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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

- Atazanavir Krka (*atazanavir*) generic of Reyataz
  Treatment of HIV infection

New medicines authorised

- Delstrigo (*doravirine / lamivudine / tenofovir disoproxil*) / Pifeltro (*doravirine*)
  Treatment of HIV infection

New information on authorised medicines

- Maviret (*glecaprevir / pibrentasvir*) - extension to existing indication
  Treatment of hepatitis C

Key to symbols used

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

Cancer

Positive CHMP opinions on new medicines

- Vizimpro (*dacomitinib*)
  Treatment of non-small cell lung cancer

New medicines authorised

- Ogivri (*trastuzumab*) biosimilar of Herceptin
  Treatment of breast cancer
- Poteligeo (*mogamulizumab*)
  Treatment of Sézary syndrome (skin and blood cancer)
- Ziextenzo (*pegfilgrastim*) biosimilar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients

New information on authorised medicines

- Keytruda (*pembrolizumab*) - new indication
  Treatment of metastatic squamous non-small cell lung carcinoma (type of lung cancer)
- Tecentriq (*atezolizumab*) - extension to existing indication
  Treatment of locally advanced or metastatic urothelial carcinoma (bladder cancer)

Withdrawal of applications for new medicines

- Cavoley (*pegfilgrastim*) biosimilar of Neulasta
  Intended for the treatment of neutropenia (low level of white blood cells) in cancer patients
- Efgratin (*pegfilgrastim*) biosimilar of Neulasta
  Intended for the treatment of neutropenia (low level of white blood cells) in cancer patients

Negative CHMP opinions on new medicines

- Doxolipad (*doxorubicin hydrochloride*)
  Intended for the treatment of breast and ovarian cancer

Safety communication update

- Review of Lartruvo (*olaratumab*) - review started (study shows that Lartruvo does not prolong the lives of patients with soft tissue sarcoma)
  Treatment of advanced soft tissue sarcoma (cancer that affects the soft, supportive tissues of the body such as muscles, blood vessels and fat tissue)

Cardiovascular system

New information on authorised medicines

- Praluent (*alirocumab*) - new indication
  Treatment of atherosclerotic cardiovascular disease (plaque build up in arteries)

Safety communication update

- Review of study results on direct oral anticoagulants (risk of major bleedings when used with non-valvular atrial fibrillation (irregular rapid contractions of the heart))
  Prevention of blood clotting

- Review of sartan medicines - CHMP Opinion (companies to review manufacturing processes to avoid presence of nitrosamine impurities)
  Treatment of high blood pressure, recent heart attack and heart failure

Dermatology

Positive CHMP opinions on new medicines

- Idacio / Kromeya (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

New medicines authorised

- Poteligeo (*mogamulizumab*) O
  Treatment of Sézary syndrome (skin and blood cancer)

Diabetes

New information on authorised medicines

- Edistride / Forxiga (*dapagliflozin*) - new indication
  Treatment of type 1 diabetes as an adjunct to insulin (when insulin alone does not control blood sugar adequately)

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Idacio / Kromeya (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

Haematology

New medicines authorised

- Jivi (*damoctocog alfa pegol*)
  Treatment of haemophilia A (congenital factor VIII deficiency)
- Poteligeo (*mogamulizumab*) O
  Treatment of Sézary syndrome (skin and blood cancer)

New information on authorised medicines

- Hemlibra (*emicizumab*) - extension to existing indication
  Treatment of bleeding episodes in patients with haemophilia A

Withdrawal of applications for new medicines

- Cavoley (*pegfilgrastim*) biosimilar of Neulasta
  Intended for the treatment of neutropenia (low level of white blood cells) in cancer patients
- Efgratin (*pegfilgrastim*) biosimilar of Neulasta
  Intended for the treatment of neutropenia (low level of white blood cells) in cancer patients

- Vynpenta (*avacopan*)
  Intended for the treatment of granulomatosis with polyangiitis or microscopic polyangiitis (inflammation of blood vessels)

HIV

Positive CHMP opinions on new medicines

- Atazanavir Krka (*atazanavir*) generic of Reyataz
  Treatment of HIV infection

New medicines authorised

- Delstrigo (*doravirine / lamivudine / tenofovir disoproxil*) / Pifeltro (*doravirine*)
  Treatment of HIV infection

