for treatment and prevention of bleeding in patients with haemophilia B (an inherited bleeding disorder caused by lack of factor IX)
- Zalmoxis (*allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2)*)
  Intended as add-on treatment to restore the immune system in adults who have had a blood stem cell transplant to replace their bone marrow

Hormone system

New medicines authorised

- Isturisa (*osilodrostat*)
  Intended for the treatment of Cushing's syndrome

Safety update

- Review of cyproterone-containing medicinal products - review started (meningioma risk with cyproterone medicines)
  Treatment of various androgen-dependent conditions such as prostate cancer, excessive hair growth, hair loss, early puberty, lack of menstrual period and acne

Immune system

New medicines authorised

- Tavlesse (*fostamatinib*)
  Intended for the treatment of primary immune thrombocytopenia (ITP), a disorder characterised by destruction of platelets and impaired platelet production

New information on authorised medicines

- Entyvio (*vedolizumab*)- new pharmaceutical form
  Treatment of ulcerative colitis and Crohn's disease (types of inflammation of the gut)
- Otezla (*apremilast*)- new indication
  Treatment of severe plaque psoriasis (scaly patches on skin) and active psoriatic arthritis

Withdrawal of authorised medicines

- Zalmoxis (*allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2)*)
  Intended as add-on treatment to restore the immune system in adults who have had a blood stem cell transplant to replace their bone marrow

Nervous system

New medicines authorised

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

Negative CHMP opinions on extension of indication

- Emgality (*galcanezumab*)
  Intended to prevent migraine in adults who have migraines at least 4 days a month. The requested extension was to add prevention of attacks in patients who suffer from episodic cluster headaches

Ophthalmology

New medicines authorised

- Beovu (*brolucizumab*)
  Treatment of neovascular (wet) age-related macular degeneration (a condition that can lead to loss of vision)

Respiratory system

New information on authorised medicines

- Ofev (*nintedanib*)- new indication
  Treatment idiopathic pulmonary fibrosis (long-term disease in the lungs that cause persistent cough and shortness of breath)

Rheumatology

New medicines authorised

- Evenity (*romosozumab*)
  Treatment of severe postmenopausal osteoporosis (reduction in bone strength)

New information on authorised medicines

- Otezla (*apremilast*)- new indication
  Treatment of severe plaque psoriasis (scaly patches on skin) and active psoriatic arthritis

Other medicines

Arbitration procedures

- Panexcell Clinical Laboratories Priv. Ltd - start of review of medicines (Art. 31)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Adopted guidelines

- Products Management Services - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe

Key to symbols used

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- ICH S5 (R3) guideline on reproductive toxicology: Detection of Toxicity to Reproduction for Human Pharmaceuticals
- ICH M9 on biopharmaceutics classification system based biowaivers
- Careers at EMA - Guidance on selection and recruitment not sure it has to be here

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - January 2020
- CAT - agendas, minutes and reports
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: February 2020
- CHMP - Work Plan 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: February 2020
- PRAC recommendations on safety signals
- PCWP & HCPWP - European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties Joint meeting

Other publications

- Management Board meeting: 19 March 2020
- European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties Joint meeting - 3-4 March 2020, EMA, Amsterdam, the Netherlands - Agenda
- EU flags are up in EMA's new building in Amsterdam
- European Medicines Agency budget for 2020
- EMA to support development of vaccines and treatments for novel coronavirus
- Public access to suspected side effect reports of veterinary medicines
- Information Management Strategy 2020-2022
- Direct healthcare professional communications
- European Medicines Agency's privacy statement: Public and targeted consultation
- European Medicines Agency privacy statement: For the organisation of meetings and events
- Direct Heatlhcare Professional Communication: Mepact 4mg (mifamurtide): Potential for filter leakage or malfunction

- Direct Healthcare Professional Communication: Risks associated with systemic exposure to estradiol creams
- Report: Final programming document 2020-2022

Events

- From data to evidence in medicines regulation – 22 March 2020 - EMA, Amsterdam, the Netherlands

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

In particular, you may be interested in these links:

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European Medicines Agency

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