Immune system

Positive CHMP opinions on new medicines

- Idacio / Kromeya (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

New information on authorised medicines

- MabThera (*rituximab*) - new indication
  Treatment of pemphigus vulgaris (autoimmune disease that causes painful blistering on skin and mucous membranes)

Metabolic disorders

Positive CHMP opinions on new medicines

- Febuxostat Krka (*febuxostat*) generic of Adenuric
  Treatment of hyperuricaemia (high blood levels of uric acid)

Musculoskeletal system

New medicines authorised

- Namuscla (*mexiletine hydrochloride*)
  Treatment of non-dystrophic myotonia (diseases where muscles are slow to relax after contraction)

Nervous system

New medicines authorised

- Ajovy (*fremanezumab*)
  Prevention of migraine

Ophthalmology

Positive CHMP opinions on new medicines

- Idacio / Kromeya (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

New medicines authorised

- Luxturna (*voretigene neparvovec*)
  Treatment of hereditary retinal dystrophy (a rare genetic disorder which causes vision loss)

Respiratory system

Positive CHMP opinions on new medicines

- Vizimpro (*dacomitinib*)
  Treatment of non-small cell lung cancer

New information on authorised medicines

- Keytruda (*pembrolizumab*) - new indication
  Treatment of metastatic squamous non-small cell lung carcinoma (type of lung cancer)

Rheumatology

Positive CHMP opinions on new medicines

- Idacio / Kromeya (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

New information on authorised medicines

- Orencia (*abatacept*) - new indication and change to existing indication
  Treatment of polyarticular juvenile idiopathic arthritis (pJIA)

Withdrawal of applications for new medicines

- Vynpenta (*avacopan*)
  Intended for the treatment of granulomatosis with polyangiitis or microscopic polyangiitis (inflammation of blood vessels)

Urology

New medicines authorised

- Silodosin Recordati (*silodosin*) generic of Urorec
  Treatment of prostatic hyperplasia (enlarged prostate)

New information on authorised medicines

- Tecentriq (*atezolizumab*) - extension to existing indication
  Treatment of locally advanced or metastatic urothelial carcinoma (bladder cancer)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the revision of the guideline on the evaluation of anticancer medicinal products in man
  Deadline for comments: 14 April 2019
- Evaluation of medicinal products indicated for treatment of bacterial infections
  Deadline for comments: 31 July 2019
- Electronic product information for human medicines in the European Union – draft key principles
  Deadline for comments: 31 July 2019

Other scientific recommendations

Classification of advanced therapy medicinal products (ATMPs)

- Recombinant adeno-associated virus serotype 9 vector encoding the soluble lysosomal enzyme TPP1
- Codon-optimized mRNA that will be translated to functional human cystic fibrosis transmembrane conductance regulator protein after cellular uptake
- *In vitro* cultured autologous mesenchymal stem cells isolated from bone marrow
- *In vitro* cultured autologous mesenchymal stem cells isolated from bone marrow
- Allogeneic Epstein-Barr Virus specific cytotoxic T lymphocytes

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - December 2018
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: January 2019
- CAT - agendas, minutes and reports
- COMP - agendas, minutes and meetings reports
- HMPC - agendas, minutes and meetings reports
- PDCO - agendas, minutes and meeting reports
- PRAC - agendas, minutes and highlights

- PRAC recommendations on safety signals
- Mandate, objectives and rules of procedure for the CHMP Safety Working Party (SWP)

Other publications

- EMA relocation updates
- EMA budget for 2019
- Human medicines: highlights of 2018 - report
- No new patients should start treatment with Lartruvo after study shows cancer medicine does not prolong life
- Revised guideline aims to strengthen global approach to development of new antibacterial medicines
- Public consultation on key principles for the electronic product information of EU medicines
- EMA / HMA / EC workshop on electronic product information (ePI) - November 2018 - video and report
- EU Innovation Network workshop with academia - November 2018 - meeting documents
- Stakeholder workshop on support to quality development in early access approaches, such as PRIME and Breakthrough Therapies - November 2018 - meeting documents

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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